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Toxicology Study No. S.0036333-15

Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically-Disseminated M18 Red Smoke

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14. ABSTRACT

This toxicology study was conducted to provide toxicity data relevant to the exposure in rats to test atmospheres of pyrotechnically disseminated M18 red smoke. Acute nose-only inhalation exposure to an average atmospheric concentration of 1.92 mg/L red smoke for 30 minutes did not induce mortality in male and female rats. Subacute (2-week) nose-only inhalation exposure to average atmospheric concentrations of 0, 0.1, 0.5, and 1.5 mg/L red smoke for 30 minutes/day did not result in any mortality or significant clinical signs at any exposure level. Test article-related histopathological findings were primarily observed in the anterior regions of the nose in male and female rats at all exposure levels. Increased incidence of nasal mucosal degeneration was identified as the critical endpoint in this study and was used to derive BMDL10 of 0.351 and 0.054 mg/L for male and female rats, respectively. Red smoke-induced histopathological findings at the 1.5 mg/L exposure level exhibited a regression of injury following a 4-week recovery period.

15. SUBJECT TERMS

red smoke, M18 smoke, signaling smoke, pyrotechnic, inhalation, acute inhalation, subacute inhalation, rat

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Study Title

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Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically-Disseminated M18 Red Smoke

Data Requirements

U.S. EPA Health Effects Test Guidelines
OPPTS 870.1300 (1998)

OECD Guideline for the Testing of Chemicals
Section 4: Health Effects, 412 (2009)

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Study Completed On

April 2017

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Laboratory Project ID

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Good Laboratory Practice Compliance Statement

The study described in this report was conducted in compliance with Title 40, Code of Federal Regulations (CFR), Part 792, Good Laboratory Practice Standards, except for the following:

1. The statistical analyses of the data were conducted by the Army Public Health Center statisticians. It is not known if these analyses were conducted in accordance with Good Laboratory Practice (GLP) Standards.

2. Combustion gas monitoring and analysis was performed by the Army Aberdeen Test Center. Volatile organic compound analysis was performed by Eurofins Lancaster Laboratories. It is not known if these analyses were conducted in accordance with GLP Standards; however, both contract laboratories maintain the appropriate International Organization for Standardization (ISO) certification.

3. The undesiminated M18 red smoke grenades were evaluated on an "as received" basis. The manufacturer provided an ingredient composition list but the actual composition was not confirmed by a GLP analysis. However, the ingredient composition supplied with the grenades was considered sufficient characterization of the test substance for the purposes of this study.

Lee C.B. Crouse
Study Director
Toxicity Evaluation Division

12 April 2017
Date

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ACUTE AND SUBACUTE INHALATION TOXICITY STUDY IN RATS EXPOSED TO PYROTECHNICALLY-DISSEMINATED M18 RED SMOKE
APRIL - SEPTEMBER 2015

1 Summary

1.1 Purpose

This study was conducted to evaluate the acute and repeated-exposure toxicity of pyrotechnically disseminated red smoke when administered by inhalation to male and female rats. Toxicity data in a mammalian system needed to be generated to assess acute and repeated-dose inhalation toxicity health hazards associated with the material to assure its safety before use by military personnel and to determine an occupational exposure level for workers.

1.2 Conclusions

The LC_{50} resulting from acute nose-only exposure to pyrotechnically disseminated red smoke particulate for 30 minutes was greater than 1.92 milligrams per liter (mg/L). Repeated nose-only inhalation of red smoke at average particulate concentrations of 0.1, 0.5, and 1.5 mg/L for 30 minutes did not induce mortality in male and female rats. Clinical signs observed following exposure, occurring in a concentration-related manner, included red-stained fur (primarily on the head, face, and forelimbs) from deposition of the test material and salivation. Changes in body mass only occurred in the male 1.5 mg/L recovery group and consisted of a decrease at the initiation of exposures (days 1-3) and subsequent increase during the second recovery week. Male and female organ mass and mass ratios (body and brain), for both main study and recovery groups, were unaffected by repeated exposure to red smoke relative to controls. Main study males exposed to 0.1 mg/L red smoke had reduced percent basophils while males exposed to 0.5 mg/L had increased percent basophils. Following a 4-week recovery period, males exposed to 1.5 mg/L red smoke had reduced albumin and hemoglobin. Histology on the collected tissues resulted in exposure-related changes in the nose of male and female rats. Hyperplasia of the transitional or respiratory epithelium at level 1 of the nasal turbinates, occasionally accompanied by mucosal degeneration and granulocytic infiltration, was observed in the majority of rats at all exposure levels. Male and female rats exhibited a regression of injury to the anterior regions of the nasal turbinates following a recovery period of 4 weeks. Mucosal degeneration of the level 1 nasal turbinates was identified as the critical endpoint in this study based on the exposure level-related response and was used to derive $BMDL_{10}$ of 0.351 and 0.054 mg/L for males and females, respectively.

2 References

See Appendix A for a list of references.

3 Authority

This study was conducted with funding from the Army Environmental Quality, Technology, Pollution Prevention Program (AMSRD-MSF) via Military Interdepartmental Purchase Request (MIPR) No.10453954. This toxicology study addresses, in part, the environmental safety and occupational health requirements outlined in Army Regulations (AR) 200-1, AR 40-5, and AR 70-1; Department of Defense Instruction 4715.4; and Army Environmental Requirements and Technology Assessments (Department of the Army (DA), 2007a and b; DA, 2003; Department of Defense (DOD), 1996; and U.S. Army Environmental Command (USAEC), 2009). It was performed as part of an on-going effort by the U.S. Army Environmental Quality Technology (EQT), Ordnance Environmental Program Pollution Prevention Team, to produce safer ordnance. This program is under the direction of the U.S. Army Research, Development, and Engineering Command (USARDECOM) Technology Acquisition Program and EQT Pollution Prevention.

4 Background

The U.S. Military uses colored smokes in a variety of ways including identification of potential targets and friendly troops, simulation of battlefield events, and as a means of communication. Previously-used colored smoke formulations were developed strictly based on their ability to produce the desired color for a specified period of time. Recent changes made to the smoke formulations and dissemination systems used in M18 colored smoke grenades have focused more on soldier safety during training and deployed scenarios as well as the public living or working near military training facilities. The primary changes made to the colored smoke formulations involved the use of sugar instead of sulfur as the fuel and the replacement of sodium bicarbonate by magnesium carbonate as the coolant; however, additional changes have also been made to refine burn times and the colors produced (Gretel Raibeck, email message to author, 10/30/13, subject: red smoke grenades).

At the onset of the transition, the Army requested the National Research Council (NRC) to independently review the available toxicity data on certain smokes and obscurants and recommend exposure guidance levels for each. In response to this request, the NRC's Committee on Toxicology (COT) convened the Subcommittee on Military Smokes and Obscurants, which published three volumes on the toxicity of military smokes and obscurants. Volume 3 of this series assesses toxicity data for seven old and new colored smoke formulations (NRC, 1999). Briefly, the Subcommittee found that the database for all seven smoke formulations, including the old and new red smokes, was inadequate for assessing the potential toxicity of the combustion products. They further recommended that acute inhalation studies be conducted in experimental animals to evaluate the toxicity of the combusted smoke formulations for emergency and short-term exposure guidance levels. Repeated exposure inhalation toxicity studies were recommended for military training instructors and people living in communities near military training facilities. Since the time of this review, the red dye proposed for use in the new red smoke formulation has changed from a mixture of solvent red 1 (α-meth-oxybenzenazo-β-naphthol) and disperse red 11 (1,4-diamino-2-methoxyanthraquionone) to solvent red 169 ((1-(isopropylamino) anthraquinone) only (Gretel Raibeck, email message to author, 10/30/13, subject: red smoke grenades). Neat solvent red 169 was evaluated by this Center for acute inhalation toxicity and was found to be non-toxic in rats up to 2.4 milligrams per liter (mg/L) (USACHPPM, 2009). The toxicity of the combusted red smoke formulation has not been evaluated.

Pyrotechnic colored smoke M18 grenades are used by the military for ground-to-ground and ground-to-air signaling. It is imperative that soldiers are trained in a similar manner in which they fight, therefore, these training exercises often result in soldiers and training instructors being repeatedly exposed to materials used to simulate battlefield scenarios. Current Army policy regarding colored smokes (old formulation) states that, during training, troops must carry a protective mask, mask when passing through or operating in a dense smoke cloud (visibility < 50 meters), mask when operating or passing through a smoke haze (visibility > 50 meters) if exposure duration exceeds 4 hours, and mask anytime exposure to smoke produces breathing difficulty. In addition, production personnel who are exposed to the dyes/mixtures, or propellant and fuse system materials must wear coveralls, butyl rubber gloves, head and shoe coverings, and a NIOSH-approved full face or hood type supplied air respirator (AEHA, 1992, 1993a, 1993b). A health risk assessment was performed on the combustion products of the old red smoke grenade formulation to determine the risk associated with living near military training facilities that conduct colored smoke exercises. The risk assessment concluded that residents who live as close as 100 meters directly downwind from training areas are safe from breathing air emissions from the old red-colored M18 (AEHA, 1992, 1993a, 1993b). As the Army transitions to colored smoke formulations believed to pose less of a health risk, the toxicity of the combustion products must be evaluated so that exposure guidance can be updated.

Research, development, testing, and training with explosives and pyrotechnics potentially less hazardous to human health and the environment is vital to the readiness of the U.S. Army. The Army Environmental Quality, Technology, Pollution Prevention Program is dedicated to finding replacements for substances causing environmental and/or occupational risks to health. Toxicity assessments such as this proposed study are necessary for safeguarding the health of Soldiers, civilians, and the environment and, if begun early in the research, development, testing, and evaluation process, can save significant time and effort by identifying unacceptable replacement compounds (ASTM, 2008).

Table 1. Critical Study Events

Critical Event	Date of Event
Animal Use Protocol Approved	January 27, 2015
Acute Exposure 1 Initiation	April 29, 2015
Acute Exposure 1 Necropsies	May 13, 2015
Subacute Exposure Initiation	June 2, 2015
Subacute Exposure Completion	June 16, 2015
Subacute Exposure Necropsies (Main Study Animals)	June 16 & 17, 2015
Subacute Exposure Necropsies (Recovery Animals)	July 14, 2015
Acute Exposure 2 Initiation	July 28, 2015
Acute Exposure 2 Necropsies	July 29 & August 11, 2015
Acute Exposure 3 Initiation	August 18, 2015
Acute Exposure 3 Necropsies	August 18 & September 1, 2015
Study Completion	April 2017

5 Materials

5.1 Test Substance

Both the acute and subacute phases of this study were conducted on the emission products from the sugar-based red smoke formulation in a M18 style grenade. A list of the neat ingredients in the red smoke formulation along with their recommended parts by weight is provided in table 2. No further attempt to characterize the undisseminated test material was made by the test facility. The M18 smoke grenade is approximately 5.75 inches long, 2.50 inches in diameter and weighs approximately 14 ounces. The smoke mixture itself weighs approximately 11.5 ounces and is pressed into a total of 4 pellets inside the canister. The grenades were initiated inside the test chamber using the standard M201A1 fuse. All of the smoke grenades used to conduct this toxicity study were supplied by the Pyrotechnic Research and Development Pilot Plant Branch, U.S. Army Armament Research, Development and Engineering Center (ARDEC), Picatinny Arsenal, Picatinny, NJ and were identified as lot number PB-14D000E001. The smoke grenades were shipped to the U.S. Army Research, Development, and Engineering Command (RDECOM), Engineering Directorate, Pyrotechnics Team, APG-EA, MD 21010 and were stored at their facility until use.

Table 2. Composition of Red Smoke Formulation

Component	Recommended Parts By Weight
Dye, Solvent Red 169	36.5
Magnesium Carbonate	16.5
Potassium Chlorate	20.5
Sugar, Type 1, Style C	19
Sugar, Type 1, Style B	6.5
Polyvinyl Acetate	1

5.2 Animals*†

All studies were conducted using young adult male and female Sprague-Dawley (Crl:CD(SD)CD®) rats obtained from Charles River Laboratories, Wilmington, Massachusetts. A total of 5 male and 5 female rats, approximately 8-weeks old at test initiation, were used for each of the three acute studies. A total of 36 male and 36 female rats, approximately 8-weeks old at test initiation, were selected for the subacute study. The attending veterinarian examined the animals and found them to be in acceptable health. The animals were quarantined/acclimated for a minimum 5-day period following their arrival to this testing facility. All animals were housed in temperature-, relative humidity-, and light-controlled rooms with the target conditions of 68-79ºF, 30-70 percent humidity, and a 12:12 light/dark cycle. Room temperature averaged 74.4, 71.7, and 71.5 ºF during the first,

* Research was conducted in compliance with DoD and federal statutes and regulations relating to animals and experiments involving animals and adheres to principles stated in the Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. National Academy Press, Washington, D.C. 1996.

† The studies reported herein were performed in animal facilities fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

second, and third acute study periods, respectively. Room relative humidity averaged 51.5, 56.7, and 56.8% during the first, second, and third acute study periods, respectively. Room temperature averaged 71.6ºF and relative humidity averaged 57.6% during the subacute study period. The relative humidity exceeded the targeted range on May 27 & 30, 2015 but the problem was corrected by the following day. The 12:12 light/dark cycle was interrupted on July 6, 13, & 28, 2015 due to a combination of human error during routine caretaking duties and a malfunctioning light timer. These deviations were not considered to have compromised the integrity or validity of the study results. A certified pesticide-free rodent chow (Harlan Teklad®, 2016C Certified Rodent Diet) and drinking quality water were available *ad libitum* except during each 30-minute exposure period and overnight fasting prior to final blood collection for the subacute study. All rats were individually housed in suspended polycarbonate boxes with Sani-Chip® bedding. Each rat was uniquely identified by number via cage card and tail marking. (CD® is a registered trademark of Charles River Laboratories International, Inc.; Teklad® and Sani-Chip® are registered trademarks of Harlan, Teklad).

5.3 Quality Assurance

The APHC Quality Systems Office audited critical phases of this study. Appendix B provides the dates of these audits, the phases audited, along with the dates that the results of the inspections were reported to the Study Director and Management.

5.4 Study Personnel

Appendix C contains the names of persons contributing to the performance of this study.

6 Methods

6.1 General Description

6.1.1 Acute Studies

A total of three acute toxicity exposures were performed with the disseminated red smoke atmosphere. The first acute exposure was designed to evaluate the toxicity associated with a single, high-concentration exposure to the disseminated red smoke. Five male rats weighing 261 ± 12.3 grams and 5 female rats weighing 193 ± 16.4 grams on the day of exposure were exposed for 30 minutes to an average atmospheric concentration of the test material targeted to at least 2 mg/L. Following the exposure, the rats were held for a 14-day recovery period and monitored for morbidity/mortality, body mass changes, and clinical signs of toxicity. On the last day of the recovery period, all of the rats were euthanized by carbon dioxide (CO_2) and necropsied. All rats received a gross necropsy with limited histopathology (lung only).

The second and third acute exposures were performed following the completion of the subacute study and were designed to confirm/clarify gross observations noted during necropsy of animals from the first acute exposure. Similar gross lesions were rarely observed during necropsy of the subacute animals. The second acute exposure was designed to repeat the same exposure scenario used for the first acute exposure to verify the presence of similar gross lesions. In addition, a modified necropsy schedule was used to determine if the gross lesion was present

shortly after exposure or was the result of a healing response mechanism during the recovery period. Five male rats weighing 254 ± 7.6 grams and 5 female rats weighing 221 ± 11.3 grams on the day of exposure were exposed for 30 minutes to an average atmospheric concentration of the test material targeted to at least 2 mg/L for the second exposure. Three rats per sex were euthanized and necropsied on the day after exposure and 2 rats per sex were held for a 14-day recovery period prior to being euthanized and necropsied. Body mass changes and clinical signs of toxicity were monitored daily during the week regardless of the recovery period length. All rats were euthanized by CO_2 and received a gross necropsy with limited tissues retained for histopathology (lung only).

Due to the apparent continued presence of gross lesions observed during necropsy, a third acute exposure was performed in an attempt to determine a safe level exposure that would not induce these lesions. Five male rats weighing 246 ± 4.8 grams and 5 female rats weighing 198 ± 7.2 grams on the day of exposure were exposed for 30 minutes to an average atmospheric concentration of the test material targeted to 0.5 mg/L for the third exposure. The same modified necropsy schedule was used for the third exposure such that 3 rats per sex were euthanized and necropsied on the day after exposure and 2 rats per sex were held for a 14-day recovery period prior to being euthanized and necropsied. Body mass changes and clinical signs of toxicity were monitored daily during the week regardless of the recovery period length. All rats were euthanized by CO_2 and received a gross necropsy with limited tissues retained for histopathology (lung only).

6.1.2 Subacute Study

Four groups of 12 rats each (6 rats/sex/group) were exposed to concentrations of red smoke particulate targeted to 0, 0.1, 0.5, or 1.5 mg/L. In addition, the control and high concentration level groups exposed additional rats (6 rats/sex/group) to be retained following the exposure period for a 4-week recovery period. Exposure schedules of the rats were staggered over 2 days to compensate for the limited number of animals able to be necropsied on a given day by this facility. Rats were exposed 30 minutes per day, 5 days per week over a 3-week period (weekends excluded). Due to the staggered start, rats received a partial week of exposures during the first and last weeks of the study, however, all rats received a total of 10 exposures. All rats were weighed at least once per week and were observed daily for clinical signs. The amount of food consumed by each rat was determined at least weekly during the study on the same days as body mass measurements. Blood samples were collected from all rats just prior to necropsy for clinical pathology analyses. At the end of the exposure period, 6 rats/sex/group were euthanized, necropsied, and examined for gross and microscopic pathological changes. Following a one-month recovery period, 6 rats/sex/group from the control and 1.5 mg/L groups were euthanized, necropsied, and examined for gross and microscopic pathological changes.

The experimental design of the subacute main study was modeled primarily on the Organisation for Economic Co-Operation and Development (OECD) Guideline for Testing of Chemicals, No. 412, Repeated Dose Inhalation Toxicity: 28-Day Study (OECD, 2009). Changes to the 28-day study guidelines were made to appropriately reflect a 2-week exposure period as well as accurately mimic a typical daily exposure duration to red smoke (e.g., 30 minutes).

6.2 Selection of Exposure Chamber Design Concentration

The initial particulate concentration for the high level exposure chamber for the subacute main study was targeted to be 1.5 mg/L of red smoke particulate. This concentration was based on the gross observation of respiratory tract lesions following the first acute study conducted at approximately 2 mg/L. The targeted low concentration level (0.1 mg/L) was 15-fold lower than the high concentration and was expected to be without adverse toxicological effects. The targeted intermediate concentration (0.5 mg/L) represented 3-fold reduction from the high concentration and was expected to produce some degree of toxicity. Control animals were exposed to room air only in a separate chamber each day prior to beginning the red smoke exposures.

6.3 Inhalation Exposure System (Figure 1)

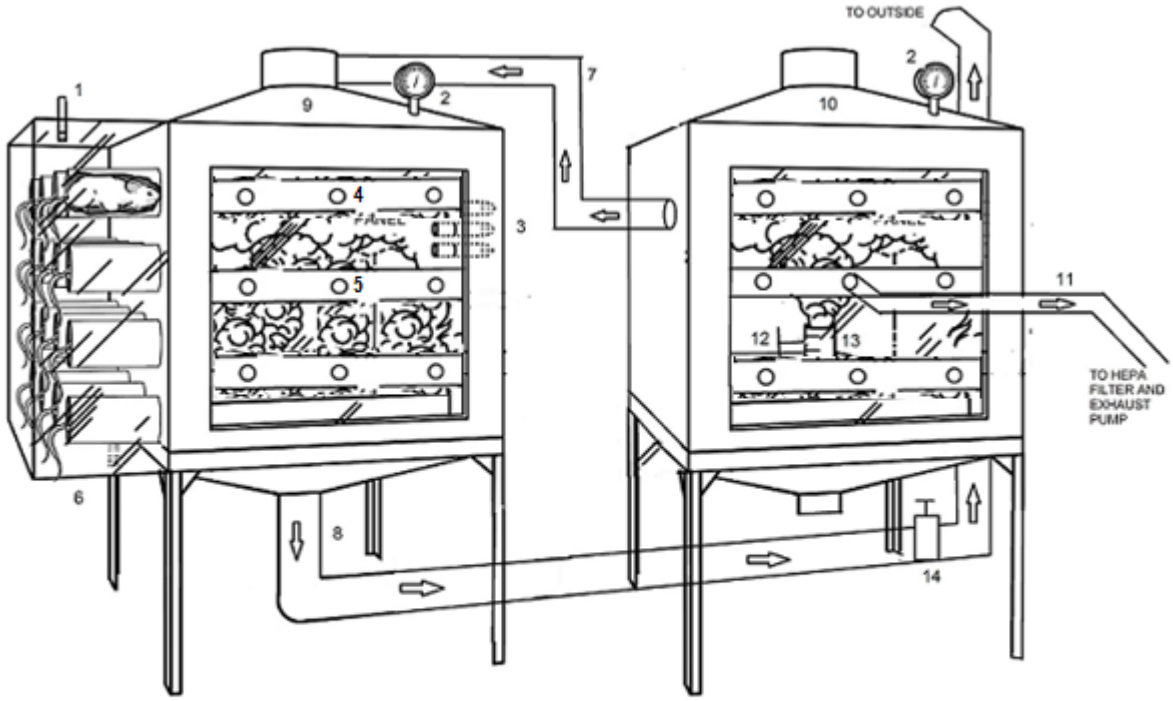
6.3.1 Test Atmosphere Generation

Test atmospheres were generated in the exposure chamber by pyrotechnic dissemination of a red smoke grenade in a separate initiation chamber connected to the exposure chamber. A single grenade was used for each acute exposure. For the subacute inhalation study, a single grenade also produced adequate test atmosphere concentration levels for all 3 test groups each day (design concentration levels of 0.1, 0.5, and 1.5 mg/L). In order to facilitate the generation of test atmospheres, the grenades were placed upside down and secured to a ring stand attached to the floor of the initiation chamber. Each grenade was ignited with its own fuse by pulling the fuse pin that was attached to a lanyard run through a port in the initiation chamber. The initiation chamber was connected to the exposure chamber via a 2 inch polyvinyl chloride (PVC) pipe connected to a side port on the initiation chamber and leading to the top turret of the exposure chamber. The positive pressure created by the burning smoke grenade in the initiation chamber forced the test material through the pipe into the top of the exposure chamber. In addition, feeding the test material into the top turret of the exposure chamber promoted a uniform atmosphere throughout the exposure chamber. The exposure chamber was connected from the bottom to a 3 inch exhaust pipe to prevent both chambers from over pressurizing. A valve was placed in the exhaust pipe to contain the test atmospheres in the exposure chamber once the grenade had completed its burn (see figure 1). Extreme temperatures created by the burning grenade prevented the inhalation exposures from being performed in the same chamber as the one in which the grenade was initiated.

The burn time for each grenade was approximately one minute and was determined by fluctuations in the magnehelic gauges attached to the chambers. The exposure chamber was operated under semi-static conditions. During the initial grenade burn period, the valve in the exhaust pipe was left open and all of the ports in the faceplates attached to the wall of the exposure chamber were stoppered. The faceplate was stoppered in order to prevent the test atmosphere from leaking uncontrollably out of the chamber and the exhaust valve was opened to prevent over pressurization of both chambers. When the grenade completed its burn, the valve in the exhaust line was closed and preliminary gravimetric samples were taken to determine the particulate concentration in the exposure chamber. Once the concentration of particulate in the exposure chamber was considered to be within the acceptable range for each concentration of the animal exposures, the stoppers in the faceplate were removed and the rats were placed in the faceplate for their 30-minute exposure period. In an attempt to minimize loss of the test atmosphere from the exposure chamber, the stoppers in the faceplate were removed one at a time and an exposure cylinder with a rat contained

in it were placed into the faceplate immediately after removing the stopper. Once all of the rats were positioned within the faceplate, a cover was placed over the faceplate to prevent leakage of the test atmosphere into the laboratory where the exposure was being conducted. Test atmospheres for the high and intermediate concentration levels were allowed to naturally settle in the exposure chamber until the appropriate concentration was obtained. For the low concentration exposures, an exhaust pump fitted with a HEPA filter was connected to the initiation chamber and the exhaust line valve was opened. The red smoke particulate was drawn out of the exposure chamber into the initiation chamber until the exposure chamber reached the appropriate concentration for the low level exposures. The exhaust pump was then disconnected and the valve in the exhaust line was closed.

Figure 1. Generation/Exhaust/Exposure System



1. Thermohygrometer
2. Magnehelic Gauge
3. Temp/RH/Oxygen Probes
4. Analytical Sampling Port
5. Gravimetric Sampling Port
6. Exposure Box
7. 2 inch PVC Transfer Pipe
8. 3 inch PVC Exhaust Overpressure Pipe
9. Exposure Chamber
10. Ignition Chamber
11. 1.5 inch PVC Exhaust Pipe (used to remove smoke from exposure chamber)
12. Ring Stand
13. Smoke Grenade
14. Exhaust Overpressure Gate Valve

6.3.2 Exposure Chamber

The initiation and exposure chambers were constructed of stainless steel and glass with a nominal internal volume of approximately 1200 liters. The exposure chambers were New York University (NYU) style with cubical midsections and square-pyramidal inlets and outlets (Drew, 1978). A

different but identical chamber was used for the exposure of the control rats. The chamber distribution of red smoke particulate was determined prior to animal exposure. Analyses of the distribution data indicated that the distribution of particulate test atmosphere was sufficiently homogenous for inhalation toxicology testing (USAPHC, 2013).

6.3.3 Exposure Mode

Animals were exposed to test atmospheres of red smoke via the nose-only (head-only) route of exposure. The nose-only exposure mode was selected for this study in an attempt to minimize deposition of the red smoke particulate onto the fur of the exposed rats, and therefore, minimizing inadvertent dermal and oral exposure of the test substance to the rats. Rats were individually restrained during exposures in perforated, stainless steel cylinders with conical nosepieces.

6.3.4 Exposure Duration

Rats were exposed for 30 minutes to the test atmosphere during each exposure in an attempt to accurately mimic a potential human exposure scenario. Acute study rats were exposed to a single exposure. The subacute study rats were exposed 30 minutes per day, 5 days per week over a 3-week period (weekends excluded). Due to the staggered start, rats received a partial week of exposures during the first and last weeks of the study, however, all rats received a total of 10 exposures. Control rats were exposed to air only in a separate chamber for the same daily duration as the red smoke-exposed rats. Recovery control and 1.5 mg/L animals were exposed simultaneously with their respective main study groups.

6.4 Characterization of Exposure Chamber Atmosphere

6.4.1 Test Substance Atmospheric Concentration

The atmospheric concentration of red smoke particulate in the exposure chamber was determined by gravimetric analysis at regular intervals (e.g., beginning, middle, end) during each 30-minute exposure. Known volumes of chamber atmosphere were drawn from a sampling port in the middle of the exposure chamber representative of the animals' breathing zone. Samples were drawn through a 25-mm filter cassette that contained a pre-weighed Gelman glass fiber (Type A/E) filter. All filters were weighed on a Cahn model C-30 Microbalance. The atmospheric concentration of red smoke particulate was calculated from the difference in the pre- and post-sampling filter weights divided by the volume of chamber atmosphere sampled. The final concentration of each of the daily exposures for each concentration was reported as the average of each of the three samples during the 30-minute exposure.

The vapor/gas component of the test atmosphere was also characterized via three different methods of sampling and analysis. Combustion gas concentrations were monitored during the first acute exposure and on exposure days 2, 6, and 10 for each of the 3 exposure levels during the subacute study. Continuous real-time gas measurements were made by Fourier Transform Infrared (FTIR) spectroscopy. H30 high capacity sorbent tubes were used to collect aldehyde (carbonyl) analytes in the air which were then extracted and analyzed by High Performance Liquid Chromatography (HPLC) following Environmental Protection Agency (EPA) Method TO-11. Finally, whole air (canister) samples were collected and submitted for laboratory analysis for volatile organic compounds (VOCs) by Gas Chromatography / Mass Spectrometry (GC/MS) following EPA

Method TO-15. Analyte concentrations monitored by two or more of the above methods (e.g., acrolein) were reported based on the most reliable method of sampling and/or analysis. A detailed description of the combustion gas monitoring methods is provided in Appendix R.

6.4.2 Particle Size Analysis

Samples to determine atmospheric particle size distribution (mass median aerodynamic diameter) of the red smoke particulate were collected at least once during each of the 3 acute exposures and at 3 different times during the subacute study from the low-, intermediate-, and high-concentration level exposure chambers. Each particle size sample was collected with a Sierra® Series 210 8-Stage Cascade Impactor fitted with a Cyclone Preseparator and Anderson model SE113 Constant Flow Air Sampler. Particle size sample data were analyzed by log normal regression of particle size versus cumulative relative mass (Sierra Instruments, Inc., 1979 and USAPHC, 2015; Sierra® is a trademark of Sierra Instruments Inc.).

6.4.3 Environmental Monitoring

Chamber temperature was targeted at 22 ± 2 ºC and chamber humidity was targeted between 30 and 70 percent. Due to the static generation system, the environmental conditions of the exposure chamber were highly dependent upon the conditions of the laboratory housing the chambers and were difficult to alter regardless of the results. Chamber and exposure box temperature and humidity were monitored continually with a digital thermo-hygrometer and recorded 2-3 times during each exposure. The exposure system was a static system so chamber airflow was not monitored during this study. However, to ensure that adequate oxygen was available to the rats while they were being exposed, the exposure chamber atmosphere was monitored for oxygen content during each exposure. Minimum oxygen concentrations were targeted at 19%. Chamber oxygen concentrations were measured with a Teledyne Instruments model GB300 Oxygen Analyzer and recorded 1-2 times during each exposure.

6.5 Body Mass and Clinical Observations

Acute study rats were weighed and individually observed for clinical signs daily (weekdays only) during the exposure/recovery period. The subacute main study rats were weighed at least once each week prior to exposure and individually observed for clinical signs of toxicity on a daily basis following exposure. In addition, subacute rats were observed for morbidity/mortality during exposure and at the end of each exposure day. Body mass measurements were collected on recovery animals once each week during the recovery period and clinical observations were collected daily (weekdays only).

6.6 Food Consumption (Subacute Main Study Only)

The amount of food consumed by individual rats was determined at least once per week throughout the exposure period and during the one-month recovery period for recovery animals.

6.7 Clinical Pathology Evaluations (Subacute Main Study Only)

Blood was obtained from CO_2 anesthetized adult animals via intracardiac puncture at the termination of the study. Blood for clinical chemistry analyses was transferred to tubes free of additives, allowed to clot for at least 20 minutes, and centrifuged to obtain serum. Blood for hematology analyses was transferred immediately to tubes containing tripotassium ethylenediamine-tetraacetic acid (K_3EDTA). Blood for average activated prothrombin time was transferred to a tube containing sodium citrate, centrifuged, and analyzed using the MCA 210 Microsample Coagulation Analyzer (BioData Corporation, Horsham, PA 19044). Animals were fasted overnight prior to blood collection.

Clinical chemistry parameters including: albumin (ALB), alkaline phosphatase (ALKP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN), calcium (Ca), cholesterol (CHOL), creatinine (CREA), glucose (non-fasting) (GLU), globulin (GLOB), lactate dehydrogenase (LDH), inorganic phosphorous (PHOS), total bilirubin (TBIL), total protein (TP), sodium (Na), potassium (K), and chloride (Cl) were determined using the VetTest 8008 Chemistry Analyzer and VetLyte Electrolyte Analyzer (IDEXX Laboratories, Inc., Westbrook, ME 04092) on all valid serum samples.

Hematology parameters including: white blood cell count (WBC), WBC differential (% neutrophils (NEU %N), % lymphocytes (LYM %L), % monocytes (MONO %M), % eosinophils (EOS %E), % basophils (BASO %B)), red blood cell count (RBC), hemoglobin (HGB), hematocrit (HCT), mean cell volume (MCV), mean cell hemoglobin (MCH), mean cell hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets (PLT), and mean platelet volume (MPV) were determined using the Cell-Dyn 3700 Hematology Analyzer (Abbott Laboratories, Abbott Park, IL 60064) on all valid samples.

6.8 Necropsy and Histopathology Evaluations (Acute and Subacute Main Studies)

For the three acute exposures, 10 rats (5 male and 5 female) were euthanized with carbon dioxide and necropsied following the appropriate recovery period specified in section 6.1.1. Gross examinations were performed on all rats and the lungs were removed and preserved in a suitable medium for future histopathological examination. For the subacute main study, 6 rats/sex/group were euthanized with carbon dioxide and necropsied following the exposure period. Following a one-month recovery period, the remaining recovery rats in the control and high concentration levels (6 rats/sex/group) were also euthanized with carbon dioxide and necropsied. All rats were fasted overnight prior to the necropsy. Gross examinations were performed on all rats and the following tissues were removed, trimmed in a uniform manner, and weighed: adrenals, brain, heart, kidneys, liver, lungs, spleen, thymus, epididymides, testes, ovaries, and uterus. Any observed lesions were retained for processing. All organs, with the exception of the testes and epididymides from each animal were placed in 10% buffered formalin for at least 24 hours for fixation. The testes and epididymides were placed in modified Davidson's fixative overnight (no longer than 24 hours), rinsed, and placed in 70% ethanol. In addition to the organs listed above, samples of the pituitary, thyroid (with attached portion of trachea), lung, trachea, nose, femur bone marrow, salivary glands, gastrointestinal tract, urinary bladder, representative lymph node, peripheral nerve, sternum with bone marrow, accessory sex organs, mammary gland, thigh musculature, eye with optic nerve,

femur (including articular surface), spinal cord at three levels (cervical, midthoracic, and lumbar), and exorbital lachrymal glands were collected and placed in 10% buffered formalin.

Tissues were trimmed, placed in cassettes labeled with the protocol and animal identification numbers, routinely processed, embedded in paraffin, sectioned to a thickness of 4 microns, and stained with hematoxylin and eosin by means of an automatic stainer. Testes and epididymides were hand-stained with Periodic Acid-Schiff (PAS) reagent to facilitate evaluation of spermatogenesis. All collected tissues from rats in the main study and recovery control and high concentration groups were processed and received a full histopathological examination by the American College of Veterinary Pathology board certified military veterinary pathologist via light microscopy. The lungs, trachea, thyroid gland, tracheal lymph node, adrenal gland, kidney, liver, and nasal turbinates were processed and examined from male rats in the 0.5 mg/L group. Only the nasal turbinates were processed and examined from rats in the male 0.1 mg/L group and female 0.5 and 0.1 mg/L groups. Findings were assigned as; 0 (none) = less than 1% of the tissue section affected, 1 (minimal) = 1-5% of the tissue section affected, 2 (mild) = 6-15% of the tissue section affected, 3 (moderate) = 16-30% of the tissue section affected, and 4 (marked) = > 30% of the tissue section affected.

6.9 Statistical Analysis of Data

For variables that were measured only at the end of the subacute exposure (clinical pathology and organ mass), the exposure levels were compared using a one-factor analysis of variance (ANOVA). Organ to brain and organ to body mass ratios were calculated and analyzed similarly to the other parameters measured at the end of the study. If the dose group effect was significant, an appropriate post hoc test was used to compare pairs of dose groups and dose groups to the control group. Data was tested for normality and variance equality and adjusted if necessary. The study protocol stated that absolute organ mass would be analyzed via an analysis of covariance (ANCOVA) with body mass at the end of the study being the covariate used. The current Center statistician believed that this was not necessary because this information was captured in organ to body mass ratios. Therefore, absolute organ mass was analyzed using a one-factor ANOVA and represents a protocol deviation.

Exposure levels were also compared with respect to absolute body mass, changes in body mass and net mass changes, and changes in food consumption and net consumption using a one-factor ANOVA. If the ANOVA was significant, an appropriate post hoc test was used to compare pairs of dose groups. Data was tested for normality and variance equality and adjusted if necessary.

All in-life and end of study parameters for the control and high level recovery groups were compared using a t-test. This represents a deviation from what was stated in the study protocol. Recovery animal data was inadvertently included with the main study animals in the data analysis plan in the protocol. An ANOVA is not an appropriate statistical analysis for recovery animals due to the use of only 2 (control and 1.5 mg/L) recovery groups.

Statistical analysis on the histologic scores of animals in the subacute study was performed using a Fisher's Exact Test. The number of animals within a given exposure group with a non-zero score (i.e., lesion present) was compared to the number of control animals with a non-zero score.

An appropriate statistical software package, such as SPSS® and/or SAS® was used to perform all analyses and statistical significance was defined as $p < 0.05$ for all tests. In addition, descriptive statistics (e.g., mean, standard deviation) were used to summarize experimental data (e.g., atmospheric concentrations).

7 Results

7.1 General

7.1.1 Purity and Stability of Red Smoke

A Good Laboratory Practice (GLP)-analysis of the test substance was not performed prior to initiation of the study since the smoke grenades were received fully-assembled. The grenade fill material information supplied by the sponsor (see Table 2) is considered to be sufficient and the red smoke grenades used in this study were considered to be stable and within acceptable limits for conduct of this study.

7.1.2 Generation Method Development

Prior to the initiation of the test exposures, pre-test trials were conducted to determine the most suitable method of generating test atmospheres of red smoke. The goal of this preliminary work was to achieve reasonably stable average atmospheric concentrations at the targeted levels of test particulate for the acute study (approximately 2 mg/L) and the subacute study (approximately 0.1, 0.5, and 1.5 mg/L). The generation system used for the animal exposures was selected based on its ability to generate relatively stable atmospheres of red smoke at the targeted concentrations for a 30 minute period while containing the overpressure generated during the time that the grenade was burning.

7.1.3 Chamber Distribution of Test Atmosphere

Prior to initiation of the test exposures, a study of the chamber distribution of the particulate concentration of red smoke was performed in the exposure chamber. A series of gravimetric sample sets were collected at each targeted exposure concentration following the ignition of a single red smoke grenade in the ignition chamber. Each sample set consisted of 5 individual samples, with 3 of the samples collected at the same time from different spatial regions of the chamber faceplate and 2 samples collected from the anticipated chamber sample port locations. This process was repeated twice for each targeted exposure concentration to determine the particulate concentration at each possible animal faceplate location in the exposure chamber. Two chamber sample port locations were included in the chamber distribution to determine which location was most representative of the animal breathing zone. No significant differences were observed between gravimetric samples collected at 6 different spatial locations in the exposure chamber faceplate for each targeted exposure concentration. Therefore, the test substance was considered to be homogenously distributed throughout the area of the exposure chamber where the rats were being exposed. Gravimetric samples collected from the 2 chamber sampling ports during this pretest trial also indicated that the chamber concentration was similar at the exposure chamber sampling ports when compared to samples collected from the chamber faceplate in the area where the rats were to be positioned during exposure. Therefore, all gravimetric chamber

samples were collected from these 2 chamber sample ports during the animal exposure and this data was considered to be representative of the breathing zone of the rats. See Appendix D for details.

7.2 Acute Studies

7.2.1 General

A total of 3 acute exposures, each with 10 rats (5 male and 5 female), were conducted. All animals were exposed nose-only for a single 30 minute period for each acute exposure. The first acute exposure was used to determine the median lethal concentration (LC_{50}) for exposure to red smoke and the results are summarized below as well as in Appendix E. The second and third acute exposures were primarily designed to confirm/clarify possible lesions observed during necropsy of animals from the first acute exposure. These exposures used a modified necropsy schedule outlined in section 6.1.1 so the results were not used for the LC_{50} determination. Exposure information for the second and third acute exposures is summarized in Appendix E and is not reported below except for histopathology results. All 3 acute exposures were performed using the same methods described in section 6.3.1.

7.2.2 Exposure Chamber Concentration and Particle Size Data

The mean atmospheric concentration of red smoke particulate in the exposure chamber for the first acute exposure was determined to be 1.92 ± 0.312 mg/L. The particulate concentration during this exposure ranged from 1.56 – 2.10 mg/L. The particle size distribution of the test atmosphere during the exposure was characterized by measurement of the mass median aerodynamic diameter (MMAD). Two particle size samples were taken during the 30 minute exposure. The MMAD of the test atmosphere generated ranged from 1.6 – 1.9 microns (µm) and the geometric standard deviation (GSD) ranged from 1.9 – 2.1. The percent particles by mass were similar between the 2 particle size samples with 13 - 28% of the particles less than 1 µm, 89% of the particles less than 4 µm for both samples, and 100% of the particles less than 10 µm for both samples.

7.2.3 Exposure Chamber Environmental Conditions

The internal exposure chamber temperature ranged from 74 - 75°F and the relative humidity ranged from 36 - 39%. Exposure chamber oxygen remained constant at 21%. The animal exposure box temperature ranged from 72 – 73°F and the relative humidity ranged from 40 – 55%. All environmental conditions within the exposure chamber and animal exposure box were considered to be acceptable for the conduct of this study.

7.2.4 Body Mass of Rats

Rats were weighed on test days 1, 2, 3, 6, 8, 10, 13, and 15. Slight body mass losses were observed in some rats on the day following exposure, however, all rats exhibited normal mass gain patterns following post-exposure day 1 and experienced an overall mass gain by the end of the 14-day recovery period.

7.2.5 Clinical Observation of Rats

Immediately following exposure, clinical signs observed in rats included red-stained fur (primarily on the head, face, and forelimbs), and salivation. With the exception of one female with dried red material around the nose on day 3, the red-stained fur and salivation resolved by test day 2. One female rat exhibited slight red staining of the urogenital area from test days 6 -15. Other signs observed but not necessarily attributed to the test material included one male rat with a scab on its right shoulder and one female rat with barbering (hair loss) on both forelimbs.

7.2.6 Gross Necropsy

Following a 14-day recovery period, all ten rats from the first acute exposure (1.92 mg/L) received a gross necropsy with limited histopathology of the respiratory tract (lungs only). Upon gross observation, all male rats appeared to have dark patches in various areas of the lung and 2 of 5 appeared partially atelectatic and necrotic. One male rat also appeared to have dark colored kidneys and liver. Four of 5 female rats appeared to have dark and/or necrotic areas on various regions of the lung and 1 female had small white patches throughout the lung.

Rats were exposed to an average atmospheric concentration of 1.69 mg/L red smoke nose-only for 30 minutes for the second acute exposure. Three of 5 male and 3 of 5 female rats were necropsied the day following exposure. Although all 3 male rats exhibited pale pink regions throughout the lung, 1 male also exhibited multifocal to coalescing dark brown to red regions on the ventral surface of both sides of the lung with portions of the lung having a reticular pattern. Two of 3 female rats necropsied on the day following exposure also had pale pink regions throughout the lung. One female had a focal brown area on the right side of the lung and 1 female exhibited whitish areas on the fringes of all lobes of the lung. Two of 5 male and female rats were necropsied following the standard 14-day recovery period. No gross lesions were recognized in any of these rats.

Rats were exposed to an average atmospheric concentration of 0.56 mg/L red smoke nose-only for 30 minutes for the third acute exposure. The same necropsy schedule was employed for the third acute exposure as the second exposure with 3 of 5 males and females necropsied the day after exposure and the remainder necropsied after a 14-day recovery period. Gross findings in male rats necropsied 1 day after exposure included 1 animal with multifocal dark brown areas on the ventral pulmonary surface, 1 animal with a pale pink left ventral pulmonary surface, and 1 animal with no gross lesions recognized. One female rat exhibited brown focal spots on the anterior portions of right & left lobes of the lung with pale pink outer edges, a mildly dark liver, and a 1 millimeter white focal area on the left kidney. One female rat had a pale pink right anterior portion of lung and 1 had no gross lesions recognized. Of the 2 male rats necropsied following a 14-day recovery period, 1 exhibited scattered pale, slightly raised areas, in the distal right caudal and left lobes and 1 had whitish pink parenchyma peripheral to central dark red discoloration of the lung. One female had hydronecrosis of right kidney and 1 had no gross lesions recognized.

7.2.7 Histopathology

Due to the apparent findings in the lungs observed during necropsy of animals from the first acute exposure, the lungs were preserved for future histology from all 3 acute exposures. Acute inhalation exposures typically do not employ the use of control animals. Therefore, the histology results from the acute exposures were compared against the age-matched control animals from the

subacute exposures for statistical purposes. Histology findings from the acute studies are summarized below in Table 3.

Table 3. Acute Histology Findings

		Control* (0 mg/L)		Acute #1 (1.92 mg/L)		Acute #2 (1.69 mg/L)		Acute #3 (0.56 mg/L)	
Tissue	**Histologic Finding**	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**
Lung	Congestion, alveolar septal	1/6	0/6	4/5	2/5	4/5	4/5[1]	5/5[1]	2/5
Lung	Congestion, venous	2/6	1/6	1/5	0/5	4/5	4/5	4/5	4/5
Lung	Erythrocyte extravasation, alveolar	4/6	1/6	4/5	2/5	5/5	1/5	5/5	3/5
Lung	Erythrophagocytosis	1/6	0/6	0/5	0/5	2/5	0/5	2/5	1/5
Lung	Hemorrhage, perivascular /peribronchiolar	4/6	3/6	2/5	1/5	3/5	2/5	5/5	4/5
Lung	Edema, perivascular	0/6	0/6	2/5	2/5	0/5	0/5	1/5	1/5
Lung	Ateletasis, alveolar	2/6	2/6	4/5	3/5	5/5	2/5	4/5	0/5
Lung	Histiocytosis, alveolar	1/6	0/6	4/5	1/5	2/5	0/5	1/5	0/5
Lung	Infiltrate, granulocytic	0/6	2/6	2/5	1/5	1/5	1/5	4/5[1]	4/5
Lung	Edema, subpleural	0/6	0/6	3/5	3/5	1/5	0/5	0/5	0/5
Lung	Fibrosis, alveolar, focal	0/6	0/6	1/5	0/5	0/5	0/5	0/5	0/5
Lung	Crystals, eosinophilic, alveolar	0/6	0/6	0/5	0/5	1/5	0/5	0/5	0/5

* = Control animals from age-matched subacute study
[1] = Increased incidence vs. subacute controls, $p<0.05$

The only statistically significant findings observed in the histology of the male lungs from the acute exposures included alveolar septal congestion and granulocytic infiltration from the third exposure. The recovery period length did not appear to have an effect on the presence or severity of these findings. Alveolar septal congestion was also significantly increased in female rats following the second acute exposures. Although the length of the recovery period did not affect the presence of this finding, the severity scores of those necropsied 14-days after exposure were mild to moderate compared to minimal for those necropsied on the day after exposure. In addition, both female rats with alveolar septal congestion following the third exposure were necropsied 14-days after exposure with moderate severity scores. Other lung lesions noted following the acute exposures were either common background lesions noted in the subacute control lungs or incidental findings not linked to exposure to the test article.

7.2.8 Mortality and LC_{50} Determination

All ten rats exposed to 1.92 mg/L red smoke particulate during the first acute exposure survived the exposure and recovery period. Therefore, the 30-minute, inhalation median lethal concentration (LC_{50}) of red smoke in rats is greater than 1.92 mg/L.

7.2.9 Combustion Gas Analytical Results

Of the analytes measured using the 3 different analytical methods, a total of 24 compounds measured in the exposure chamber during these experiments were identified as the primary combustion by-products of the pyrotechnic formulation in the red smoke grenades. These analytes were detected in most of the samples collected during both the acute and subacute exposures and

are not believed to be laboratory carry-over and/or contaminants. The concentrations of these analytes were compared against applicable short-term exposure limits (STEL) when available. Both acrolein and formaldehyde concentrations exceeded reported STELs during the acute exposure. Table 4 provides a summary of the significant combustion gases monitored during the first acute study, the analytical method providing the most reliable results, and reported exposure limits. See Appendix R for details.

Table 4. Acute Exposure Combustion Gases

Analyte	Analytical Method	Concentration (ppm)	Exposure Limit (ppm)
Carbon Dioxide	FTIR	1986	STEL[1] 30,000 IDLH[2] 40,000
Carbon Monoxide	FTIR	149	Ceiling[3] 200 IDLH[2] 1200
Methane	FTIR	12	Asphixiant[4]
Acetylene	FTIR	1.1	Ceiling[3] 2500
Ethylene	FTIR	2.6	Excursion Limit[5] 600
Nitric Oxide	FTIR	5.6	Excursion Limit[5] 75 IDLH[2] 100
Formaldehyde	TO-11 HPLC	26	STEL[1] 0.1 STEL[6] 2 Ceiling[3] 0.3 (sensitizer)
Acetaldehyde	TO-11 HPLC	13	Ceiling[3] 25
Propionaldehyde	TO-11 HPLC	0.44	Excursion Limit[5] 60
Crotonaldehyde	TO-11 HPLC	0.61	Ceiling[3] 0.3 (skin) IDLH[2] 50
2-Butanone	TO-15 GC/MS	0.71	STEL[1] 300 IDLH[2] 3000
Acetone	TO-15 GC/MS	3.96	IDLH[2] 2500
Acetonitrile	TO-15 GC/MS	0.83	IDLH[2] 500
Acrolein	TO-15 GC/MS	2.92	Ceiling[3] 0.1 (skin) STEL[1] 0.3 IDLH[2] 2
Benzene	TO-15 GC/MS	0.18	STEL[1] 1 STEL[7] 2.5 (skin)
Butadiene	TO-15 GC/MS	0.23	STEL[6] 5 Excursion Limit[5] 6
Chloromethane	TO-15 GC/MS	0.16	STEL[7] 100 (skin) Ceiling[8] 200
Ethylbenzene	TO-15 GC/MS	0.058	STEL[7] 125 STEL[1] 125 IDLH[2] 800
m,p-Xylene	TO-15 GC/MS	0.21	STEL[7] 150 STEL[1] 150 IDLH[2] 900
Methylene Chloride	TO-15 GC/MS	0.013	STEL[6] 125 Excursion Limit[5] 150
o-Xylene	TO-15 GC/MS	0.041	STEL[7] 150 STEL[1] 150 IDLH[2] 900
Propylene	TO-15 GC/MS	4.42	Excursion Limit[5] 1500
Styrene	TO-15 GC/MS	0.0094	Ceiling[8] 200 STEL[7] 40 STEL[1] 100 IDLH[2] 700

Toluene	TO-15 GC/MS	0.072	Excursion Limit[5] 60 STEL[1] 150 IDLH[2] 500 Ceiling[8] 300

GC/MS = Gas Chromotography/Mass Spectrometry
FTIR = Fourier Transform Infrared Spectrometer
HPLC= High Performance Liquid Chromotagraphy
ppm=parts per million
[1] National Institute for Occupational Safety and Health (NIOSH) 15-minute short-term exposure limit (STEL)
[2] NIOSH Immediately Dangerous to Life and Health (IDLH) value
[3] American Conference of Governmental Industrial Hygienists (ACGIH) ceiling limit
[4] Simple asphyxiant, oxygen must be maintained above 18%
[5] ACGIH Excursion Limit, 3 times the threshold limit value (TLV) for no more than 15 minutes
[6] Occupational Safety and Health Administration (OSHA) 15-minute STEL
[7] ACGIH 15-minute STEL
[8] OSHA permissible exposure limit ceiling value

7.3 Subacute Main Study

7.3.1 Atmospheric Concentration of Red Smoke Particulate

A total of 11 animal exposures were conducted. In order to accommodate a reasonable necropsy schedule at the end of the exposure period, all animals (including recovery animals) were divided into 2 equal groups designated as group A and group B. The initial exposure for the 2 groups was staggered by one day. Group A rats were exposed from exposure #1 through #10 and group B rats were exposed from exposure #2 through #11. All rats received a total of 10 exposures. Although slight differences in the chamber concentrations of red smoke were noted between the 2 groups (Table 5), the slight differences between them has no toxicologically-relevant consequences in the interpretation of the data. Therefore, the combined exposure concentration data for red smoke will be reported. The gravimetrically determined overall (combined) mean concentrations ± standard deviation of red smoke in the exposure chambers targeted to 0.1, 0.5, and 1.5 mg/L were 0.11 ± 0.013, 0.50 ± 0.096, or 1.52 ± 0.059 mg/L, respectively. Combined chamber concentrations for red smoke were calculated by including all chamber concentration data collected over the 11 exposures conducted. The overall mean concentrations were 110, 100, or 101 percent of the targeted concentrations of 0.1, 0.5, and 1.5 mg/L, respectively. The daily mean concentrations ranged from 95-132, 88-117, or 77-143 percent of the overall mean concentrations of 0.1, 0.5, and 1.5 mg/L, respectively. The difference between the overall actual mean concentrations and the targeted concentrations, the range of daily mean concentrations, and the standard deviations (daily and overall) were greater than what is typically desired (e.g., <10 percent), however, the difficulties associated with maintaining consistent particulate atmospheres are to be expected with the type of generation system used during this study. The mean concentrations of red smoke particulate were as consistent as can be reasonably expected for generating test atmospheres with pyrotechnically disseminated grenades, and therefore, were considered acceptable for evaluating the toxicity of the test substance in this study. Exposure concentration data are presented in Appendix F and summarized in Table 5.

Table 5. Subacute Main Study: Summary of Chamber Concentrations of Red Smoke Particulate

DESIGN CONCENTRATION	GROUP IDENTIFICATION	MEASURED CONCENTRATION (mg/L)

(mg/L)		MEAN	S.D.	RANGE	N
0	Group A	0	N/A	0 – 0	10
	Group B	0	N/A	0 – 0	10
	Combined	**0**	**N/A**	**0 – 0**	**11**
0.1	Group A	0.11	0.013	0.09 – 0.16	30
	Group B	0.11	0.012	0.09 – 0.16	30
	Combined	**0.11**	**0.13**	**0.09 – 0.16**	**33**
0.5	Group A	0.50	0.097	0.37 – 0.71	30
	Group B	0.50	0.094	0.37 – 0.67	30
	Combined	**0.50**	**0.096**	**0.37 – 0.71**	**33**
1.5	Group A	1.56	0.60	0.76 – 2.82	30
	Group B	1.53	0.62	0.76 – 2.82	30
	Combined	**1.52**	**0.59**	**0.76 – 2.82**	**33**

mg/L = milligrams per liter
S.D. = standard deviation
N = number of samples collected
N/A = not applicable

7.3.2 Nominal Concentration of Test Substance

The generation system used during this study utilized a single red smoke grenade to generate test atmospheres for each of the 3 acute exposures and all 3 daily exposure concentrations for the subacute study. The total amount disseminated from each grenade was determined daily and recorded in the study records but the generation system used for this study did not lend itself to the calculation of a nominal concentration at each exposure level. In addition, the actual exposure chamber concentrations of red smoke particulate were measured on a frequent basis for each exposure concentration, therefore the determination of nominal concentrations was not considered a useful parameter for this study.

7.3.3 Particle Size Distribution of Test Substance Atmosphere

The red smoke particulate atmospheres generated during this study were within respirable ranges for rats and were similar across the 3 exposure concentrations. The mass median aerodynamic diameter (MMAD) for the test particulate atmospheres ranged from 2.0 to 2.6 µm, the geometric standard deviation (GSD) ranged from 1.7 to 2.6 with 4-16 percent of the particles less than 1µm, 54-74 percent of the particles less than 3 µm, and 95->99 percent of the particles less than 10 µm. Particle size distribution data are summarized in Table 6.

Table 6. Subacute Main Study: Summary of Chamber Atmosphere Particle Size Data

CONCENTRATION (mg/L)	EXPOSURE NUMBER	MMAD (µm)	GSD	% PARTICLES BY MASS		
				<1 µm	<3 µm	<10 µm

0.1	4	2.6	2.0	9	54	96
	7	2.0	1.7	15	74	>99
	10	2.3	1.9	10	68	>99
0.5	3	2.4	1.7	4	70	>99
	6	2.2	1.7	8	70	>99
	9	2.4	2.0	10	66	99
1.5	2	2.4	1.7	5	68	>99
	5	2.4	2.0	11	62	98
	8	2.4	2.6	16	60	95

mg/L = milligrams per liter GSD = geometric standard deviation µm = micron
MMAD = mass median aerodynamic diameter % = percent

7.3.4 Exposure Chamber Environmental Conditions

Chamber environmental conditions were reasonably similar between the exposure chamber and the control chamber. The temperature in both the exposure and control chambers during the 11 exposures ranged from 67-74 ºF with a targeted range of 68-79 ºF. The relative humidity in the exposure and control chambers ranged from 49-79 percent with a targeted range of 30-70 percent. The oxygen concentration in both chambers throughout all 11 exposures ranged from 20.1-21.2 percent with a targeted range of 19-22 percent. The exposure box (surrounding the faceplate on the side of the exposure chamber) temperature ranged from 68-75 ºF. Exposure box relative humidity varied more than other environmental conditions since the bodies of the rats were inside an enclosed exposure box with little to no air flow during each 30 minute exposure. The relative humidity of the 2 exposure boxes ranged from 53-96 percent. Targeted exposure box environmental conditions were identical to the targeted exposure chamber environmental conditions. Although both the exposure chamber and exposure box environmental conditions were outside of targeted ranges at certain times throughout the 11 exposures, these instances did not appear to adversely affect the health of the animals based on their clinical appearance. In addition, due to the semi-static nature of the generation system used there was no way to control the environmental conditions once the grenade was initiated inside the ignition chamber. Exposure chamber environmental conditions were highly dependent upon the conditions of the laboratory housing the chambers at the time of grenade initiation. In an effort to keep the relative humidity down during the control exposures, the back plate was not placed on the exposure box starting on the fourth exposure day. This was not feasible during the smoke exposures since the smoke atmospheres would pass around the heads of the rats and leak into the laboratory without the back plates of the exposure box. Overall, the environmental conditions in the exposure chambers and boxes were within acceptable comfort levels for the rats and were considered adequate for 30 minute exposures. See Appendix G for details.

7.3.5 Body Mass, Body Mass Change, and Food Consumption

Mean male and female body mass did not differ between exposed and control groups for main study or recovery rats when measured at designated time points throughout the study. Mean body mass change in the male recovery 1.5 mg/L exposure group was decreased during exposure days 1-3 ($p=0.042$) and increased during recovery week 2 ($p=0.027$) compared to recovery controls. Body mass change did not differ between exposed and control groups for main study or female recovery rats at any time point throughout the study. See Appendices H and I for details.

Mean male and female food consumption did not differ between exposed and control groups for main study or recovery rats when measured at designated time points throughout the study. See Appendix J for details.

7.3.6 Clinical Observation of Rats

All main study and recovery rats from the study survived the exposure and subsequent recovery period. No adverse clinical observations were noted in rats while they were in the exposure chambers although visibility was somewhat limited during the 0.5 and 1.5 mg/L exposures. Immediately following exposures, clinical signs observed in an exposure level-related manner (e.g., staining was more prevalent in 1.5 mg/L rats than in the rats exposed to 0.1 or 0.5 mg/L) were limited to red-stained fur on the head, wet/red stained nose, and wet/red stains around the mouth. The presence of these signs was expected given the nature of the test substance and was not considered to be necessarily adverse. The presence of the test material on the fur/skin of the rats following exposure did not appear to have any immediate or obvious adverse effects and typically cleared by the next morning. One female rat in the 1.5 mg/L exposure group was observed with orange-colored urine on exposure day 9 which was likely a result of ingestion of the test material from grooming. Clinical observations not necessarily related to exposure to the test material noted in rats during the study and recovery period included dried red material around eyes/nose and hair loss. The observation of dried red material around eyes/nose was only noted in the control groups since the test material would have obscured this observation in rats exposed to red smoke. This sign is typically observed in many animals following inhalation exposures and is treated as a stress-related response involving the secretion of porphyrin from the Harderian gland. See Appendix K for details.

7.3.7 Clinical Chemistry and Prothrombin Time

Male and female clinical chemistry parameters and prothrombin time measurements, for both main study and recovery groups, were mostly unaffected by subacute exposure to red smoke relative to controls. Following the 4-week recovery period, albumin (ALB) concentrations in the male 1.5 mg/L recovery group were decreased ($p=0.043$ and 1.1 fold) relative to recovery controls. Albumin concentrations in the male 1.5 mg/L recovery group were below those of historical age-matched controls (Giknis and Clifford, 2006). Female 1.5 mg/L recovery albumin concentrations were also 1.1 fold lower, but were not decreased relative to female recovery controls. See Appendices L and N for details.

7.3.8 Hematology

Hematological differences between main study exposed and control animals was limited to the leukocyte differential in male rats. Percent basophils (BASO %) in the 0.1 mg/L group were decreased ($p=0.038$ and 1.7 fold) and percent lymphocytes (LYM %) in the 0.5 mg/L group were increased ($p=0.014$ and 1.1 fold), relative to main study controls. The percent basophils of all exposure groups were well above the ranges for historical age-matched controls. Lymphocyte percentages of all exposure groups, except the 0.5 mg/L group, were below those of historical age-matched controls (Giknis and Clifford, 2006). Neither hematological parameter was part of a relevant exposure concentration-related trend.

Following the 4-week recovery period, male hemoglobin concentrations (HGB) in the 1.5 mg/L recovery group were reduced (p=0.031 and 1 fold), relative to recovery controls. The hemoglobin concentrations of both male recovery groups remained with the ranges reported for age-matched historical controls (Giknis and Clifford, 2006). No additional hematological differences were observed in the male and female recovery groups. See Appendix M for details.

7.3.9 Gross Necropsy

Light or dark patches in the lungs were observed in male and female main study rats exposed to red smoke at concentrations of 0 mg/L (three male, two female), 0.1 mg/L (three male, three female), 0.5 mg/L (four male, three female), and 1.5 mg/L (four male, five female). This observation was only noted in two 1.5 mg/L recovery male rats. Dark or pale livers were observed in male and female main study rats at concentrations of 0 mg/L (two female), 0.1 mg/L (one male, one female), 0.5 mg/L (two male, three female), and 1.5 mg/L (four male, one female). One recovery control female rat also appeared to have a discolored liver. One male rat in both the 1.5 and 0.1 mg/L main study exposure groups had a single, small mass on the liver and one male recovery control rat was noted as having a reticular pattern in the liver. Additional gross observations noted at necropsy included; two male main study rats (one 1.5 mg/L and one 0.5 mg/L) with dark white contents in the urinary bladder, one 0.1 mg/L main study female with orange contents in the ileum, one 1.5 mg/L recovery male with small testes, and one 1.5 mg/L female with a distended uterus. See Appendix O for details.

7.3.10 Organ Mass and Mass Ratios

Male and female organ mass and mass ratios (body and brain), for both main study and recovery groups, were unaffected by subacute exposure to red smoke relative to controls. See Appendix P for details.

7.3.11 Histopathology

Histologic changes resulting from exposure to red smoke was primarily limited to the nasal turbinates in both male and female rats. A number of level 1 nasal turbinates were coded as not present in the original pathology report. It was discovered later that the pathologist did not feel that these turbinate sections were adequate for evaluation. A second board certified military pathologist examined the level 1 nasal turbinate sections from the main study animals only, scored those that were deemed adequate, and requested duplicate slides for those that were determined to be poor quality. These results are included as an addendum to the original pathology report in Appendix Q and summarized separately in Table 7 below. Reevaluation of the level 1 nasal turbinates revealed 6 of 6 (p=0.0152) 1.5 mg/L male rats exhibited transitional or respiratory epithelial hyperplasia. Granulocytic infiltration (6 of 6) accompanied the hyperplasia in 1.5 mg/L males but was not increased compared to main study controls. Level 1 hyperplasia of the transitional or respiratory epithelium was also present in male rats exposed to 0.5 mg/L (4 of 6) and 0.1 mg/L (1 of 4) but was not increased compared to controls. In female main study rats, the incidence of level 1 transitional or respiratory epithelial hyperplasia was increased at the 1.5 and 0.1 mg/L exposure levels with 5 of 6 (p=0.0152) exposed animals affected in both groups. Granulocytic infiltration was occasionally present at all exposure levels but was not increased compared to female controls. Although the incidence of level 1 mucosal degeneration was only increased females at the 1.5 mg/L exposure

concentration (5 of 6, p=0.0152) compared to controls, this finding did exhibit an exposure concentration-related trend in both male and female rats with the small sample size obscuring the statistical significance.

At level 2 of the nasal turbinates, granulocytic infiltration was the primary histologic finding in male and female rats exposed to red smoke. This finding did not exhibit an exposure level-related trend and was only increased in the 1.5 mg/L males (5 of 6 and p=0.015) and 0.1 mg/L females (4 of 5 and p=0.048) compared to controls. At level 3, the only significant histologic finding was an increase in the incidence of respiratory epithelial hyperplasia (4 of 4 and p=0.029) in male rats exposed to 0.1 mg/L red smoke.

Red smoke exposed male and female rats (main study) did not exhibit any increase in histologic changes in the lung. Sporadic findings in the 1.5 and 0.5 mg/L males and 1.5 mg/L females were similar to those observed following the acute exposures and included alveolar septal congestion, venous congestion, alveolar atelectasis, and granulocytic infiltrates. No additional histologic changes were observed in the other tissues evaluated for the 1.5 mg/L male and female rats compared to controls.

No histologic changes were noted in male and female 1.5 mg/L recovery groups evaluated following a 4 week recovery period compared to recovery controls. Changes noted in the tissues evaluated for the main study animals (primarily nasal turbinates) were either not present in the 1.5 mg/L recovery rats or were also prevalent in the respective recovery control groups. See Table 7 and Appendix Q for details.

Table 7. Summary of Subacute Histologic Findings

Tissue	Finding	Control		1.5 mg/L		0.5 mg/L		0.1 mg/L		R. Control		R. 1.5 mg/L	
		M	F	M	F	M	F	M	F	M	F	M	F
NT, Level 1	Hyperplasia, transitional epithelium	0/6	0/4	6/6*	5/5*	4/6	3/3*	1/1	4/4*	0/5	1/6	0/5	1/5
NT, Level 1	Hyperplasia, respiratory epithelium	2/6	2/4	5/6	3/5	2/6	1/3	1/1	2/4	2/5	2/6	1/5	3/5
NT, Level 1	Nasoturbinate, mucosal degeneration	0/6	0/4	2/6	3/5	0/6	1/3	1/1	1/4	0/5	1/6	0/5	0/5
NT, Level 1	Infilitrate, granulocytic	1/6	0/4	4/6	1/5	3/6	1/3	1/1	4/4*	1/5	3/6	0/5	3/5
NT, Level 1	Infiltrate, lymphocytic	1/6	0/4	3/6	0/5	0/6	1/3	1/1	4/4*	0/5	0/6	2/5	1/5
NT, Level 2	Infilitrate, granulocytic	0/6	0/4	5/6*	2/6	0/5	0/6	3/6	4/5*	0/5	1/6	0/6	1/5
NT, Level 2	Hyperplasia, respiratory epithelium	4/6	0/4	4/6	1/6	2/5	4/6	3/6	1/5	0/5	3/6	4/6	1/5
NT, Level 2	Infiltrate, lymphocytic	2/6	1/4	0/6	0/6	0/5	0/6	1/6	4/5	1/5	2/6	2/6	2/5
NT, Level 2	Nasoturbinate, mucosal degeneration	0/6	-	3/6	-	1/5	-	0/6	-	0/5	-	0/6	-
NT, Level 3	Hyperplasia, respiratory epithelium	0/3	2/6	2/2	2/5	3/6	1/5	4/4*	2/6	2/5	1/5	NE	2/3
Lung	Congestion, alveolar septal	1/6	0/6	3/6	1/6	5/6	NE	NE	NE	6/6	3/5	5/6	2/6
Lung	Congestion, venous	2/6	1/6	1/6	4/6	2/6	NE	NE	NE	4/6	1/5	5/6	2/6
Lung	Atelectasis, alveolar	2/6	2/6	5/6	4/6	3/6	NE	NE	NE	2/6	3/5	4/6	3/6
Lung	Infiltrate, granulocytic	0/6	1/6	1/6	1/6	0/6	NE	NE	NE	0/6	0/5	0/6	2/6
Lung	Hemorrhage, perivascular or peribronchiolar	4/6	3/6	2/6	0/6	5/6	NE	NE	NE	4/6	1/5	0/6	2/6
Lung	Histiocytosis, alveolar	1/6	0/6	2/6	2/6	2/6	NE	NE	NE	0/6	0/5	1/6	1/6
NASAL TURBINATE DATA BELOW IS FROM PATHOLOGY REPORT ADDENDUM													
NT, Level 1	Hyperplasia, transitional or respiratory epithelium	1/6	0/5	6/6*	5/6*	4/6	2/6	1/4	5/6*	NE	NE	NE	NE
NT, Level 1	Infiltrate, granulocytic	3/6	0/5	6/6	2/6	4/6	1/6	1/4	2/6	NE	NE	NE	NE
NT, Level 1	Nasal turbinate, mucosa, degeneration	0/6	0/5	4/6	5/6*	0/6	2/6	0/4	1/6	NE	NE	NE	NE

NT, Level 1	Nasal turbinate, mucosa, metaplasia, squamous	0/6	0/5	1/6	1/6	1/6	0/6	0/4	0/6	NE	NE	NE	NE
NT, Level 1	Goblet cell hyperplasia	2/6	1/5	5/6	3/6	3/6	1/6	0/4	4/6	NE	NE	NE	NE

* Increased incidence compared to controls, p<0.05
NT = Nasal turbinates
R. = Recovery
NE = Not evaluated
M = Males
F = Females

7.3.12 Benchmark Dose Determination

Incidence of mucosal degeneration in the level 1 nasoturbinates was identified as the critical endpoint in this study based on the exposure level-related response in male and female rats. Inhibition of the nasal mucociliary function can be a sensitive indicator of toxicity in response to certain inhaled xenobiotics, such as formaldehyde. The mucociliary apparatus plays an important role as an upper airway defense mechanism and, if compromised, could lead to an increase in nasal infections and susceptibility to lower respiratory tract diseases (Harkema et al., 2006). Additional findings in the nasal turbinates associated with red smoke exposure, including hyperplasia of the transitional or respiratory epithelium and granulocytic/lymphocytic infiltration, were not selected for benchmark dose (BMD) modeling as they did not demonstrate a clear exposure concentration-response. Incidence rates of granulocytic/lymphocytic infiltration were frequently higher at the lowest exposure level and did not yield any models with an acceptable fit. Transitional epithelial hyperplasia was observed in nearly all of the turbinates microscopically evaluated and hyperplasia of the respiratory epithelium was frequently observed in control animals as well as exposed animals. Benchmark Dose Software (BMDS v.2.6) was used to fit mathematical models to the level 1 nasoturbinate mucosal degeneration data from the pathology addendum data for males and females separately and calculate a lower-bound confidence limit on a dose corresponding to a 10 percent response rate ($BMDL_{10)}$ (EPA, 2002). Appropriate models were selected based on goodness-of-fit and statistical parameters (p>0.1, lowest AIC and residuals). A mean BMD of 1.135 mg/L was calculated for the male rats based on the Gamma, Logistic, Log Logistic, Log Probit, Multistage 3, Probit, and Weibull models. Although the incidence of level 1 mucosal degeneration in main study male and female rats was similar at the highest exposure level, several female rats exhibited this finding in the 0.5 and 0.1 mg/L exposure levels. A mean BMD of 0.099 mg/L was calculated for the female rats based on the Gamma, Multistage 2, Multistage 3, Weibull, and Quantal-Linear models for the finding of mucosal degeneration. The benchmark doses of 1.135 and 0.099 mg/L corresponded to $BMDL_{10}$ of 0.351 and 0.054 mg/L for males and females, respectively.

7.3.13 Analytical Results

As expected, the same 24 significant combustion gases were identified for the subacute exposures as the acute exposure. Combustion gas concentrations did not decrease proportionately with particulate concentrations due to the containment of the combustion atmosphere within the two 1200-liter exposure chambers (initiation and exposure chambers). Dilution room air was only added to reach favorable particulate concentrations for the 0.1 mg/L exposure level. Acrolein and formaldehyde exposure levels typically exceeded exposure limits at all 3 exposure levels. Table 8 provides a summary of the significant combustion gas concentrations at each exposure level for each of the 3 exposure days when they were monitored. The reporting method for each analyte

and applicable exposure limits were listed in Table 4 and also apply to the subacute exposures. See Appendix R for details.

Table 8. Subacute Exposure Combustion Gases

Analyte	Exposure Level (mg/L)	Exposure Day 2 Avg. Conc. (ppm)	Exposure Day 6 Avg. Conc. (ppm)	Exposure Day 10 Avg. Conc. (ppm)	3-Day Avg. Conc. (ppm)
Carbon Dioxide	1.5	1940	2242	2372	2185
	0.5	3312	3279	3933	3508
	0.1	3514	2280	2683	2826
Carbon Monoxide	1.5	133	141	190	155
	0.5	108	121	163	131
	0.1	75	46	62	61
Methane	1.5	9.1	10	14	11
	0.5	7.6	8.6	12.1	9.5
	0.1	5.8	4.3	5.5	5.2
Acetylene	1.5	ND	1.0	1.2	1.1
	0.5	ND	1.3	1.1	1.2
	0.1	ND	ND	ND	NA
Ethylene	1.5	2.1	2.5	4.1	2.9
	0.5	2.0	2.3	3.7	2.7
	0.1	1.6	1.0	1.6	1.4
Nitric Oxide	1.5	4.1	5.3	8.5	6.0
	0.5	3.5	4.9	6.9	5.1
	0.1	3.2	ND	3.7	3.4
Formaldehyde	1.5	23	11	16	17
	0.5	18	13	13	14
	0.1	13	8.0	8.1	9.6
Acetaldehyde	1.5	13	2.5	6.5	7.5
	0.5	12	5.3	8.5	8.5
	0.1	11	6.1	8.0	8.2
Propionaldehyde	1.5	0.44	ND	0.40	0.42
	0.5	0.54	0.22	0.45	0.40
	0.1	0.56	0.33	0.41	0.43
Crotonaldehyde	1.5	0.61	0.45	0.60	0.55
	0.5	0.66	0.58	0.60	0.61
	0.1	0.76	0.38	0.52	0.55
2-Butanone	1.5	0.54	0.44	0.58	0.52
	0.5	0.41	0.41	0.44	0.42
	0.1	0.31	0.098	0.13	0.18
Acetone	1.5	3.83	4.17	5.47	4.49
	0.5	3.79	4.00	5.47	4.42
	0.1	3.2	2.0	2.5	2.6
Acetonitrile	1.5	0.77	0.57	1.91	1.08
	0.5	0.66	0.58	0.60	0.61
	0.1	0.47	0.12	0.19	0.26
Acrolein	1.5	1.92	2.53	3.45	2.63
	0.5	2.09	2.36	3.05	2.5
	0.1	1.8	1.2	1.5	1.5
Benzene	1.5	0.19	0.12	0.29	0.20
	0.5	0.14	0.14	0.24	0.17
	0.1	0.11	0.041	0.063	0.071
Butadiene	1.5	0.068	0.021	0.045	0.045
	0.5	0.11	0.042	ND	0.075
	0.1	0.099	0.050	0.036	0.062
Chloromethane	1.5	0.13	0.10	0.11	0.11
	0.5	0.11	0.087	0.097	0.097
	0.1	0.082	0.034	0.030	0.049
Ethylbenzene	1.5	0.12	0.039	0.069	0.077

	0.5	0.097	0.046	0.058	0.067
	0.1	0.085	0.012	0.013	0.037
m,p-Xylene	1.5	0.46	0.13	0.23	0.27
	0.5	0.37	0.15	0.18	0.23
	0.1	0.32	0.041	0.044	0.14
Methylene Chloride	1.5	0.095	0.012	0.16	0.088
	0.5	0.086	0.014	0.16	0.088
	0.1	0.032	0.006	0.008	0.015
o-Xylene	1.5	0.18	0.023	0.062	0.088
	0.5	0.14	0.025	0.055	0.073
	0.1	0.12	0.008	0.009	0.047
Propylene	1.5	1.80	2.27	4.01	2.69
	0.5	2.44	2.27	0.70	1.8
	0.1	2.1	0.76	1.5	1.4
Styrene	1.5	0.068	0.0023	0.026	0.032
	0.5	0.056	0.0040	0.028	0.030
	0.1	0.045	ND	0.0022	0.023
Toluene	1.5	0.69	0.042	0.19	0.31
	0.5	0.58	0.05	0.18	0.27
	0.1	0.34	0.015	0.024	0.13

ND = No data
NA = Not applicable
mg/L=milligrams per liter
ppm=parts per million

8 Discussion

Sugar-based colored smoke formulations are currently being developed as less hazardous replacements for the conventional sulfur-based formulations. This study was designed to provide information regarding the potential health effects resulting from acute and subacute inhalation exposure to the dissemination products of M18 red smoke grenades. Although changes, such as daily exposure duration, were made to the standard acute and subacute inhalation study exposure guidelines in an attempt to accurately mimic typical military exposures, these red smoke exposures still represent a worst-case exposure scenario for soldiers. M18 red smoke grenade burn times were estimated from observed fluctuations on the magnehelic gauges on both the initiation and exposure chambers. Visual confirmation of grenade burn times could not be performed due to the concentrated smoke atmospheres in the initiation chamber. Typical red smoke burn times were estimated to be slightly over one minute. Acute and subacute exposure durations were set at 30 minutes mainly due to the rats' ability to decrease respiration in response to harsh environmental conditions. Humans, especially in stressful situations, tend to have higher respiration rates and typically breathe more through the mouth which provides less filtration than the nose. In addition, the M18 red smoke grenade is not designed for use in enclosed spaces. In order to maintain relatively stable atmospheres of red smoke particulate for 30-minute periods, a semi-static generation method was employed for these exposures. Once each smoke grenade completed its burn, the overpressure valve in the PVC pipe leading to the exterior of the laboratory was closed for the duration of all acute exposures and for the 1.5 and 0.5 mg/L exposure concentrations of the subacute study. The overpressure valve was opened and smoke atmospheres were drawn out of the exposure chamber through the initiation chamber for the 0.1 mg/L subacute exposures. Smoke atmospheres from M-18 grenades, when used as intended, would undergo significantly higher and more immediate dilution rates than those experienced contained within the two 1200-Liter chambers used for these exposures. Red smoke particulate and combustion gas concentrations were monitored for the purpose of correlation with potential health effects resulting from these

exposures but would not necessarily mimic the numerous possible exposure scenarios experienced by soldiers on the battlefield or during training.

Acute inhalation exposure to an average atmospheric concentration of 1.92 mg/L red smoke particulate did not induce mortality in male or female rats. No test material-induced adverse clinical signs of toxicity were observed in any animals throughout the 14-day observation period. Due to the appearance of potential gross findings in the lungs of animals from the first exposure, the lungs were retained for future microscopic evaluation. Two additional acute exposures with average atmospheric concentrations of 1.69 and 0.56 mg/L were performed following the subacute exposure in an attempt to clarify the possible gross lung lesions observed and determine a safe acute exposure level. All microscopic evaluations of the lungs from these acute exposures were performed at the same time as the subacute tissues. A summary of all histologic findings in the lungs retained from the acute exposures, along with the control animals from the subacute study, was provided in Table 3. With the exception of alveolar septal and venous congestion, all other histologic findings were interpreted as incidental/background lesions or perimortem findings resulting from the CO_2 euthanasia. The incidences of minimal to mild alveolar septal and venous congestion following acute exposure may have been test article-related and could explain the gross finding of dark areas throughout the lung observed during necropsy. However, corroborating evidence of passive congestion, such as hemosiderin-laden or enlarged alveolar macrophages, was not observed in any of the lungs from the acute exposures. The lungs of acute-exposed animals were not weighed prior to preservation since acute inhalation studies do not typically include control animals for organ mass comparison.

The acute inhalation toxicity of neat Solvent Red 169 was previously evaluated by this Center in 2008 (USACHPPM, 2009). Rats exposed nose-only to an average atmospheric concentration of 2.4 mg/L Solvent Red 169 for 4 hours did not exhibit any toxic signs, body mass changes, or gross necropsy findings. Although acute exposure to neat Solvent Red 169 at similar concentrations to these acute exposures did not result in any gross lesions, atmospheres of red smoke disseminated from the M18 smoke grenade represent a complex mixture of particulate and combustion gases. In addition, the incidence of alveolar septal and/or venous pulmonary congestion observed following the 3 acute exposures did not decrease as the particulate red smoke concentration decreased. Combustion gas concentrations were not monitored during the second and third acute exposures but can be estimated from the monitoring results during the subacute study. In general, these concentrations would have been very similar between the first and second acute exposures due to the similar average atmospheric particulate concentrations of 1.92 and 1.69 mg/L. Combustion gas concentrations experienced during the third acute exposure (0.56 mg/L) would have been nearly identical to those reported for the intermediate exposure level of the subacute study (0.5 mg/L). Combustion gases did not decrease proportionately with particulate concentration during the subacute study due to the semi-static nature of the exposure system and, in some cases, actually increased with decreasing particulate concentration.

Of the combustion gases monitored during the first acute exposure, both acrolein and formaldehyde exceeded recommended short-term exposure levels and/or values considered to be immediately dangerous to life and health. Both of these aldehydes are respiratory tract irritants capable of producing histopathological changes following inhalation exposure at levels exceeding recommended exposure concentrations (ATSDR 2007 & 1999). Formaldehyde levels during the first acute exposure averaged 26.1 ppm via EPA TO-11 analysis. The 30-minute LC_{50} for formaldehyde exposure in rats is 668 ppm. Acute animal exposures have confirmed that the upper

respiratory tract is the critical target for inhaled formaldehyde with epithelial tissue damage being the primary effect at appropriate exposure concentrations. Typically lung damage is only produced at concentrations exceeding those affecting the upper respiratory tract (HSDB, 2016). Acrolein concentrations during the first acute exposure averaged 2.92 ppm via EPA TO-15 analysis. Reported rat 30-minute LC_{50} values for acrolein range from 60 to131 ppm (HSDB, 2016 & Ballantyne et al., 1989). Acute inhalation exposure to acrolein at average analytic vapor concentrations of 14.5, 41.5, 93.5, and 251 ppm for up to 30 minutes induced clinical signs of toxicity including teary/squinted eyes, nasal discharge, labored breathing, gasping, and prostration at all exposure levels. Necropsy of pre-term mortalities revealed gross histological findings of nasal turbinate congestion (41.5 ppm), congested appearance of apical and cardiac regions of lungs with failure to collapse upon incision (41.5 ppm), mouth and nose exudate (93.5 ppm), and pulmonary edema (251 ppm), among other findings. All animals survived the 14.5 ppm exposures with no treatment-related gross pathology (HSDB, 2016). Clinical observations and histological findings following the 3 acute exposures were consistent with exposure to lower concentrations of these combustion gases, however, the complex nature of the combustion atmospheres generated from M-18 red smoke grenades and limited histopathology precludes the identification of a single cause. Short-term animal exposures with aldehyde mixtures (acrolein, formaldehyde, and acetaldehyde) have resulted in more severe histopathological changes in the respiratory and olfactory epithelium of the nose of rats than exposure to identical concentrations of the individual aldehydes (HSDB, 2016).

Subacute (2-week) inhalation exposure to atmospheres of red smoke did not result in any pre-term mortality in male and female rats. No adverse clinical signs of toxicity were observed throughout the exposure period for the main study animals or during the recovery period for the recovery animals. In addition, no changes in organ mass or mass ratios were observed in the male or female main study or recovery animals compared to their respective controls. The only changes for body mass, body mass change, or food consumption compared to controls occurred in the 1.5 mg/L male recovery group. Body mass change for this group was decreased during exposure days 1-3 and subsequently increased during the second week of recovery. Reduced body mass change during the first couple days of a repeated-exposure inhalation study can occur in response to stress, regardless of the exposure level. Although this trend was not observed in any main study exposure groups or the female recovery group, net body mass change for the male 1.5 mg/L recovery group was not reduced at the end of the 4-week recovery period and may be related to the exposure process rather than the test material. Changes in male and female (main study and recovery) clinical chemistry and prothrombin time measurements were limited to albumin concentrations in the male 1.5 mg/L recovery group. Following the 4-week recovery period, male 1.5 mg/L recovery albumin levels were decreased relative to controls. Hypoalbuminemia, in most cases, is a result of acute or chronic inflammatory responses. Histologic evidence of inflammation, primarily in the nasal turbinates, observed in the main study animals at the conclusion of the exposures had resolved by the end of the recovery period. Albumin levels in the main study animals were unaffected by exposure so the relevance of this finding in the recovery male rats is not clear. Sporadic differences in leukocyte differentials were observed in the main study 0.1 and 0.5 mg/L male rats relative to controls as well as decreased hemoglobin concentrations in the male 1.5 mg/L recovery group. Although altered leukocyte counts can be indicative of an inflammatory response, these changes were not part of a relevant exposure-level related trend and could be part of a stress-induced change in circulating leukocyte counts and/or red blood cell mass parameters (Everds et al., 2013). Similar to the changes in albumin concentration, histologic evidence of

increased inflammation incidence or severity was not apparent in the exposure groups exhibiting altered leukocyte counts.

Microscopic evaluation of all tissues from the main study 1.5 mg/L and control males and females revealed that nasal turbinate injury in the anterior regions (Levels 1 and 2) of the rat nasal passages was the primary lesion associated with subacute exposure to red smoke. At level 1, transitional or respiratory epithelial hyperplasia was the predominant injury throughout all exposure levels in both male and female rats. This effect was evident in nearly all of the level 1 turbinates evaluated at the highest exposure level as well as approximately half of the 0.5 and 0.1 mg/L level 1 turbinates. Average severity scores in males and females were nearly identical between the 1.5 and 0.5 mg/L exposure levels with the 0.1 mg/L level showing a decrease in severity. In male and female rats, the hyperplasia was occasionally accompanied by mucosal degeneration and granulocytic infiltration. Mucosal degeneration was evident primarily in 1.5 mg/L males (67%) and females (83%) with a decreased incidence in the 0.5 and 0.1 mg/L exposure levels. Although the transitional or respiratory epithelial hyperplasia was observed more frequently than the mucosal degeneration, the latter was interpreted to be more of an adverse effect resulting from red smoke exposure. Degeneration of the mucosal tissue in the nasal passages could lead to an increased susceptibility to nasal infections and lower respiratory tract diseases. Hyperplasia is typically reversible upon cessation of exposure. At level 2 of the nasal turbinates, granulocytic infiltration was the primary histologic finding but was only increased in the 1.5 mg/L males and 0.1 mg/L females compared to controls. Mucosal degeneration affected the level 2 transitional or respiratory epithelium in the 1.5 mg/L males only. Hyperplasia of the respiratory epithelium was occasionally observed at all exposure levels and anatomic levels although it was only evident in the 0.1 mg/L males at level 3. As discussed earlier, complex combustion atmospheres typically prevent identification of a single cause for the health effects observed following exposure. Although the potential health effects resulting from repeated exposure to neat Solvent Red 169 have not been investigated, evidence does suggest that the nasal turbinate injury resulting from these exposures was primarily due to the combustion gases. Exposure level concentrations were monitored and reported based only on the average particulate concentration during each 30-minute exposure and the incidence of the histologic findings did not correlate well with the exposure levels. In addition, it has been reported that rodents exposed to water-soluble, gaseous irritants typically have lesions in the surface epithelium of the lateral margins of the naso- and maxilloturbinate and on the lateral wall (Renne et al., 2007). The pathologist indicated that the location of the lesions in this study matched this description. The role of the red smoke particulate as a carrier of absorbed combustion gases could not be determined since the particulate was not characterized. Average aerodynamic particle sizes were similar across the exposure levels (2.3 – 2.4 microns) and were small enough to enable passage into the lower respiratory tract with alveolar deposition. Acrolein and formaldehyde vapor concentrations during the subacute exposures were the only 2 combustion gases that frequently exceeded short-term exposure limits. Acrolein concentrations averaged 2.6, 2.5, and 1.5 ppm via EPA TO-15 analysis during the 1.5, 0.5, and 0.1 mg/L subacute exposures. Formaldehyde concentrations averaged 16.5, 14.4, and 9.6 ppm via EPA TO-11 analysis during the 1.5, 0.5, and 0.1 mg/L subacute exposures. While the entire respiratory system can be affected by acrolein and formaldehyde inhalation, the available data from acute, intermediate, and chronic duration studies in experimental animals indicate that the deeper respiratory regions are only sensitive to higher exposure levels well above those experienced during this study. Exposure to lower levels of both gases, consistent with the odor threshold and perception of nasal irritation in humans, is typically associated with irritation of the nasal epithelium as observed following the subacute exposures (ATSDR, 2007 &1999).

Histology on the lungs of the control, 1.5, and 0.5 mg/L males and control and 1.5 mg/L females revealed nearly identical findings to those acutely exposed. Minimal to mild (in most cases) incidences of alveolar septal or venous congestion, perivascular or peribronchiolar hemorrhage, alveolar atelectasis, and granulocytic infiltration was observed in all of the exposure levels evaluated, including controls. The pathologist stated that none of the lesions showed evidence of having occurred earlier than immediately prior to euthanasia. The fact that these findings were observed in the control animals and there was no additional confirmation of congestion (macrophage accumulation or changes in lung mass) adds evidence to the interpretation that these observations were perimortem in nature for both the acute and subacute studies.

Level 1 transitional epithelial hyperplasia was only observed in 1 of 6 female recovery controls and 1 of 5 female recovery 1.5 mg/L exposed animals while mucosal degeneration was only observed in 1 of 6 female recovery controls following a 4-week recovery period. Therefore, it would appear that both effects are reversible upon cessation of red smoke exposure. Many of the histologic findings observed in the respiratory tract of main study animals were also observed in the recovery animals but the incidence was never increased compared to the recovery controls. Nasal turbinate level 1 and 2 respiratory epithelial hyperplasia was evident in both male and female recovery controls and 1.5 mg/L rats. This finding was observed in many of the main study control and exposed animals in addition to the recovery animals and was not interpreted as a relevant test material-related finding. In addition, such hyperplastic changes in the nasal respiratory epithelium often observed following animal exposures of subchronic duration have been shown to regress following a recovery period of several weeks (Renne et al., 2007).

9 Conclusions

The LC_{50} resulting from acute nose-only exposure to pyrotechnically disseminated red smoke particulate for 30 minutes was greater than 1.92 milligrams per liter (mg/L). Repeated nose-only inhalation of red smoke at average particulate concentrations of 0.1, 0.5, and 1.5 mg/L for 30 minutes did not induce mortality in male and female rats. Clinical signs observed following exposure, occurring in a concentration-related manner, included red-stained fur (primarily on the head, face, and forelimbs) from deposition of the test material and salivation. Changes in body mass only occurred in the male 1.5 mg/L recovery group and consisted of a decrease at the initiation of exposures (days 1-3) and subsequent increase during the second recovery week. Male and female organ mass and mass ratios (body and brain), for both main study and recovery groups, were unaffected by repeated exposure to red smoke relative to controls. Main study males exposed to 0.1 mg/L red smoke had reduced percent basophils while males exposed to 0.5 mg/L had increased percent basophils. Following a 4-week recovery period, males exposed to 1.5 mg/L red smoke had reduced albumin and hemoglobin. Histology on the collected tissues resulted in exposure-related changes in the nose of male and female rats. Hyperplasia of the transitional or respiratory epithelium at level 1 of the nasal turbinates, occasionally accompanied by mucosal degeneration and granulocytic infiltration, was observed in the majority of rats at all exposure levels. Male and female rats exhibited a regression of injury to the anterior regions of the nasal turbinates following a recovery period of 4 weeks. Mucosal degeneration of the level 1 nasal turbinates was identified as the critical endpoint in this study based on the exposure level-related response and was used to derive $BMDL_{10}$ of 0.351 and 0.054 mg/L for males and females, respectively.

10 Point of Contact

Questions pertaining to this report should be referred to Lee Crouse at DSN 584-3980, commercial 410-436-3980, or by e-mail: usarmy.apg.medcom-phc.mbx.tox-info@mail.mil.

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Appendix A

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Appendix B

Quality Assurance Statement

APPENDIX B

QUALITY ASSURANCE STATEMENT

For: Toxicology Study No. S0036333-15, Protocol No. 35-15-01-01, Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically-Disseminated M18 Red Smoke, April - September 2015, the following critical phases were audited by the Quality Systems and Regulatory Compliance Office's Quality Assurance Unit:

PRE IN-LIFE PHASE OF THE STUDY

Critical Phase Inspected/Audited	Date Inspected /Audited	Date Reported to Management/SD
Study Protocol Good Laboratory Practice Standards and Animal Care Review	01/21/2015	01/21/2015

IN-LIFE PHASE OF THE STUDY

Critical Phase Inspected/Audited	Date Inspected /Audited	Date Reported to Management/SD
Acute Study -Test System Restrainer Procedures, Pre and Post Procedural Provisions and Observations.	04/29/2015	05/11/2015
Acute Study - Test System Facilities, Identification, Husbandry, Feed and Water Supply & Enrichment	04/29/2015	05/11/2015
Acute Study - Test Substance Atmosphere Generation and Analysis of the Test Atmosphere	04/29/2015	05/12/2015
Acute Study - Administration of Test Substance and Exposure Mode	04/29/2015	05/12/2015
Acute Study - Necropsy Study Personnel Qualifications and Training Records Review	05/13/2015	05/21/2015
Acute Study - Animal Euthanasia, Necropsy & Gross Macroscopic Pathology Exam Procedures	05/13/2015	05/21/2015
Acute Study - Sub-study Endpoint Criteria Compliance	05/13/2015	05/21/2015
Subacute Study - Compliance with Protocol Study Personnel Identification and Qualifications	06/04/2015	06/11/2015
Compliance with Protocol and Test Facility Standing Operating Procedure Requirements	06/04/2015	06/11/2015
Subacute Study-Test System Husbandry, Restraint Procedures, Body Weight, Food Consumption, Observations	06/04/2015	06/15/2015
Subacute Study - Administration of Test Substance & Exposure Mode & Analysis of the Test Atmosphere	06/04/2015	06/15/2015
Subacute Study - Anesthesia / Analgesia / Tranquilization and Histopathology Procedures	06/16/2015	07/02/2015
Subacute Study - Terminal Observations - Clinical Chemistry and Hematology Assessments	06/16/2015	07/02/2015
Subacute Study - Terminal Observations - Gross Necropsy, Organ Weight, and Tissue Preservation	06/16/2015	07/02/2015
Subacute Study - Gross Necropsy, Organ Weight, and Tissue Preservation	08/11/2015	09/24/2015

APPENDIX B

QUALITY ASSURANCE STATEMENT

For: Toxicology Study No. S0036333-15, Protocol No. 35-15-01-01, Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically-Disseminated M18 Red Smoke, April - September 2015, the following critical phases were audited by the Quality Systems and Regulatory Compliance Office's Quality Assurance Unit

IN-LIFE PHASE OF THE STUDY (continued)

Critical Phase Inspected/Audited	Date Inspected /Audited	Date Reported to Management/SD
Subacute Study - Clinical Chemistry, Hematology Assessments and Histopathology	08/11/2015	09/24/2015
Subacute additional exposure - Test Substance Admin & Exposure Mode & Analysis of the Test Atmosphere	08/18/2015	08/25/2015
Subacute additional exposure - Test System Husbandry, Restraint, Body Weight, Observations & GDPs	08/18/2015	08/25/2015

POST IN-LIFE PHASE OF THE STUDY

Critical Phase Inspected/Audited	Date Inspected /Audited	Date Reported to Management/SD
Pathology Contributing Scientist Inspection-QA audit of statistician's report and Excel Entered Data	04/25/2016	5/18/2016
Pathology Contributing Scientist Inspection - Final Report Summary Data and Summary Table Review	04/28/2016	05/18/2016
Pathology Contributing Scientist Inspection-Interim Pathology Report GLP Standard Regulation Review	05/17/2016	05/18/2016
Pathology Contributing Scientist Inspection- Final Pathology Report GLP Standard Regulation Review	05/26/2016	05/26/2016
Pathology Contributing Scientist Inspection- Final Pathology Report GLP Standard Regulation Review	06/14/2016	06/15/2016
Pathology Addendum Report Inspection - Final Study Data GLP Standard Regulations Review	01/13/2017	4/11/2017
Pathology Addendum Report Inspection -Final Report Summary Data and Summary Table Review	01/13/2017	4/11/2017
Final Study Report Good Laboratory Practice Quality Assurance Review	04/11/2017	04/11/2017

Note 1 All findings were made known to the Study Director and the Program Manager at the time of the audit/inspection. If there were no findings during the inspection, the inspection was reported to Management and the Study Director on the date shown in the table.

Note 2 In addition to the study specific critical phase inspections listed here, general facility and process based inspection not specifically related to this study are done monthly or annually in accordance with QA Standard Operating Procedure.

Note 3 This report has been audited by the Quality Assurance Unit (QSARC), and is considered to be an accurate account of the data generated and of the procedures followed

Michael P. Kefauver
Quality Assurance Specialist, QSARC-QAU

04/17/2017
Date

Appendix C

Archives and Study Personnel

1. ARCHIVES.

a. All raw data, documentation, records, protocol, and a copy of the final report generated as a result of this study will be archived in room 1026, Building E-2100, APHC, for a minimum of five (5) years following submission of the final report to the Sponsor.

b. Records on animal receipt, diet, and facility environmental parameters will be archived by the Veterinary Medical Division, QSARC, for a minimum of five (5) years following submission of the final report to the Sponsor.

c. Some ancillary records pertaining to this study, such as instrument maintenance logs, animal room observation logs, etc., will not be archived until those logbooks have been completed. Once complete they will be archived in room 1026, Building E-2100, APHC.

d. Wet tissues, histology slides, and paraffin blocks are stored in building E-5158.

2. PERSONNEL.

a. Management

(1) Management (In-Life): Dr. Mark S. Johnson, Ph.D., Director, Toxicology; Arthur J. O'Neill, Division Chief, Toxicity Evaluation Division (TEV); Dr. Michael J. Quinn, Ph.D., Division Chief, Health Effects Research Division (HEF).

(2) Management (Report): Dr. Mark S. Johnson, Ph.D., Portfolio Director, Toxicology; Arthur J. O'Neill, Division Chief, Toxicity Evaluation Division (TEV); Dr. Michael J. Quinn, Ph.D., Division Chief, Health Effects Division (HEF).

b. Study Director: Lee C.B. Crouse, Biologist, TEV.

c. Quality Assurance: Michael P. Kefauver, Quality Assurance Specialist, Quality Systems Office.

d. Veterinary Support and Animal Care: Dr. Mary Sprangel, DVM, MAJ, VC; Robert Sunderland, Animal Health Technician; Rebecca Kilby, Animal Health Technician; Lindsey Ward, Animal Health Technician.

e. Pathology Lab Coordinator: Alicia Shiflett, Histotechnician, DTP.

f. Histopathology: Erica E. Carroll, DVM, DACVP, LTC, VC, Pathologist, DTP.

g. In-Life Support: Emily May Lent, Toxicologist, TEV.

h. Hematology, Clinical Chemistry: Matthew A. Bazar, Biologist, TEV; Mark R. Way, Biologist, TEV.

i. Archivist: Martha L. Thompson, Data Acquisition Specialist, TEV.

Appendix D

Chamber Distribution

Table D-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Chamber Distribution Summary of Red Smoke Atmosphere

Sample Set #1 (High Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	0955	A	2.719	92
2	0955	B	2.959	101
3	0955	C	3.152	107
			Mean = 2.943	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	0955	R1	2.872	98
5	0955	R2	2.837	96

Sample Set #2 (High Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	1005	D	2.501	95
2	1005	E	2.796	107
3	1005	F	2.57	98
			Mean = 2.622	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	1005	R1	2.803	107
5	1005	R2	2.764	105

Sample Set #1 (Intermediate Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	1051	A	0.591	75
2	1051	B	0.867	109
3	1051	C	0.917	116
			Mean = 0.792	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	1051	R1	0.804	102
5	1051	R2	0.756	95

Sample Set #2 (Intermediate Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	1101	D	0.727	103
2	1101	E	0.692	98
3	1101	F	0.698	99
			Mean = 0.706	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	1101	R1	0.713	101
5	1101	R2	0.596	84

Sample Set #1 (Low Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	1229	A	0.199	104
2	1229	B	0.192	100
3	1229	C	0.186	97
			Mean = 0.192	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	1229	R1	0.205	107
5	1229	R2	0.206	107

Sample Set #2 (Low Exposure)

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
1	1239	D	0.180	97
2	1239	E	0.179	96
3	1239	F	0.199	107
			Mean = 0.186	

SAMPLE ID #	TIME SAMPLE COLLECTED	SAMPLE PORT LOCATION	CONCENTRATION (mg/L)	% COMPARISON
4	1239	R1	0.190	102
5	1239	R2	0.195	105

Appendix E

Summary of Acute Exposure Results

Table E-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Acute Exposure Concentration and Particle Size Summary

Exposure Number	Date	Target Concentration (mg/L)	Mean Concentration (mg/L)	Standard Deviation (mg/L)	Concentration Range (mg/L)	N	Mass Median Aerodynamic Diameter (microns)	Geometric Standard Deviation	N
1	04/29/15	2.0	1.92	0.312	1.559 - 2.100	3	1.6 - 1.9	1.9 - 2.13	2
2	07/28/15	2.0	1.69	0.550	1.212 - 2.289	3	2.6	1.86	1
3	08/18/15	0.5	0.56	0.118	0.457 - .689	3	2.2	1.83	1

Table E-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Acute Exposure Body Mass Summary (grams)

Exposure No.	Animal ID	Sex	Day 1	Day 2	Day 3	Day 6	Day 8	Day 10	Day 13	Day 15
1	0525	Male	273.8	279.4	287.9	307.8	319.5	340.8	352.4	374.6
1	0526	Male	255.1	262.7	271.6	291.5	300.6	326.8	340.5	364.0
1	0527	Male	272.1	266.1	276.1	299.8	312.2	335.7	344.5	369.7
1	0528	Male	260.5	262.9	272.4	297.3	304.7	330.1	342.6	361.9
1	0529	Male	244.3	241.4	249.0	263.5	273.1	294.3	297.5	315.3
1	0530	Female	171.1	164.4	171.8	179.2	189.3	188.9	200.1	205.3
1	0531	Female	197.1	202.3	204.8	212.2	216.9	224.5	222.0	234.2
1	0532	Female	208.6	202.8	207.6	222.0	225.9	235.3	235.3	245.6
1	0533	Female	181.4	179.4	184.0	192.7	197.5	212.5	212.4	223.8
1	0534	Female	207.4	211.3	215.8	217.4	224.0	241.9	234.5	252.1

Exposure No.	Animal ID	Sex	Day 1	Day 2	Day 3	Day 4	Day 7	Day 9	Day 15
2	0732	Male	258.1	252.5					
2	0733	Male	244.3	246.2					
2	0734	Male	256.9	250.2					
2	0735	Male	247.5	240.9	249.6	265.0	281.2	302.3	341.5
2	0736	Male	262.2	267.8	271.7	289.0	313.6	338.6	390.7
2	0737	Female	223.6	216.4					
2	0738	Female	209.0	209.9					
2	0739	Female	211.1	209.4					
2	0740	Female	227.7	224.6	231.1	234.6	248.5	255.5	276.2
2	0741	Female	235.8	229.1	235.4	234.2	250.0	256.7	277.5

Exposure No.	Animal ID	Sex	Day 1	Day 2	Day 10	Day 15
3	0780	Male	245.6	247.2		
3	0781	Male	250.3	250.2		
3	0782	Male	243.7	243.6		
3	0783	Male	238.9	238.2	307.7	353.3
3	0784	Male	250.2	253.8	317.0	368.7
3	0785	Female	190.6	186.2		
3	0786	Female	208.8	210.8		
3	0787	Female	193.9	193.8		
3	0788	Female	195.0	191.9	231.3	242.4
3	0789	Female	201.4	194.0	235.3	255.7

Table E-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Acute Exposure Individual Clinical Observations

Exposure No.	Animal ID	Sex	Observation	First Day[a]	Last Day[b]
1	0525	Male	Red-colored face, nose, forelimbs & chin	1	1
			Salivation	1	1
			Scab on right shoulder	8	15
1	0526	Male	Red-colored face, nose, & forelimbs	1	1
1	0527	Male	Red-colored face, nose, & forelimbs	1	1
			Slight red staining of face	2	2
			Dried red material around nose	2	2
1	0528	Male	Red-colored face, nose, & forelimbs	1	1
			Slight red staining of face	2	2
1	0529	Male	Red-colored face, nose, forelimbs & chin	1	1
			Salivation	1	1
1	0530	Female	Red-colored face, nose, forelimbs & chin	1	1
			Salivation	1	1
			Red staining of face, shoulders, & urogenital area	2	3
			Slight red urogenital staining	6	15
1	0531	Female	Red-colored face, nose, forelimbs & chin	1	1
			Salivation	1	1
			Slight red staining of face & head	2	2
1	0532	Female	Red-colored face, nose, & forelimbs	1	1
			Slight red staining of urogenital area	2	2
			Dried red material around nose	3	3
			Barbering both front limbs	10	15
1	0533	Female	Red-colored face, nose, & forelimbs	1	1
1	0534	Female	Red-colored face, nose, forelimbs & chin	1	1
			Salivation	1	1
			Slight red staining of face & head	2	2

Exposure No.	Animal ID	Sex	Observation	First Day[a]	Last Day[b]
2	0732	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
2	0733	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
2	0734	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
			Red-colored head and nose	2	2
2	0735	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
2	0736	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
2	0737	Female	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
			Slight red-colored head	2	2
2	0738	Female	Red-colored face, nose, & forelimbs	1	1
2	0739	Female	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
2	0740	Female	Red-colored face, nose, & forelimbs	1	1
			Slight red-colored head	2	2
2	0741	Female	Red-colored face, nose, & forelimbs	1	1
			Slight red-colored head	2	2

Exposure No.	Animal ID	Sex	Observation	First Day[a]	Last Day[b]
3	0780	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
3	0781	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
3	0782	Male	Red-colored face & nose	1	1
			Salivation	1	1
			Minor congested breathing	1	1
3	0783	Male	Red-colored face, nose, & forelimbs	1	1
			Salivation	1	1
3	0784	Male	Red-colored face & nose	1	1
			Salivation	1	1
3	0785	Female	Red-colored face & nose	1	1
			Salivation	1	1
3	0786	Female	Red-colored face & nose	1	1
			Salivation	1	1
3	0787	Female	Red-colored face & nose	1	1
3	0788	Female	Red-colored face & nose	1	1
			Salivation	1	1
3	0789	Female	Red-colored face & nose	1	1
			Salivation	1	1

[a] Represents the first day the clinical sign was observed.
Day 1 is the day of the exposure
[b] Represents the last day the clinical sign was observed.

Table E-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Acute Exposure Gross Observation Summary

Exposure No.	Animal ID	Sex	Gross Observation
1	0525[a]	Male	Edges of right & left lobes of lung appear dark and collapsed
1	0526[a]	Male	Left caudal lobe appears dark in color and collapsed.
1	0527[a]	Male	Left and right lung appears dark in color with dark spots Kidneys and liver appear dark
1	0528[a]	Male	Apparent necrotic & dark areas in left & right lobes of lung
1	0529[a]	Male	Apparent necrotic & dark areas in left & right lobes of lung
1	0530[a]	Female	Apparent necrotic & dark areas in left & right lobes of lung
1	0531[a]	Female	Minimal white patches throughout lung
1	0532[a]	Female	Apparent necrotic & dark areas in left & right lobes of lung
1	0533[a]	Female	Possible necrotic areas on fringes of middle pulmonary lobe & accessory pulmonary lobe of lung
1	0534[a]	Female	Apparent necrotic & dark areas in left & right lobes of lung
Exposure No.	**Animal ID**	**Sex**	
2	0732[b]	Male	Cranial aspect of left and right lobes of lung pale pink
2	0733[b]	Male	Cranial aspect of left and right lobes of lung pale pink
2	0734[b]	Male	Diffuse multifocal to coalescing dark brown to red regions of left & right lobes of lung Cranial aspect of left and right lobes of lung pale pink Caudal left lung has reticular pattern
2	0735[a]	Male	No gross lesions recognized
2	0736[a]	Male	No gross lesions recognized
2	0737[b]	Female	Focal dark brown region on cranial lobe of right lung Cranial aspect of left lung is pale pink
2	0738[b]	Female	Fringes of all lobes of lung are white Left and right lobes of lung appear pale pink
2	0739[b]	Female	No data
2	0740[a]	Female	No gross lesions recognized
2	0741[a]	Female	No gross lesions recognized
Exposure No.	**Animal ID**	**Sex**	
3	0780[b]	Male	Anterior portion of right and left lung appear to have dark brown focal regions
3	0781[b]	Male	Anterior portion of left lung is pale pink
3	0782[b]	Male	No gross lesions recognized
3	0783[a]	Male	Diffuse whitish, raised areas in distal region of right caudal and left pulmonary lobes of lung
3	0784[a]	Male	Left pulmonary lobe is whitish pink around edges with dark red center
3	0785[b]	Female	No gross lesions recognized
3	0786[b]	Female	Right anterior portion of lung is pale pink
3	0787[b]	Female	Liver is mildly dark Anterior portions of right & left lobes of lung have brown focal spots & outer edges are pale pink Left kidney has white focal area 1 mm in diameter
3	0788[a]	Female	No gross lesions recognized
3	0789[a]	Female	Hydronecrosis of right kidney

[a] = 14-day recovery period prior to necropsy
[b] = Necropsied the day after exposure

Appendix F

Summary of Subacute Exposure Chamber Concentrations

Table F-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Subacute Exposure Concentration Summary

Control Exposures

Exposure Number	Date	Daily Mean (mg/L)	Daily Standard Deviation (mg/L)	Concentration Range (mg/L)	N
1	06/02/15	0	-	-	1
2	06/03/15	0	-	-	1
3	06/04/15	0	-	-	1
4	06/05/15	0	-	-	1
5	06/08/15	0	-	-	1
6	06/09/15	0	-	-	1
7	06/10/15	0	-	-	1
8	06/11/15	0	-	-	1
9	06/12/15	0	-	-	1
10	06/15/15	0	-	-	1
11	06/16/15	0	-	-	1
Total Mean:		**0.000**	**-**	**-**	**11**
A Group Mean:		**0.000**	**-**	**-**	**10**
B Group Mean:		**0.000**	**-**	**-**	**10**

Intermediate (0.5 mg/L) Concentration Exposures

Exposure Number	Date	Daily Mean (mg/L)	Daily Standard Deviation (mg/L)	Concentration Range (mg/L)	N
1	06/02/15	0.583	0.1193	0.475 - 0.711	3
2	06/03/15	0.511	0.1372	0.386 - 0.658	3
3	06/04/15	0.462	0.0936	0.370 - 0.557	3
4	06/05/15	0.470	0.0852	0.388 - 0.558	3
5	06/08/15	0.514	0.0722	0.439 - 0.583	3
6	06/09/15	0.534	0.1225	0.430 - 0.669	3
7	06/10/15	0.533	0.0932	0.447 - 0.632	3
8	06/11/15	0.511	0.0816	0.436 - 0.598	3
9	06/12/15	0.442	0.0774	0.374 - 0.526	3
10	06/15/15	0.473	0.0860	0.387 - 0.559	3
11	06/16/15	0.509	0.0882	0.425 - 0.601	3
Total Mean:		**0.504**	**0.0960**	**0.370 - 0.711**	**33**
A Group Mean:		**0.503**	**0.0968**	**0.370 - 0.711**	**30**
B Group Mean:		**0.496**	**0.0937**	**0.370 - 0.669**	**30**

Low (0.1 mg/L) Concentration Exposures

Exposure Number	Date	Daily Mean (mg/L)	Daily Standard Deviation (mg/L)	Concentration Range (mg/L)	N
1	06/02/15	0.130	0.0145	0.116 - 0.145	3
2	06/03/15	0.132	0.0233	0.113 - 0.158	3
3	06/04/15	0.115	0.0115	0.103 - 0.126	3
4	06/05/15	0.104	0.0121	0.095 - 0.118	3
5	06/08/15	0.109	0.0124	0.096 - 0.121	3
6	06/09/15	0.100	0.0140	0.086 - 0.114	3
7	06/10/15	0.111	0.0132	0.101 - 0.126	3
8	06/11/15	0.099	0.0075	0.092 - 0.107	3
9	06/12/15	0.096	0.0075	0.088 - 0.103	3
10	06/15/15	0.101	0.0111	0.091 - 0.113	3
11	06/16/15	0.095	0.0113	0.085 - 0.107	3
Total Mean:		**0.108**	**0.0126**	**0.085 - 0.158**	**33**
A Group Mean:		**0.110**	**0.0127**	**0.086 - 0.158**	**30**
B Group Mean:		**0.106**	**0.0124**	**0.085 - 0.158**	**30**

High (1.5 mg/L) Concentration Exposures

Exposure Number	Date	Daily Mean (mg/L)	Daily Standard Deviation (mg/L)	Concentration Range (mg/L)	N
1	06/02/15	1.425	0.2895	1.146 - 1.724	3
2	06/03/15	1.407	0.4207	1.016 - 1.852	3
3	06/04/15	1.207	0.5235	0.763 - 1.784	3
4	06/05/15	1.645	0.4863	1.168 - 2.140	3
5	06/08/15	1.149	0.6957	0.680 - 1.948	3
6	06/09/15	1.504	0.6051	0.984 - 2.168	3
7	06/10/15	1.657	0.7100	1.081 - 2.450	3
8	06/11/15	1.496	0.9167	0.887 - 2.550	3
9	06/12/15	1.965	0.7605	1.370 - 2.822	3
10	06/15/15	2.149	0.6377	1.535 - 2.808	3
11	06/16/15	1.157	0.4292	0.820 - 1.640	3
Total Mean:		**1.524**	**0.5886**	**0.763 - 2.822**	**33**
A Group Mean:		**1.560**	**0.6045**	**0.763 - 2.822**	**30**
B Group Mean:		**1.533**	**0.6185**	**0.763 - 2.822**	**30**

Appendix G

Exposure Environmental Conditions

Table G-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Daily Environmental Data
Control Exposure Chamber

Exposure No.	Date	Chamber Oxygen Range (%)	Chamber Temperature Range (°F)	Chamber Relative Humidity Range (%)	(N)	Exposure Box Temperature Range (°F)	Exposure Box Relative Humidity Range (%)	(N)
1	06/02/15	20.9 - 21.2	68	49 - 54	3	-	-	0*
2	06/03/15	20.3 - 20.6	67	58 - 59	3	68	66 - 87	3
3	06/04/15	20.4	68	57 - 58	3	68 - 70	66 - 87	3
4	06/05/15	20.1 - 20.4	68	56	3	68	57 - 58[1]	3
5	06/08/15	20.9	69 - 70	53 - 58	3	69 - 70	54 - 56	3
6	06/09/15	20.2 - 20.5	70 - 71	61 - 65	3	70	65 - 67	3
7	06/10/15	20.6 - 20.9	69	56 - 57	3	70	53 - 57	3
8	06/11/15	20.1 - 20.4	71	60 - 64	3	70	63 - 66	3
9	06/12/15	20.8 - 21.1	71 - 72	65 - 66	3	70	72	3
10	06/15/15	20.8 - 21.1	71	60 - 68	3	70	65 - 67	3
11	06/16/15	20.5 - 20.8	70 - 71	63 - 67	3	70	68 - 70	3

* = Temperature and humidity samples were not taken on this day.
[1] = Starting this day the back plate of the exposure box was not put on in an effort to keep the humidity down in the exposure boxes.

Legend: °F = degrees Fahrenheit
% = percent
N = number of samples collected

Table G-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Daily Environmental Data
Low (0.1 mg/L) Concentration Exposures

Exposure No.	Date	Chamber Oxygen Range (%)	Chamber Temperature Range (°F)	Chamber Relative Humidity Range (%)	(N)	Exposure Box Temperature Range (°F)	Exposure Box Relative Humidity Range (%)	(N)
1	06/02/15	21.2	72 - 73	53 - 55	3	68	64 - 78	3
2	06/03/15	20.4	72	65 - 67	3	68 - 70	66 - 90	3
3	06/04/15	20.7	71 - 72	61 - 62	3	68 - 70	60 - 88	3
4	06/05/15	20.7	70	64 - 66	3	70	77 - 89	3
5	06/08/15	20.6	72	64 - 65	3	72 - 73	70 - 88	3
6	06/09/15	20.6	71 - 72	69 - 71	3	72 - 74	67 - 80	3
7	06/10/15	21.0	72	67 - 68	3	72 - 73	64 - 83	3
8	06/11/15	20.8	72	73 - 74	3	72 - 75	71 - 89	3
9	06/12/15	20.5 - 20.8	74	76 - 77	3	73 - 75	74 - 86	3
10	06/15/15	20.8	73	76 - 77	3	73 - 75	73 - 85	3
11	06/16/15	20.6 - 20.9	73	72	3	73	79 - 88	3

Legend: °F = degrees Fahrenheit
% = percent
N = number of samples collected

Table G-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Daily Environmental Data
Intermediate (0.5 mg/L) Concentration Exposures

Exposure No.	Date	Chamber Oxygen Range (%)	Chamber Temperature Range (°F)	Chamber Relative Humidity Range (%)	(N)	Exposure Box Temperature Range (°F)	Exposure Box Relative Humidity Range (%)	(N)
1	06/02/15	21.2	70	61	3	68	67 - 79	3
2	06/03/15	20.4 - 20.7	70	69 - 71	2	70 - 72	77 - 88	2
3	06/04/15	20.7	70	66 - 67	3	70 - 72	67 - 82	3
4	06/05/15	20.7	70	66 - 69	3	70	72 - 86	3
5	06/08/15	20.6	72	71 - 73	3	73 - 75	70 - 87	3
6	06/09/15	20.5	72	75 - 78	3	72 - 73	63 - 88	3
7	06/10/15	20.7 - 21.0	73	72 - 74	3	72 - 73	69 - 89	3
8	06/11/15	20.5	72 - 73	75 - 77	3	73 - 75	80 - 92	3
9	06/12/15	20.5	74	78 - 79	3	73 - 75	75 - 92	3
10	06/15/15	20.8	72 - 73	77	3	73 - 75	71 - 89	3
11	06/16/15	20.9	72	72	3	73	76 - 89	3

Legend: °F = degrees Fahrenheit
% = percent
N = number of samples collected

Table G-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Daily Environmental Data
High (1.5 mg/L) Concentration Exposures

Exposure No.	Date	Chamber Oxygen Range (%)	Chamber Temperature Range (°F)	Chamber Relative Humidity Range (%)	(N)	Exposure Box Temperature Range (°F)	Exposure Box Relative Humidity Range (%)	(N)
1	06/02/15	21.2	70	59 - 60	3	68 - 70	68 - 83	3
2	06/03/15	20.4 - 20.7	70	56 - 61	3	68 - 70	75 - 82	3
3	06/04/15	20.7	68 - 69	58 - 61	3	68 - 72	77 - 90	3
4	06/05/15	20.7	69	55 - 61	3	68 - 72	76 - 90	3
5	06/08/15	20.3 - 20.9	71 - 72	62 - 73	2	71 - 72	58 - 84	2
6	06/09/15	20.8	72	63 - 72	3	72 - 73	77 - 86	3
7	06/10/15	21.0	72 - 73	61 - 71	3	72 - 75	79 - 92	3
8	06/11/15	20.8	72 - 73	65 - 71	3	72 - 74	82 - 92	3
9	06/12/15	20.8	73	70 - 78	3	73 - 75	86 - 96	3
10	06/15/15	21.1	71 - 72	70 - 74	3	72 - 75	85 - 94	3
11	06/16/15	20.9	71 - 73	69 - 70	2	72 - 73	79 - 91	3

Legend: °F = degrees Fahrenheit
% = percent
N = number of samples collected

Appendix H

Individual and Summary of Body Mass Data

Table H-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass (grams)
Main Study Male Animals

GROUP	ANIMAL ID	Day 1	Day 3	Day 5	Day 8	Day 10	Final*
Control	550	245.6	260.6	299.3	312.6	338.2	306.8
	552	253.5	264.8	298.4	297.8	329.4	303.9
	553	232.3	244.6	286.5	303.6	339.5	315.7
	560	250.0	262.1	292.6	303.7	329.1	310.0
	566	247.5	257.6	287.7	307.0	320.7	300.3
	579	245.0	256.5	289.7	314.0	338.1	316.6
	Mean	**245.7**	**257.7**	**292.4**	**306.5**	**332.5**	**308.9**
	S.D.	**7.25**	**7.09**	**5.44**	**6.09**	**7.39**	**6.48**
0.1 mg/L	551	249.5	259.7	305.8	322.3	361.2	335.9
	557	240.3	249.2	283.0	296.7	330.3	302.9
	571	233.8	245.3	278.8	297.8	328.2	297.0
	572	267.5	269.6	305.1	323.2	356.7	328.9
	573	245.7	250.9	280.8	297.8	324.0	305.0
	582	243.6	254.2	289.2	311.0	331.6	299.5
	Mean	**246.7**	**254.8**	**290.5**	**308.1**	**338.7**	**311.5**
	S.D.	**11.48**	**8.72**	**12.13**	**12.49**	**15.98**	**16.54**
0.5 mg/L	554	215.7	230.2	263.5	269.8	296.0	265.2
	555	226.2	231.7	269.7	277.4	307.8	282.3
	561	244.6	253.4	286.7	293.6	326.0	297.6
	569	246.6	256.3	286.8	296.5	313.2	286.4
	575	267.7	277.5	311.7	330.2	357.6	336.4
	580	247.8	262.0	294.1	310.0	331.8	308.6
	Mean	**241.4**	**251.9**	**285.4**	**296.3**	**322.1**	**296.1**
	S.D.	**18.23**	**18.21**	**17.30**	**21.93**	**21.61**	**24.58**
1.5 mg/L	556	238.9	248.9	284.6	294.7	327.3	296.7
	564	243.7	256.3	289.4	299.4	330.4	295.4
	565	263.7	277.7	314.0	329.2	359.6	327.9
	567	258.4	271.0	304.3	322.9	349.0	328.9
	574	244.8	250.2	284.4	298.2	318.4	297.8
	577	232.5	236.8	266.4	283.9	311.5	286.9
	Mean	**247.0**	**256.8**	**290.5**	**304.7**	**332.7**	**305.6**
	S.D.	**11.84**	**15.13**	**16.71**	**17.52**	**18.32**	**18.08**

* Final fasted body mass

Table H-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass (grams)
Main Study Female Animals

GROUP	ANIMAL ID	Day 1	Day 3	Day 5	Day 8	Day 10	Final*
Control	586	179.0	179.4	193.6	193.4	200.6	184.8
	591	198.8	198.4	216.0	211.2	224.4	212.0
	601	209.2	209.0	226.2	219.6	236.3	218.6
	602	226.2	217.1	231.7	240.8	249.5	236.4
	605	197.7	199.7	204.9	205.6	214.0	205.6
	612	190.9	197.1	200.3	208.5	224.5	212.4
	Mean	**200.3**	**200.1**	**212.1**	**213.2**	**224.9**	**211.6**
	S.D.	**16.13**	**12.72**	**15.04**	**15.99**	**17.00**	**16.85**
0.1 mg/L	595	206.5	201.0	217.2	218.6	229.9	211.6
	596	223.5	210.6	226.8	232.3	250.0	227.1
	607	162.0	160.6	167.5	172.1	191.7	171.0
	616	194.5	196.8	209.7	210.8	219.9	207.0
	618	191.7	187.7	196.7	204.3	213.4	206.1
	619	214.2	206.8	215.3	222.6	225.4	212.4
	Mean	**198.7**	**193.9**	**205.5**	**210.1**	**221.7**	**205.9**
	S.D.	**21.59**	**18.17**	**21.10**	**20.97**	**19.26**	**18.67**
0.5 mg/L	588	191.4	189.3	191.4	202.3	216.8	197.3
	590	192.9	193.7	216.2	209.9	230.3	208.5
	594	185.0	163.8	190.5	186.5	199.5	182.6
	600	171.2	173.5	179.0	185.6	201.8	186.1
	603	231.9	234.2	239.9	241.3	253.1	239.2
	610	202.5	203.3	212.1	216.3	225.7	212.8
	Mean	**195.8**	**193.0**	**204.9**	**207.0**	**221.2**	**204.4**
	S.D.	**20.48**	**24.70**	**22.20**	**20.84**	**19.94**	**20.78**
1.5 mg/L	584	205.0	207.8	216.0	213.7	229.3	213.7
	597	206.9	200.3	208.5	213.4	229.3	213.8
	606	182.7	179.4	194.2	193.4	201.2	189.3
	609	185.4	194.6	207.8	213.1	225.3	211.8
	614	214.1	218.7	228.3	242.0	249.3	233.1
	615	188.0	198.2	205.1	201.8	216.0	203.2
	Mean	**197.0**	**199.8**	**210.0**	**212.9**	**225.1**	**210.8**
	S.D.	**13.22**	**13.17**	**11.42**	**16.44**	**15.97**	**14.39**

* Final fasted body mass

Table H-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass (grams)
Recovery Male Animals

		Exposure Weekdays					Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Day 1**	**Day 3**	**Day 5**	**Day 8**	**Day 10**	**Day 17**	**Day 24**	**Day 31**	**Day 37/38**	**Final***
Control	548	252.2	268.4	307.5	329.3	354.4	399.7	439.5	479.7	507.4	476.2
	558	228.6	239.9	277.8	294.6	334.7	383.4	416.9	462.8	491.1	453.7
	559	236.6	249.9	294.1	307.5	340.8	385.8	427.7	475.2	507.9	470.1
	562	246.9	252.5	279.0	295.3	314.5	361.4	399.5	430.5	447.0	424.4
	568	262.2	272.1	308.9	335.5	362.6	414.3	457.4	491.8	527.9	502.5
	570	247.1	261.5	292.6	313.8	338.6	388.3	428.3	464.1	498.9	462.9
	Mean	**245.6**	**257.4**	**293.3**	**312.7**	**340.9**	**388.8**	**428.2**	**467.4**	**496.7**	**465.0**
	S.D.	**11.77**	**12.17**	**13.35**	**17.05**	**16.70**	**17.65**	**19.66**	**20.98**	**27.28**	**25.84**
1.5 mg/L	549	250.2	255.2	295.7	307.2	338.6	383.1	432.9	475.8	512.6	487.0
	563	253.2	259.4	300.7	312.9	332.0	382.0	427.4	465.1	488.6	466.3
	576	247.2	254.7	300.5	317.2	355.4	412.8	458.7	502.8	542.3	521.3
	578	240.9	249.7	280.6	296.3	320.2	358.6	399.1	443.0	470.4	456.3
	581	238.6	244.9	270.2	282.3	303.2	345.5	386.3	435.5	471.6	447.3
	583	238.2	249.3	274.6	282.2	303.5	336.1	381.0	410.8	443.3	417.7
	Mean	**244.7**	**252.2**	**287.1**	**299.7**	**325.5**	**369.7**	**414.2**	**455.5**	**488.1**	**466.0**
	S.D.	**6.37**	**5.20**	**13.58**	**15.21**	**20.58**	**28.38**	**30.37**	**32.54**	**35.02**	**35.43**

* Final fasted body mass

Table H-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass (grams)
Recovery Female Animals

		Exposure Weekdays					Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Day 1**	**Day 3**	**Day 5**	**Day 8**	**Day 10**	**Day 17**	**Day 24**	**Day 31**	**Day 37/38**	**Final***
Control	585	164.2	164.0	185.9	191.7	211.4	217.1	222.4	236.0	239.4	225.0
	589	193.6	191.4	210.4	205.8	221.9	243.6	256.2	267.8	272.4	258.6
	592	187.0	186.5	200.7	205.1	215.1	227.9	239.5	250.0	251.8	237.4
	599	214.6	213.8	226.3	235.8	240.4	257.1	253.0	268.0	275.6	256.2
	604	215.9	210.4	219.2	228.7	243.4	261.5	270.4	273.6	291.2	273.8
	611	198.5	202.6	209.8	211.4	223.4	238.0	256.5	261.4	277.1	258.3
	Mean	**195.6**	**194.8**	**208.7**	**213.1**	**225.9**	**240.9**	**249.7**	**259.5**	**267.9**	**251.6**
	S.D.	**19.21**	**18.41**	**14.20**	**16.35**	**13.16**	**16.96**	**16.60**	**14.04**	**18.86**	**17.42**
1.5 mg/L	587	235.2	242.5	243.9	243.8	263.1	266.1	279.1	297.7	285.1	278.3
	593	181.8	180.9	191.3	194.6	208.5	220.0	228.9	240.4	242.7	227.3
	598	204.2	195.1	211.7	213.2	229.0	244.0	256.9	268.9	269.9	259.3
	608	180.2	173.8	186.1	189.1	195.6	214.1	211.8	230.9	241.8	218.9
	613	189.1	196.8	205.6	212.7	223.7	243.1	240.4	245.3	249.2	234.6
	617	203.7	204.4	212.1	212.0	223.4	240.9	263.2	274.4	291.0	269.3
	Mean	**199.0**	**198.9**	**208.5**	**210.9**	**223.9**	**238.0**	**246.7**	**259.6**	**263.3**	**248.0**
	S.D.	**20.53**	**24.10**	**20.41**	**19.15**	**22.81**	**18.74**	**24.50**	**25.12**	**21.78**	**24.31**

* Final fasted body mass

Table H-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass (grams)
Main Study Male Animals

Period		Control	Red Smoke Exposed		
			0.1 mg/L	0.5 mg/L	1.5 mg/L
Day 1	Mean	245.7	246.7	241.4	247.0
	S.D.	7.25	11.48	18.23	11.84
	N	6	6	6	6
Day 3	Mean	257.7	254.8	251.9	256.8
	S.D.	7.09	8.72	18.21	15.13
	N	6	6	6	6
Day 5	Mean	292.4	290.5	285.4	290.5
	S.D.	5.44	12.13	17.30	16.71
	N	6	6	6	6
Day 8	Mean	306.5	308.1	296.3	304.7
	S.D.	6.09	12.49	21.93	17.52
	N	6	6	6	6
Day 10	Mean	332.5	338.7	322.1	332.7
	S.D.	7.39	15.98	21.61	18.32
	N	6	6	6	6
Final[1]	Mean	308.9	311.5	296.1	305.6
	S.D.	6.48	16.54	24.58	18.08
	N	6	6	6	6

[1] Fasted Final Body Mass

Table H-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass (grams)
Main Study Female Animals

Period		Control	Red Smoke Exposed 0.1 mg/L	0.5 mg/L	1.5 mg/L
Day 1	Mean	200.3	198.7	195.8	197.0
	S.D.	16.13	21.59	20.48	13.22
	N	6	6	6	6
Day 3	Mean	200.1	193.9	193.0	199.8
	S.D.	12.72	18.17	24.70	13.17
	N	6	6	6	6
Day 5	Mean	212.1	205.5	204.9	210.0
	S.D.	15.04	21.10	22.20	11.42
	N	6	6	6	6
Day 8	Mean	213.2	210.1	207.0	212.9
	S.D.	15.99	20.97	20.84	16.44
	N	6	6	6	6
Day 10	Mean	224.9	221.7	221.2	225.1
	S.D.	17.00	19.26	19.94	15.97
	N	6	6	6	6
Final[1]	Mean	211.6	205.9	204.4	210.8
	S.D.	16.85	18.67	20.78	14.39
	N	6	6	6	6

[1] Fasted Final Body Mass

Table H-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass (grams)
Recovery Male Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Day 1	Mean	245.6	244.7
	S.D.	11.77	6.37
	N	6	6
Day 3	Mean	257.4	252.2
	S.D.	12.17	5.20
	N	6	6
Day 5	Mean	293.3	287.1
	S.D.	13.35	13.58
	N	6	6
Day 8	Mean	312.7	299.7
	S.D.	17.05	15.21
	N	6	6
Day 10	Mean	340.9	325.5
	S.D.	16.70	20.58
	N	6	6
Elapsed Recovery Days			
Day 17	Mean	388.8	369.7
	S.D.	17.65	28.38
	N	6	6
Day 24	Mean	428.2	414.2
	S.D.	19.66	30.37
	N	6	6
Day 31	Mean	467.4	455.5
	S.D.	20.98	32.54
	N	6	6
Day 37/38	Mean	496.7	488.1
	S.D.	27.28	35.02
	N	6	6
Final[1]	Mean	465.0	466.0
	S.D.	25.84	35.43
	N	6	6

[1] Fasted Final Body Mass

Table H-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass (grams)
Recovery Female Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Day 1	Mean	195.6	199.0
	S.D.	19.21	20.53
	N	6	6
Day 3	Mean	194.8	198.9
	S.D.	18.41	24.10
	N	6	6
Day 5	Mean	208.7	208.5
	S.D.	14.20	20.41
	N	6	6
Day 8	Mean	213.1	210.9
	S.D.	16.35	19.15
	N	6	6
Day 10	Mean	225.9	223.9
	S.D.	13.16	22.81
	N	6	6
Elapsed Recovery Days			
Day 17	Mean	240.9	238.0
	S.D.	16.96	18.74
	N	6	6
Day 24	Mean	249.7	246.7
	S.D.	16.60	24.50
	N	6	6
Day 31	Mean	259.5	259.6
	S.D.	14.04	25.12
	N	6	6
Day 37/38	Mean	267.9	263.3
	S.D.	18.86	21.78
	N	6	6
Final[1]	Mean	251.6	248.0
	S.D.	17.42	24.31
	N	6	6

[1] Fasted Final Body Mass

Appendix I

Individual and Summary of Body Mass Change Data

Table I-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass Change (grams)
Main Study Male Animals

GROUP	ANIMAL ID	Days 1-3	Days 3-5	Days 5-8	Days 8-10	Net
Control	550	15.0	38.7	13.3	25.6	92.6
	552	11.3	33.6	-0.6	31.6	75.9
	553	12.3	41.9	17.1	35.9	107.2
	560	12.1	30.5	11.1	25.4	79.1
	566	10.1	30.1	19.3	13.7	73.2
	579	11.5	33.2	24.3	24.1	93.1
	Mean	**12.1**	**34.7**	**14.1**	**26.1**	**86.9**
	S.D.	**1.64**	**4.69**	**8.55**	**7.55**	**13.06**
0.1 mg/L	551	10.2	46.1	16.5	38.9	111.7
	557	8.9	33.8	13.7	33.6	90.0
	571	11.5	33.5	19.0	30.4	94.4
	572	2.1	35.5	18.1	33.5	89.2
	573	5.2	29.9	17.0	26.2	78.3
	582	10.6	35.0	21.8	20.6	88.0
	Mean	**8.1**	**35.6**	**17.7**	**30.5**	**91.9**
	S.D.	**3.67**	**5.49**	**2.71**	**6.41**	**11.04**
0.5 mg/L	554	14.5	33.3	6.3	26.2	80.3
	555	5.5	38.0	7.7	30.4	81.6
	561	8.8	33.3	6.9	32.4	81.4
	569	9.7	30.5	9.7	16.7	66.6
	575	9.8	34.2	18.5	27.4	89.9
	580	14.2	32.1	15.9	21.8	84.0
	Mean	**10.4**	**33.6**	**10.8**	**25.8**	**80.6**
	S.D.	**3.43**	**2.52**	**5.13**	**5.77**	**7.69**
1.5 mg/L	556	10.0	35.7	10.1	32.6	88.4
	564	12.6	33.1	10.0	31.0	86.7
	565	14.0	36.3	15.2	30.4	95.9
	567	12.6	33.3	18.6	26.1	90.6
	574	5.4	34.2	13.8	20.2	73.6
	577	4.3	29.6	17.5	27.6	79.0
	Mean	**9.8**	**33.7**	**14.2**	**28.0**	**85.7**
	S.D.	**4.07**	**2.38**	**3.63**	**4.48**	**8.09**

Table I-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass Change (grams)
Main Study Female Animals

GROUP	ANIMAL ID	Days 1-3	Days 3-5	Days 5-8	Days 8-10	Net
Control	586	0.4	14.2	-0.2	7.2	21.6
	591	-0.4	17.6	-4.8	13.2	25.6
	601	-0.2	17.2	-6.6	16.7	27.1
	602	-9.1	14.6	9.1	8.7	23.3
	605	2.0	5.2	0.7	8.4	16.3
	612	6.2	3.2	8.2	16.0	33.6
	Mean	**-0.2**	**12.0**	**1.1**	**11.7**	**24.6**
	S.D.	**5.01**	**6.22**	**6.49**	**4.14**	**5.79**
0.1 mg/L	595	-5.5	16.2	1.4	11.3	23.4
	596	-12.9	16.2	5.5	17.7	26.5
	607	-1.4	6.9	4.6	19.6	29.7
	616	2.3	12.9	1.1	9.1	25.4
	618	-4.0	9.0	7.6	9.1	21.7
	619	-7.4	8.5	7.3	2.8	11.2
	Mean	**-4.8**	**11.6**	**4.6**	**11.6**	**23.0**
	S.D.	**5.21**	**4.06**	**2.81**	**6.18**	**6.39**
0.5 mg/L	588	-2.1	2.1	10.9	14.5	25.4
	590	0.8	22.5	-6.3	20.4	37.4
	594	-21.2	26.7	-4.0	13.0	14.5
	600	2.3	5.5	6.6	16.2	30.6
	603	2.3	5.7	1.4	11.8	21.2
	610	0.8	8.8	4.2	9.4	23.2
	Mean	**-2.9**	**11.9**	**2.1**	**14.2**	**25.4**
	S.D.	**9.13**	**10.16**	**6.49**	**3.81**	**7.90**
1.5 mg/L	584	2.8	8.2	-2.3	15.6	24.3
	597	-6.6	8.2	4.9	15.9	22.4
	606	-3.3	14.8	-0.8	7.8	18.5
	609	9.2	13.2	5.3	12.2	39.9
	614	4.6	9.6	13.7	7.3	35.2
	615	10.2	6.9	-3.3	14.2	28.0
	Mean	**2.8**	**10.2**	**2.9**	**12.2**	**28.1**
	S.D.	**6.70**	**3.14**	**6.41**	**3.81**	**8.11**

Table I-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass Change (grams)
Recovery Male Animals

		Exposure Weekdays				Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Days 1-3**	**Days 3-5**	**Days 5-8**	**Days 8-10**	**Days 10-17**	**Days 17-24**	**Days 24-31**	**Days 31-37/38**	**Net**
Control	548	16.2	39.1	21.8	25.1	45.3	39.8	40.2	27.7	255.2
	558	11.3	37.9	16.8	40.1	48.7	33.5	45.9	28.3	262.5
	559	13.3	44.2	13.4	33.3	45.0	41.9	47.5	32.7	271.3
	562	5.6	26.5	16.3	19.2	46.9	38.1	31.0	16.5	200.1
	568	9.9	36.8	26.6	27.1	51.7	43.1	34.4	36.1	265.7
	570	14.4	31.1	21.2	24.8	49.7	40.0	35.8	34.8	251.8
	Mean	**11.8**	**35.9**	**19.4**	**28.3**	**47.9**	**39.4**	**39.1**	**29.4**	**251.1**
	S.D.	**3.76**	**6.25**	**4.76**	**7.36**	**2.63**	**3.38**	**6.58**	**7.15**	**25.96**
1.5 mg/L	549	5.0	40.5	11.5	31.4	44.5	49.8	42.9	36.8	262.4
	563	6.2	41.3	12.2	19.1	50.0	45.4	37.7	23.5	235.4
	576	7.5	45.8	16.7	38.2	57.4	45.9	44.1	39.5	295.1
	578	8.8	30.9	15.7	23.9	38.4	40.5	43.9	27.4	229.5
	581	6.3	25.3	12.1	20.9	42.3	40.8	49.2	36.1	233.0
	583	11.1	25.3	7.6	21.3	32.6	44.9	29.8	32.5	205.1
	Mean	**7.5**	**34.9**	**12.6**	**25.8**	**44.2**	**44.6**	**41.3**	**32.6**	**243.4**
	S.D.	**2.19**	**8.85**	**3.26**	**7.45**	**8.72**	**3.48**	**6.70**	**6.12**	**31.20**

Table I-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Body Mass Change (grams)
Recovery Female Animals

		Exposure Weekdays				Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Days 1-3**	**Days 3-5**	**Days 5-8**	**Days 8-10**	**Days 10-17**	**Days 17-24**	**Days 24-31**	**Days 31-37/38**	**Net**
Control	585	-0.2	21.9	5.8	19.7	5.7	5.3	13.6	3.4	75.2
	589	-2.2	19.0	-4.6	16.1	21.7	12.6	11.6	4.6	78.8
	592	-0.5	14.2	4.4	10.0	12.8	11.6	10.5	1.8	64.8
	599	-0.8	12.5	9.5	4.6	16.7	-4.1	15.0	7.6	61.0
	604	-5.5	8.8	9.5	14.7	18.1	8.9	3.2	17.6	75.3
	611	4.1	7.2	1.6	12.0	14.6	18.5	4.9	15.7	78.6
	Mean	**-0.8**	**13.9**	**4.4**	**12.9**	**14.9**	**8.8**	**9.8**	**8.5**	**72.3**
	S.D.	**3.11**	**5.71**	**5.34**	**5.25**	**5.46**	**7.68**	**4.75**	**6.66**	**7.53**
1.5 mg/L	587	7.3	1.4	-0.1	19.3	3.0	13.0	18.6	-12.6	49.9
	593	-0.9	10.4	3.3	13.9	11.5	8.9	11.5	2.3	60.9
	598	-9.1	16.6	1.5	15.8	15.0	12.9	12.0	1.0	65.7
	608	-6.4	12.3	3.0	6.5	18.5	-2.3	19.1	10.9	61.6
	613	7.7	8.8	7.1	11.0	19.4	-2.7	4.9	3.9	60.1
	617	0.7	7.7	-0.1	11.4	17.5	22.3	11.2	16.6	87.3
	Mean	**-0.1**	**9.5**	**2.5**	**13.0**	**14.2**	**8.7**	**12.9**	**3.7**	**64.3**
	S.D.	**6.89**	**5.07**	**2.70**	**4.41**	**6.16**	**9.72**	**5.30**	**9.93**	**12.45**

Table I-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass Change (grams)
Main Study Male Animals

Period		Control	Red Smoke Exposed		
			0.1 mg/L	0.5 mg/L	1.5 mg/L
Days 1-3	Mean	12.1	8.1	10.4	9.8
	S.D.	1.64	3.67	3.43	4.07
	N	6	6	6	6
Days 3-5	Mean	34.7	35.6	33.6	33.7
	S.D.	4.69	5.49	2.52	2.38
	N	6	6	6	6
Days 5-8	Mean	14.1	17.7	10.8	14.2
	S.D.	8.55	2.71	5.13	3.63
	N	6	6	6	6
Days 8-10	Mean	26.1	30.5	25.8	28.0
	S.D.	7.55	6.41	5.77	4.48
	N	6	6	6	6
Net	Mean	86.9	91.9	80.6	85.7
	S.D.	13.06	11.04	7.69	8.09
	N	6	6	6	6

Table I-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass Change (grams)
Main Study Female Animals

Period		Control	Red Smoke Exposed		
			0.1 mg/L	0.5 mg/L	1.5 mg/L
Days 1-3	Mean	-0.2	-4.8	-2.9	2.8
	S.D.	5.01	5.21	9.13	6.70
	N	6	6	6	6
Days 3-5	Mean	12.0	11.6	11.9	10.2
	S.D.	6.22	4.06	10.16	3.14
	N	6	6	6	6
Days 5-8	Mean	1.1	4.6	2.1	2.9
	S.D.	6.49	2.81	6.49	6.41
	N	6	6	6	6
Days 8-10	Mean	11.7	11.6	14.2	12.2
	S.D.	4.14	6.18	3.81	3.81
	N	6	6	6	6
Net	Mean	24.6	23.0	25.4	28.1
	S.D.	5.79	6.39	7.90	8.11
	N	6	6	6	6

Table I-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass Change (grams)
Recovery Male Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Days 1-3	Mean	11.8	7.5*
	S.D.	3.76	2.19
	N	6	6
Days 3-5	Mean	35.9	34.9
	S.D.	6.25	8.85
	N	6	6
Days 5-8	Mean	19.4	12.6
	S.D.	4.76	3.26
	N	6	6
Days 8-10	Mean	28.3	25.8
	S.D.	7.36	7.45
	N	6	6
Elapsed Recovery Days			
Days 10-17	Mean	47.9	44.2
	S.D.	2.63	8.72
	N	6	6
Days 17-24	Mean	39.4	44.6*
	S.D.	3.38	3.48
	N	6	6
Days 24-31	Mean	39.1	41.3
	S.D.	6.58	6.70
	N	6	6
Days 31-37/38	Mean	29.4	32.6
	S.D.	7.15	6.12
	N	6	6
Net	Mean	251.1	243.4
	S.D.	25.96	31.20
	N	6	6

* $p < 0.05$

Table I-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Body Mass Change (grams)
Recovery Female Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Days 1-3	Mean	-0.8	-0.1
	S.D.	3.11	6.89
	N	6	6
Days 3-5	Mean	13.9	9.5
	S.D.	5.71	5.07
	N	6	6
Days 5-8	Mean	4.4	2.5
	S.D.	5.34	2.70
	N	6	6
Days 8-10	Mean	12.9	13.0
	S.D.	5.25	4.41
	N	6	6
Elapsed Recovery Days			
Days 10-17	Mean	14.9	14.2
	S.D.	5.46	6.16
	N	6	6
Days 17-24	Mean	8.8	8.7
	S.D.	7.68	9.72
	N	6	6
Days 24-31	Mean	9.8	12.9
	S.D.	4.75	5.30
	N	6	6
Days 31-37/38	Mean	8.5	3.7
	S.D.	6.66	9.93
	N	6	6
Net	Mean	72.3	64.3
	S.D.	7.53	12.45
	N	6	6

Appendix J

Individual and Summary of Food Consumption Data

Table J-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Food Consumption (grams)
Main Study Male Animals

GROUP	ANIMAL ID	Days 1-3	Days 3-5	Days 5-8	Days 8-10	Net
Control	550	50.1	110.2	73.5	102.1	335.9
	552	53.1	111.7	53.6	125.8	344.2
	553	46.2	111.1	80.6	118.8	356.7
	560	47.8	105.1	73.8	104.8	331.5
	566	47.4	100.3	76.2	94.9	318.8
	579	46.5	108.5	81.2	113.9	350.1
	Mean	**48.5**	**107.8**	**73.2**	**110.1**	**339.5**
	S.D.	**2.63**	**4.38**	**10.12**	**11.49**	**13.68**
0.1 mg/L	551	47.7	111.4	81.1	122.6	362.8
	557	44.2	102.7	70.7	107.4	325.0
	571	47.5	100.7	75.4	109.9	333.5
	572	45.7	113.6	82.5	120.3	362.1
	573	45.0	107.1	78.6	108.0	338.7
	582	50.2	109.9	81.5	103.8	345.4
	Mean	**46.7**	**107.6**	**78.3**	**112.0**	**344.6**
	S.D.	**2.19**	**5.05**	**4.52**	**7.62**	**15.36**
0.5 mg/L	554	44.0	95.3	61.9	95.3	296.5
	555	30.1	97.4	64.5	99.7	291.7
	561	44.9	100.9	67.7	100.5	314.0
	569	48.1	102.2	67.7	94.6	312.6
	575	50.4	111.5	78.8	114.8	355.5
	580	55.7	117.4	81.4	115.3	369.8
	Mean	**45.5**	**104.1**	**70.3**	**103.4**	**323.4**
	S.D.	**8.66**	**8.58**	**7.91**	**9.35**	**31.99**
1.5 mg/L	556	47.6	102.5	72.7	101.5	324.3
	564	44.0	96.5	65.8	104.2	310.5
	565	54.2	120.2	82.7	115.8	372.9
	567	51.0	117.2	85.4	117.2	370.8
	574	44.2	105.6	75.0	106.6	331.4
	577	38.3	93.4	72.8	102.3	306.8
	Mean	**46.6**	**105.9**	**75.7**	**107.9**	**336.1**
	S.D.	**5.65**	**10.85**	**7.20**	**6.88**	**29.10**

Table J-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Food Consumption (grams)
Main Study Female Animals

GROUP	ANIMAL ID	Days 1-3	Days 3-5	Days 5-8	Days 8-10	Net
Control	586	27.7	67.1	47.0	66.3	208.1
	591	32.1	73.4	49.5	73.4	228.4
	601	33.0	77.4	54.1	79.0	243.5
	602	36.9	90.0	68.0	89.6	284.5
	605	34.4	76.8	54.1	77.8	243.1
	612	36.4	77.7	62.8	87.0	263.9
	Mean	**33.4**	**77.1**	**55.9**	**78.9**	**245.3**
	S.D.	**3.36**	**7.49**	**8.01**	**8.61**	**26.68**
0.1 mg/L	595	33.1	83.7	53.3	76.6	246.7
	596	29.3	79.7	51.4	76.8	237.2
	607	26.8	65.3	41.7	65.6	199.4
	616	33.0	76.4	53.2	76.9	239.5
	618	30.3	74.9	54.1	77.6	236.9
	619	31.3	71.9	53.6	74.1	230.9
	Mean	**30.6**	**75.3**	**51.2**	**74.6**	**231.8**
	S.D.	**2.40**	**6.37**	**4.75**	**4.57**	**16.66**
0.5 mg/L	588	29.7	72.8	50.2	74.1	226.8
	590	30.2	80.9	48.9	83.1	243.1
	594	6.4	60.7	51.5	70.6	189.2
	600	28.4	67.2	48.9	75.6	220.1
	603	36.0	81.1	58.8	87.1	263.0
	610	27.8	70.2	50.3	69.7	218.0
	Mean	**26.4**	**72.1**	**51.4**	**76.7**	**226.7**
	S.D.	**10.23**	**7.96**	**3.74**	**6.98**	**24.95**
1.5 mg/L	584	34.1	72.5	47.4	73.4	227.4
	597	31.9	68.5	49.7	74.5	224.6
	606	26.1	66.6	43.4	66.0	202.1
	609	34.6	73.8	53.8	78.2	240.4
	614	36.3	83.6	57.2	80.2	257.3
	615	36.4	72.8	49.8	78.1	237.1
	Mean	**33.2**	**73.0**	**50.2**	**75.1**	**231.5**
	S.D.	**3.87**	**5.91**	**4.83**	**5.11**	**18.47**

Table J-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Food Consumption (grams)
Recovery Male Animals

		Exposure Weekdays				Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Days 1-3**	**Days 3-5**	**Days 5-8**	**Days 8-10**	**Days 10-17**	**Days 17-24**	**Days 24-31**	**Days 31-37/38**	**Net**
Control	548	54.6	111.7	83.2	107.9	202.2	212.3	212.6	203.9	1188.4
	558	42.3	102.0	74.9	113.3	214.7	217.9	226.7	212.8	1204.6
	559	46.0	110.0	78.6	111.4	207.6	212.2	229.0	216.8	1211.6
	562	41.2	97.8	73.0	99.5	189.5	204.2	204.1	167.1	1076.4
	568	53.8	117.7	86.9	118.1	229.8	242.5	229.5	205.0	1283.3
	570	49.1	106.5	82.3	110.8	215.9	224.7	223.1	193.5	1205.9
	Mean	**47.8**	**107.6**	**79.8**	**110.2**	**210.0**	**219.0**	**220.8**	**199.9**	**1195.0**
	S.D.	**5.67**	**7.12**	**5.29**	**6.22**	**13.68**	**13.39**	**10.29**	**17.95**	**66.92**
1.5 mg/L	549	44.7	109.9	75.0	106.9	198.3	224.2	226.1	225.7	1210.8
	563	46.6	113.2	79.3	105.8	212.8	230.1	236.6	217.8	1242.2
	576	49.3	123.4	86.8	126.3	238.8	254.9	238.7	247.4	1365.6
	578	44.2	105.3	75.0	105.7	199.6	211.2	221.9	187.8	1150.7
	581	41.2	95.1	66.2	94.8	177.7	189.3	207.8	176.3	1048.4
	583	46.4	96.1	64.1	96.4	175.1	191.9	195.9	171.4	1037.3
	Mean	**45.4**	**107.2**	**74.4**	**106.0**	**200.4**	**216.9**	**221.2**	**204.4**	**1175.8**
	S.D.	**2.73**	**10.76**	**8.39**	**11.23**	**23.62**	**24.86**	**16.66**	**30.45**	**124.66**

Table J-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Food Consumption (grams)
Recovery Female Animals

		Exposure Weekdays				Elapsed Recovery Days				
GROUP	**ANIMAL ID**	**Days 1-3**	**Days 3-5**	**Days 5-8**	**Days 8-10**	**Days 10-17**	**Days 17-24**	**Days 24-31**	**Days 31-37/38**	**Net**
Control	585	30.7	78.3	49.7	80.1	131.1	137.1	135.1	123.4	765.5
	589	27.5	82.1	52.5	80.2	145.3	145.3	142.2	142.7	817.8
	592	35.0	73.2	51.9	70.2	130.6	133.1	127.3	125.4	746.7
	599	38.2	82.7	59.1	76.6	146.7	138.9	145.0	113.2	800.4
	604	31.0	74.8	55.9	78.7	145.6	153.8	146.9	125.1	811.8
	611	35.3	74.7	53.1	76.8	140.5	149.1	137.2	125.7	792.4
	Mean	**33.0**	**77.6**	**53.7**	**77.1**	**140.0**	**142.9**	**139.0**	**125.9**	**789.1**
	S.D.	**3.89**	**4.06**	**3.32**	**3.72**	**7.38**	**7.86**	**7.27**	**9.49**	**27.68**
1.5 mg/L	587	47.1	77.0	53.9	80.4	137.9	148.2	145.4	135.8	825.7
	593	31.1	73.1	49.4	75.1	138.4	146.0	136.1	133.3	782.5
	598	29.1	77.2	47.4	71.8	144.0	140.1	142.1	134.8	786.5
	608	28.0	69.7	46.2	69.4	128.6	123.6	125.0	112.2	702.7
	613	32.0	73.2	51.4	75.9	143.6	135.7	130.2	107.7	749.7
	617	33.9	78.0	52.8	76.4	145.9	158.1	154.0	140.2	839.3
	Mean	**33.5**	**74.7**	**50.2**	**74.8**	**139.7**	**142.0**	**138.8**	**127.3**	**781.1**
	S.D.	**6.97**	**3.23**	**3.05**	**3.83**	**6.33**	**11.79**	**10.56**	**13.73**	**50.08**

Table J-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Food Consumption (grams)
Main Study Male Animals

Period		Control	Red Smoke Exposed		
			0.1 mg/L	0.5 mg/L	1.5 mg/L
Days 1-3	Mean	48.5	46.7	45.5	46.6
	S.D.	2.63	2.19	8.66	5.65
	N	6	6	6	6
Days 3-5	Mean	107.8	107.6	104.1	105.9
	S.D.	4.38	5.05	8.58	10.85
	N	6	6	6	6
Days 5-8	Mean	73.2	78.3	70.3	75.7
	S.D.	10.12	4.52	7.91	7.20
	N	6	6	6	6
Days 8-10	Mean	110.1	112.0	103.4	107.9
	S.D.	11.49	7.62	9.35	6.88
	N	6	6	6	6
Net	Mean	339.5	344.6	323.4	336.1
	S.D.	13.68	15.36	31.99	29.10
	N	6	6	6	6

Table J-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Food Consumption (grams)
Main Study Female Animals

Period		Control	Red Smoke Exposed		
			0.1 mg/L	0.5 mg/L	1.5 mg/L
Days 1-3	Mean	33.4	30.6	26.4	33.2
	S.D.	3.36	2.40	10.23	3.87
	N	6	6	6	6
Days 3-5	Mean	77.1	75.3	72.1	73.0
	S.D.	7.49	6.37	7.96	5.91
	N	6	6	6	6
Days 5-8	Mean	55.9	51.2	51.4	50.2
	S.D.	8.01	4.75	3.74	4.83
	N	6	6	6	6
Days 8-10	Mean	78.9	74.6	76.7	75.1
	S.D.	8.61	4.57	6.98	5.11
	N	6	6	6	6
Net	Mean	245.3	231.8	226.7	231.5
	S.D.	26.68	16.66	24.95	18.47
	N	6	6	6	6

Table J-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Food Consumption (grams)
Recovery Male Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Days 1-3	Mean	47.8	45.4
	S.D.	5.67	2.73
	N	6	6
Days 3-5	Mean	107.6	107.2
	S.D.	7.12	10.76
	N	6	6
Days 5-8	Mean	79.8	74.4
	S.D.	5.29	8.39
	N	6	6
Days 8-10	Mean	110.2	106.0
	S.D.	6.22	11.23
	N	6	6
Elapsed Recovery Days			
Days 10-17	Mean	210.0	200.4
	S.D.	13.68	23.62
	N	6	6
Days 17-24	Mean	219.0	216.9
	S.D.	13.39	24.86
	N	6	6
Days 24-31	Mean	220.8	221.2
	S.D.	10.29	16.66
	N	6	6
Days 31-37/38	Mean	199.9	204.4
	S.D.	17.95	30.45
	N	6	6
Net	Mean	1195.0	1175.8
	S.D.	66.92	124.66
	N	6	6

Table J-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Food Consumption (grams)
Recovery Female Animals

Period		Recovery Control	Recovery 1.5 mg/L
Exposure Weekdays			
Days 1-3	Mean	33.0	33.5
	S.D.	3.89	6.97
	N	6	6
Days 3-5	Mean	77.6	74.7
	S.D.	4.06	3.23
	N	6	6
Days 5-8	Mean	53.7	50.2
	S.D.	3.32	3.05
	N	6	6
Days 8-10	Mean	77.1	74.8
	S.D.	3.72	3.83
	N	6	6
Elapsed Recovery Days			
Days 10-17	Mean	140.0	139.7
	S.D.	7.38	6.33
	N	6	6
Days 17-24	Mean	142.9	142.0
	S.D.	7.86	11.79
	N	6	6
Days 24-31	Mean	139.0	138.8
	S.D.	7.27	10.56
	N	6	6
Days 31-37/38	Mean	125.9	127.3
	S.D.	9.49	13.73
	N	6	6
Net	Mean	789.1	781.1
	S.D.	27.68	50.08
	N	6	6

Appendix K

Clinical Observations

Table K-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Daily Clinical Observations
Main Study and Recovery Male Animals

Group	Animal ID	Observation	First Weekday* Observed	Last Weekday* Observed
Control	550	None	1	10
	552	None	1	10
	553	Dried red material on nose	7	10
	560	None	1	10
	566	Dried red material on nose	6	7
	579	None	1	10
	548	Black stain on back	3	4
		Dried red material on nose	3	8
	558	Dried red material on nose	1	9
	559	Dried red material on nose	4	8
	562	Dried red material on nose	3	3
	568	Dried red material on nose	2	10
	570	Dried red material on nose	3	7
		Hair loss-Right front limb	15	17
		Hair loss-Both front limbs	20	30
0.1 mg/L	551	Red-stained fur on head (slight)	1	4
		Wet/red-stained nose	1	1
		Wet/red-stained nose (slight)	2	10
	557	Red-stained fur on head (slight)	1	9
		Wet/red-stained nose	1	1
		Wet/red-stained nose (slight)	2	10
	571	Wet/red-stained nose	1	1
		Wet/red-stained nose (slight)	2	10
		Red-stained fur on head (slight)	3	7
		Wet/red-stained mouth and chin	8	8
	572	Wet/red-stained nose (slight)	1	9
		Red-stained fur on head (slight)	3	6
		Red-stained fur on head	10	10
		Wet/red-stained nose	10	10
	573	Red-stained fur on head (slight)	1	1
		Wet/red-stained nose (slight)	2	9
		Red-stained fur on head	10	10
		Wet/red-stained nose	10	10
	582	Red-stained fur on head (slight)	1	6
		Wet/red-stained nose (slight)	2	9
		Red-stained fur on head	10	10
		Wet/red-stained nose	10	10
		None	5	5
0.5 mg/L	554	Red-stained fur on head	1	10
		Wet/red-stained nose	1	8
		Wet/red-stained mouth and chin	1	5
		Red-stained fur on head (slight)	3	9
	555	Red-stained fur on head	1	10
		Wet/red-stained nose	5	10
		Wet/red-stained mouth and chin	5	9
	561	Red-stained fur on head (slight)	1	9
		Red-stained fur on head	2	10
		Wet/red-stained nose	3	10
		Wet/red-stained mouth and chin	5	5
	569	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
	575	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	1	6
		Red-stained fur on head (slight)	8	8
	580	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
		Wet/red-stained mouth and chin	1	5
		Red-stained fur on head (slight)	7	7
1.5 mg/L	556	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	3	10
	564	Red-stained fur on head	1	10
		Wet/red-stained nose	1	5
		Wet/red-stained mouth and chin	4	8
	565	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	1	3
	567	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
		Wet/red-stained mouth and chin	4	6
	574	Red-stained fur on head	1	10
		Wet/red-stained nose	3	9
		Wet/red-stained mouth and chin	5	8
	577	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
		Wet/red-stained mouth and chin	4	4
	549	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
	563	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	1	10
		Red-stained fur on head (slight)	3	3
	576	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
		Wet/red-stained mouth and chin	5	5
	578	Red-stained fur on head	1	10
		Wet/red-stained nose	2	10
		Wet/red-stained mouth and chin	5	10
	581	Red-stained fur on head	1	10
		Wet/red-stained nose	2	9
		Wet/red-stained mouth and chin	3	9
	583	Red-stained fur on head	1	10
		Wet/red-stained nose	2	9
		Wet/red-stained mouth and chin	2	6

* = Signs may be observed intermittently between first and last weekday.

Table K-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Daily Clinical Observations
Main Study and Recovery Female Animals

Group	Animal ID	Observation	First Weekday* Observed	Last Weekday* Observed
Control	586	None	1	10
	591	None	1	10
	601	None	1	10
	602	None	1	10
	605	None	1	10
	612	None	1	8
		Dried red material around right eye	9	11
	585	None	1	10
	589	None	1	10
	592	None	1	9
		Hair loss both front limbs	10	31
	599	None	1	10
		Dried red material around nose	6	9
		Hair loss both front limbs	20	30
	604	None	1	10
	611	None	1	10
0.1 mg/L	595	Red-stained fur on head (slight)	1	6
		Wet/red-stained nose	1	1
		Wet/red-stained nose (slight)	2	10
	596	Wet/red-stained nose (slight)	1	10
		None	3	9
		Red-stained fur on head (slight)	4	7
	607	Wet/red-stained nose (slight)	1	10
		Red-stained fur on head (slight)	1	3
		None	2	9
	616	Red-stained fur on head (slight)	1	1
		None	2	8
		Wet/red-stained nose (slight)	3	9
		Red-stained fur on head	10	10
		Wet/red-stained nose	10	10
		Wet/red-stained mouth and chin	10	10
	618	Red-stained fur on head (slight)	1	5
		Wet/red-stained nose (slight)	1	7
		None	6	8
		Hair loss both front limbs	9	9
		Red-stained fur on head	10	10
		Wet/red-stained mouth and chin	10	10
	619	Red-stained fur on head (slight)	1	5
		Wet/red-stained nose (slight)	2	9
		None	2	8
		Red-stained fur on head	10	10
		Wet/red-stained nose	10	10
0.5 mg/L	588	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Red-stained fur on head (slight)	3	3
		Wet/red-stained mouth and chin	4	4
	590	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		White/opaque right eye (Pre-existing condition)	1	11
		Wet/red-stained mouth and chin	4	8
		Red-stained fur on head (slight)	9	9
	594	Red-stained fur on head	1	10
		Red-stained fur on head (slight)	2	4
		Wet/red-stained nose	4	10
	600	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
		Wet/red-stained mouth and chin	2	8
		Red-stained fur on head (slight)	3	8
	603	Red-stained fur on head	1	10
		Wet/red-stained nose	2	9
		Wet/red-stained mouth and chin	6	6
	610	Red-stained fur on head	1	10
		Wet/red-stained nose	1	9
1.5 mg/L	584	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	3	10
	597	Red-stained fur on head	1	10
		Wet/red-stained nose	2	10
		Wet/red-stained mouth and chin	4	10
	606	Red-stained fur on head	1	10
		Wet/red-stained nose		9
	609	Red-stained fur on head	1	10
		Wet/red-stained mouth and chin	2	9
		Wet/red-stained nose	5	9
	614	Red-stained fur on head	1	10
		Wet/red-stained nose	3	9
	615	Red-stained fur on head	1	10
		Wet/red-stained nose	3	9
		Wet/red-stained mouth and chin	3	8
	587	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	1	10
		Orange-colored urine	9	9
		Hair loss both front limbs	19	31
	593	Red-stained fur on head	1	10
		Wet/red-stained mouth and chin	2	6
		Red-stained fur on head (slight)	3	8
		Wet/red-stained nose	4	10
		Alopecia - left side of abdomen & left hind limb	14	23
		Alopecia - left side of abdomen, urogenital area & left hind limb	25	31
	598	Red-stained fur on head	1	10
		Wet/red-stained nose	6	10
		Wet/red-stained mouth and chin	6	10
	608	Red-stained fur on head	1	9
		Wet/red-stained nose	1	9
		Red-stained fur on head (slight)	10	10
	613	Red-stained fur on head	1	10
		Wet/red-stained nose	1	10
		Wet/red-stained mouth and chin	8	9
	617	Red-stained fur on head	1	10
		Wet/red-stained nose	5	9
		Wet/red-stained mouth and chin	6	9

* = Signs may be observed intermittently between first and last weekday.

Appendix L

Individual and Summary of Clinical Chemistry Data

Table L-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Clinical Chemistry
Main Study Male Animals

GROUP	ANIMAL ID	ALB (g/dL)	ALKP (U/L)	ALT (U/L)	AMYL (U/L)	AST (U/L)	BUN (mg/dL)	Ca (mg/dL)	CHOL (mg/dL)	CREA (mg/dL)	GLOB (g/dL)	GLU (mg/dL)	LDH (U/L)	PHOS (mg/dL)	TBIL (mg/dL)	TP (g/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Control	550	3.8	241	68	1768	98	16	13.2	70	0.3	3.0	236	356	14.3	0.2	6.7	152	9.4	103
	552	3.5	222	46	1400	103	14	12.5	80	0.3	2.7	109	339	13.9	0.2	6.2	150	8.9	104
	553	3.3	317	72	1432	118	14	12.1	85	0.4	2.8	103	310	15.9	0.1	6.2	151	9.2	106
	560	3.7	239	66	1498	109	19	12.2	78	0.3	3.0	357	339	14.7	0.3	6.7	146	10.0	100
	566	3.2	150	58	1339	91	18	12.2	69	0.2	2.9	195	314	13.4	0.1	6.1	146	9.4	104
	579	3.0	203	60	1060	116	15	12.5	81	0.4	2.8	119	237	14.6	0.1	5.8	146	8.5	104
	Mean	**3.4**	**228.7**	**61.7**	**1416.2**	**105.8**	**16.0**	**12.5**	**77.2**	**0.3**	**2.9**	**186.5**	**315.8**	**14.5**	**0.2**	**6.3**	**148.5**	**9.2**	**103.5**
	S.D.	**0.31**	**54.69**	**9.24**	**229.70**	**10.50**	**2.10**	**0.40**	**6.37**	**0.08**	**0.12**	**99.12**	**42.28**	**0.85**	**0.08**	**0.35**	**2.81**	**0.51**	**1.97**
0.1 mg/L	551	3.0	158	58	1030	119	16	12.2	56	0.4	2.8	120	267	13.1	0.1	5.8	146	9.8	105
	557	3.5	233	63	1123	108	15	12.4	97	0.4	2.7	73	342	16.1	0.1	6.2	149	12.3	106
	571	4.7	286	61	1720	101	15	13.1	85	0.2	1.2	233	189	13.1	0.1	5.9	149	7.2	105
	572	3.4	198	51	1460	14	20	12.5	74	0.4	3.2	208	392	16.1	0.3	6.6	147	11.4	104
	573	2.9	271	74	1287	80	17	13.0	73	0.3	3.7	315	253	15.9	0.2	6.6	144	10.4	102
	582	3.3	129	88	1059	99	19	12.4	82	0.6	2.9	202	257	14.4	0.1	6.2	147	11.4	102
	Mean	**3.5**	**212.5**	**65.8**	**1279.8**	**86.8**	**17.0**	**12.6**	**77.8**	**0.4**	**2.8**	**191.8**	**283.3**	**14.8**	**0.2**	**6.2**	**147.0**	**10.4**	**104.0**
	S.D.	**0.65**	**62.29**	**13.20**	**269.09**	**37.90**	**2.10**	**0.36**	**13.79**	**0.13**	**0.84**	**85.45**	**72.15**	**1.45**	**0.08**	**0.34**	**1.90**	**1.80**	**1.67**
0.5 mg/L	554	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	149	9.6	106
	555	3.3	223	54	1293	94	15	12.0	99	0.4	3.0	131	347	15.4	0.1	6.2	148	9.2	108
	561	4.7	276	77	1788	81	14	14.2	103	0.4	1.7	213	273	16.1	0.1	6.4	152	8.4	106
	569	3.3	163	48	1145	111	17	11.6	86	0.4	3.4	95	293	14.3	0.1	6.7	147	8.7	104
	575	2.8	287	52	1411	102	12	11.7	75	0.4	2.2	143	324	13.0	0.1	5.1	148	11.3	105
	580	3.5	210	71	1702	94	12	12.2	73	0.3	3.0	178	240	12.1	0.1	6.5	150	7.9	104
	Mean	**3.5**	**231.8**	**60.4**	**1467.8**	**96.4**	**14.0**	**12.3**	**87.2**	**0.4**	**2.7**	**152.0**	**295.4**	**14.2**	**0.1**	**6.2**	**149.0**	**9.2**	**105.5**
	S.D.	**0.71**	**50.71**	**12.78**	**271.73**	**11.10**	**2.12**	**1.07**	**13.61**	**0.04**	**0.69**	**45.19**	**42.00**	**1.65**	**0.00**	**0.63**	**1.79**	**1.20**	**1.52**
1.5 mg/L	556	2.9	149	46	1269	88	16	11.7	71	0.3	3.0	185	203	13.7	0.1	5.9	148	8.6	106
	564	3.4	133	51	895	69	17	12.1	70	0.4	2.9	152	264	13.0	0.1	6.3	149	9.5	105
	565	3.3	144	42	1267	99	17	12.3	55	0.5	2.8	93	401	15.7	0.1	6.1	152	12.3	108
	567	3.2	245	69	1265	64	21	13.2	66	0.5	3.1	248	226	14.3	0.2	6.3	153	10.7	102
	574	3.5	197	60	1120	80	21	12.7	94	0.4	3.0	277	258	16.1	0.1	6.5	148	9.5	103
	577	3.2	154	60	1416	81	19	12.2	74	0.3	2.9	288	276	12.7	0.1	6.0	147	9.5	104
	Mean	**3.3**	**170.3**	**54.7**	**1205.3**	**80.2**	**18.5**	**12.4**	**71.7**	**0.4**	**3.0**	**207.2**	**271.3**	**14.3**	**0.1**	**6.2**	**149.5**	**10.0**	**104.7**
	S.D.	**0.21**	**42.65**	**10.11**	**178.54**	**12.67**	**2.17**	**0.52**	**12.79**	**0.09**	**0.10**	**77.00**	**68.98**	**1.40**	**0.04**	**0.22**	**2.43**	**1.30**	**2.16**

ND = No data

Table L-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Clinical Chemistry
Main Study Female Animals

GROUP	ANIMAL ID	ALB (g/dL)	ALKP (U/L)	ALT (U/L)	AMYL (U/L)	AST (U/L)	BUN (mg/dL)	Ca (mg/dL)	CHOL (mg/dL)	CREA (mg/dL)	GLOB (g/dL)	GLU (mg/dL)	LDH (U/L)	PHOS (mg/dL)	TBIL (mg/dL)	TP (g/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Control	586	3.7	99	51	683	140	17	12.2	76	0.4	2.9	100	183	16.1	0.3	6.6	146	9.4	108
	591	4.8	127	83	727	128	17	14.5	83	0.6	1.8	74	395	16.1	0.4	6.6	149	12.6	108
	601	3.4	92	53	619	106	18	12.3	82	0.5	2.7	104	253	14.5	0.2	6.2	145	11.6	109
	602	1.7	88	52	996	115	16	12.1	78	0.5	5.6	151	313	14.1	0.4	7.3	148	10.0	105
	605	3.4	75	86	617	102	17	12.4	80	0.4	2.9	103	312	13.5	0.2	6.3	147	12.6	107
	612	3.8	107	43	844	84	20	12.7	88	0.5	2.9	108	243	14.3	0.2	6.6	149	9.8	104
	Mean	**3.5**	**98.0**	**61.3**	**747.7**	**112.5**	**17.5**	**12.7**	**81.2**	**0.5**	**3.1**	**106.7**	**283.2**	**14.8**	**0.3**	**6.6**	**147.3**	**11.0**	**106.8**
	S.D.	**1.01**	**17.82**	**18.32**	**147.78**	**19.84**	**1.38**	**0.91**	**4.22**	**0.08**	**1.28**	**24.90**	**73.19**	**1.09**	**0.10**	**0.38**	**1.63**	**1.45**	**1.94**
0.1 mg/L	595	4.9	125	66	1193	74	17	14.9	72	0.7	2.0	143	188	16.1	0.4	6.9	145	11.5	106
	596	3.4	79	42	623	90	14	12.1	67	0.4	3.0	130	250	13.0	0.2	6.4	144	11.0	106
	607	3.3	121	35	713	109	18	11.8	73	0.5	2.6	104	212	12.2	0.1	5.9	147	10.5	108
	616	3.5	88	45	646	95	22	11.9	75	0.5	2.6	292	232	14.5	0.1	6.0	146	11.3	106
	618	3.8	96	52	765	74	18	12.3	65	0.6	2.9	133	303	15.1	0.2	6.6	148	10.0	107
	619	3.4	83	37	670	69	17	12.6	76	0.6	3.3	146	236	16.1	0.2	6.6	145	12.0	105
	Mean	**3.7**	**98.7**	**46.2**	**768.3**	**85.2**	**17.7**	**12.6**	**71.3**	**0.6**	**2.7**	**158.0**	**236.8**	**14.5**	**0.2**	**6.4**	**145.8**	**11.1**	**106.3**
	S.D.	**0.60**	**19.72**	**11.44**	**214.09**	**15.48**	**2.58**	**1.16**	**4.41**	**0.10**	**0.45**	**67.31**	**38.93**	**1.61**	**0.11**	**0.38**	**1.47**	**0.72**	**1.03**
0.5 mg/L	588	3.6	102	49	822	88	17	12.0	57	0.5	2.9	165	232	16.1	0.2	6.5	144	14.9	107
	590	3.4	94	46	777	96	15	12.0	69	0.6	3.1	81	252	12.6	0.1	6.5	145	9.9	107
	594	4.5	100	57	866	105	14	13.3	86	0.5	2.9	131	313	16.1	0.4	7.4	149	14.0	107
	600	3.5	93	44	915	97	20	12.2	76	0.5	3.4	151	222	12.7	0.2	6.8	144	12.6	106
	603	3.3	99	60	845	211	20	12.8	66	0.5	3.0	137	1251	16.1	0.3	6.3	147	8.8	108
	610	3.8	141	45	882	115	23	11.8	83	0.6	3.5	122	329	13.8	0.4	7.3	148	12.1	107
	Mean	**3.7**	**104.8**	**50.2**	**851.2**	**118.7**	**18.2**	**12.4**	**72.8**	**0.5**	**3.1**	**131.2**	**433.2**	**14.6**	**0.3**	**6.8**	**146.2**	**12.1**	**107.0**
	S.D.	**0.44**	**18.06**	**6.74**	**48.24**	**46.15**	**3.43**	**0.58**	**10.94**	**0.05**	**0.26**	**28.89**	**402.99**	**1.73**	**0.12**	**0.46**	**2.14**	**2.34**	**0.63**
1.5 mg/L	584	3.6	96	50	706	108	16	11.5	79	0.6	3.1	92	348	10.9	0.3	6.7	145	8.4	107
	597	4.1	75	44	928	121	15	12.7	80	0.5	3.1	108	488	15.1	0.4	7.2	143	ND	107
	606	3.3	91	53	556	116	20	11.6	66	0.5	3.1	93	502	15.0	0.4	6.4	149	11.6	108
	609	3.4	130	53	737	110	22	11.9	66	0.5	3.4	119	240	12.8	0.2	6.7	149	10.8	106
	614	3.5	142	51	770	188	19	12.7	89	0.5	3.5	106	641	15.5	0.3	7.1	147	13.3	106
	615	3.5	96	37	843	89	17	12.2	75	0.4	3.0	130	221	13.6	0.2	6.5	147	14.2	105
	Mean	**3.6**	**105.0**	**48.0**	**756.7**	**122.0**	**18.2**	**12.1**	**75.8**	**0.5**	**3.2**	**108.0**	**406.7**	**13.8**	**0.3**	**6.8**	**146.7**	**11.7**	**106.5**
	S.D.	**0.28**	**25.50**	**6.32**	**126.65**	**34.12**	**2.64**	**0.53**	**8.89**	**0.06**	**0.20**	**14.76**	**165.11**	**1.76**	**0.09**	**0.32**	**2.34**	**2.26**	**1.05**

ND = No data

Table L-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Clinical Chemistry
Recovery Male Animals

GROUP	ANIMAL ID	ALB (g/dL)	ALKP (U/L)	ALT (U/L)	AMYL (U/L)	AST (U/L)	BUN (mg/dL)	Ca (mg/dL)	CHOL (mg/dL)	CREA (mg/dL)	GLOB (g/dL)	GLU (mg/dL)	LDH (U/L)	PHOS (mg/dL)	TBIL (mg/dL)	TP (g/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Control	548	3.3	128	118	1602	287	22	12.3	88	0.5	3.0	265	706	14.7	0.3	6.3	146	13.9	106
	558	3.3	206	62	1535	83	22	11.7	74	0.5	3.1	259	231	13.9	0.2	6.3	149	9.4	102
	559	3.3	204	56	1744	105	20	11.5	79	0.5	3.4	217	308	12.6	0.2	6.7	153	8.5	106
	562	3.0	113	78	1362	71	20	11.8	63	0.4	3.3	268	398	11.6	0.3	6.3	148	8.1	103
	568	3.7	133	55	1563	101	22	11.9	72	0.5	3.5	206	387	12.8	0.5	7.2	148	11.3	102
	570	3.3	141	53	1714	70	22	12.1	72	0.5	3.3	281	240	13.5	0.3	6.6	149	10.2	105
	Mean	**3.3**	**154.2**	**70.3**	**1586.7**	**119.5**	**21.3**	**11.9**	**74.7**	**0.5**	**3.3**	**249.3**	**378.3**	**13.2**	**0.3**	**6.6**	**148.8**	**10.2**	**104.0**
	S.D.	**0.22**	**40.42**	**25.07**	**137.77**	**83.36**	**1.03**	**0.29**	**8.33**	**0.04**	**0.19**	**30.38**	**175.28**	**1.09**	**0.11**	**0.36**	**2.32**	**2.14**	**1.90**
1.5 mg/L	549	3.3	176	69	1470	62	18	11.9	72	0.4	3.2	191	253	12.8	0.2	6.5	149	10.2	104
	563	3.0	115	59	1805	81	19	12.4	79	0.5	3.6	345	237	12.2	0.2	6.6	147	9.1	104
	576	3.0	136	50	1855	100	19	12.3	79	0.4	3.6	338	293	15.4	0.2	6.5	147	11.8	105
	578	3.0	173	78	1638	105	25	12.5	84	0.6	3.5	358	210	11.8	0.3	6.4	148	9.1	105
	581	3.1	199	52	1334	108	17	11.9	80	0.5	3.3	249	296	12.5	0.2	6.4	149	9.4	105
	583	3.0	113	99	1264	214	20	12.2	74	0.4	3.4	213	472	13.2	0.3	6.4	152	11.3	107
	Mean	**3.1**	**152.0**	**67.8**	**1561.0**	**111.7**	**19.7**	**12.2**	**78.0**	**0.5**	**3.4**	**282.3**	**293.5**	**13.0**	**0.2**	**6.5**	**148.7**	**10.2**	**105.0**
	S.D.	**0.12**	**35.70**	**18.56**	**244.92**	**53.05**	**2.80**	**0.25**	**4.34**	**0.08**	**0.16**	**73.50**	**93.46**	**1.28**	**0.05**	**0.08**	**1.86**	**1.17**	**1.10**

Table L-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Clinical Chemistry
Recovery Female Animals

GROUP	ANIMAL ID	ALB (g/dL)	ALKP (U/L)	ALT (U/L)	AMYL (U/L)	AST (U/L)	BUN (mg/dL)	Ca (mg/dL)	CHOL (mg/dL)	CREA (mg/dL)	GLOB (g/dL)	GLU (mg/dL)	LDH (U/L)	PHOS (mg/dL)	TBIL (mg/dL)	TP (g/dL)	Na (mmol/L)	K (mmol/L)	Cl (mmol/L)
Control	585	4.1	108	60	972	152	22	12.0	94	0.7	2.9	66	537	16.1	0.4	7.1	150	13.9	107
	589	4.1	72	63	827	104	22	11.7	81	0.5	3.2	129	280	12.4	0.4	7.2	149	11.5	107
	592	4.2	72	92	954	206	23	12.3	66	0.5	2.7	154	1605	11.9	0.3	6.9	149	11.7	107
	599	3.5	82	43	815	100	18	11.5	64	0.4	2.8	145	319	10.7	0.2	6.4	142	8.1	106
	604	4.2	61	58	983	94	15	12.7	81	0.5	3.0	298	321	13.4	0.4	7.2	148	9.9	107
	611	4.3	63	67	934	193	22	12.2	102	0.6	3.1	145	1154	12.7	0.6	7.4	147	9.4	108
	Mean	**4.1**	**76.3**	**63.8**	**914.2**	**141.5**	**20.3**	**12.1**	**81.3**	**0.5**	**3.0**	**156.2**	**702.7**	**12.9**	**0.4**	**7.0**	**147.5**	**10.8**	**107.0**
	S.D.	**0.29**	**17.24**	**16.04**	**74.16**	**49.61**	**3.14**	**0.43**	**14.99**	**0.10**	**0.19**	**76.47**	**550.79**	**1.82**	**0.13**	**0.35**	**2.88**	**2.05**	**0.63**
1.5 mg/L	587	3.9	67	59	1200	119	18	11.7	91	0.6	3.1	125	500	15.0	0.4	7.0	148	9.7	107
	593	3.4	65	48	1018	91	17	12.3	72	0.4	2.8	296	239	11.8	0.3	6.2	146	11.8	107
	598	3.6	67	63	731	107	22	11.8	85	0.5	2.7	243	475	11.5	0.2	6.3	145	12.1	108
	608	3.7	112	40	970	95	17	11.3	66	0.5	2.7	177	319	9.3	0.3	6.4	146	7.8	108
	613	4.0	86	76	901	119	19	11.5	61	0.4	3.0	108	412	11.9	0.2	7.0	150	8.7	111
	617	3.9	66	53	1006	99	19	12.0	79	0.5	3.1	218	385	11.9	0.2	7.0	149	10.2	109
	Mean	**3.8**	**77.2**	**56.5**	**971.0**	**105.0**	**18.7**	**11.8**	**75.7**	**0.5**	**2.9**	**194.5**	**388.3**	**11.9**	**0.3**	**6.7**	**147.3**	**10.1**	**108.3**
	S.D.	**0.23**	**18.82**	**12.53**	**153.87**	**12.07**	**1.86**	**0.36**	**11.45**	**0.08**	**0.19**	**71.87**	**97.63**	**1.82**	**0.08**	**0.39**	**1.97**	**1.69**	**1.51**

Table L-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Clinical Chemistry
Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
ALB	Mean	3.4	3.5	3.5	3.3
(g/dL)	S.D.	0.31	0.65	0.71	0.21
	N	6	6	5	6
ALK P	Mean	228.7	212.5	231.8	170.3
(U/L)	S.D.	54.69	62.29	50.71	42.65
	N	6	6	5	6
ALT	Mean	61.7	65.8	60.4	54.7
(U/L)	S.D.	9.24	13.20	12.78	10.11
	N	6	6	5	6
AMYL	Mean	1416.2	1279.8	1467.8	1205.3
(U/L)	S.D.	229.70	269.09	271.73	178.54
	N	6	6	5	6
AST	Mean	105.8	86.8	96.4	80.2
(U/L)	S.D.	10.50	37.90	11.10	12.67
	N	6	6	5	6
BUN	Mean	16.0	17.0	14.0	18.5
(mg/dL)	S.D.	2.10	2.10	2.12	2.17
	N	6	6	5	6
Ca	Mean	12.5	12.6	12.3	12.4
(mg/dL)	S.D.	0.40	0.36	1.07	0.52
	N	6	6	5	6
CHOL	Mean	77.2	77.8	87.2	71.7
(mg/dL)	S.D.	6.37	13.79	13.61	12.79
	N	6	6	5	6
CREA	Mean	0.3	0.4	0.4	0.4
(mg/dL)	S.D.	0.08	0.13	0.04	0.09
	N	6	6	5	6
GLOB	Mean	2.9	2.8	2.7	3.0
(g/dL)	S.D.	0.12	0.84	0.69	0.10
	N	6	6	5	6
GLU	Mean	186.5	191.8	152.0	207.2
(mg/dL)	S.D.	99.12	85.45	45.19	77.00
	N	6	6	5	6
LDH	Mean	315.8	283.3	295.4	271.3
(U/L)	S.D.	42.28	72.15	42.00	68.98
	N	6	6	5	6
PHOS	Mean	14.5	14.8	14.2	14.3
(mg/dL)	S.D.	0.85	1.45	1.65	1.40
	N	6	6	5	6
TBIL	Mean	0.2	0.2	0.1	0.1
(mg/dL)	S.D.	0.08	0.08	0.00	0.04
	N	6	6	5	6
TP	Mean	6.3	6.2	6.2	6.2
(g/dL)	S.D.	0.35	0.34	0.63	0.22
	N	6	6	5	6
Na	Mean	148.5	147.0	149.0	149.5
(mmol/L)	S.D.	2.81	1.90	1.79	2.43
	N	6	6	6	6
K	Mean	9.2	10.4	9.2	10.0
(mmol/L)	S.D.	0.51	1.80	1.20	1.30
	N	6	6	6	6
Cl	Mean	103.5	104.0	105.5	104.7
(mmol/L)	S.D.	1.97	1.67	1.52	2.16
	N	6	6	6	6

Table L-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Clinical Chemistry
Main Study Female Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
ALB	Mean	3.5	3.7	3.7	3.6
(g/dL)	S.D.	1.01	0.60	0.44	0.28
	N	6	6	6	6
ALK P	Mean	98.0	98.7	104.8	105.0
(U/L)	S.D.	17.82	19.72	18.06	25.50
	N	6	6	6	6
ALT	Mean	61.3	46.2	50.2	48.0
(U/L)	S.D.	18.32	11.44	6.74	6.32
	N	6	6	6	6
AMYL	Mean	747.7	768.3	851.2	756.7
(U/L)	S.D.	147.78	214.09	48.24	126.65
	N	6	6	6	6
AST	Mean	112.5	85.2	118.7	122.0
(U/L)	S.D.	19.84	15.48	46.15	34.12
	N	6	6	6	6
BUN	Mean	17.5	17.7	18.2	18.2
(mg/dL)	S.D.	1.38	2.58	3.43	2.64
	N	6	6	6	6
Ca	Mean	12.7	12.6	12.4	12.1
(mg/dL)	S.D.	0.91	1.16	0.58	0.53
	N	6	6	6	6
CHOL	Mean	81.2	71.3	72.8	75.8
(mg/dL)	S.D.	4.22	4.41	10.94	8.89
	N	6	6	6	6
CREA	Mean	0.5	0.6	0.5	0.5
(mg/dL)	S.D.	0.08	0.10	0.05	0.06
	N	6	6	6	6
GLOB	Mean	3.1	2.7	3.1	3.2
(g/dL)	S.D.	1.28	0.45	0.26	0.20
	N	6	6	6	6
GLU	Mean	106.7	158.0	131.2	108.0
(mg/dL)	S.D.	24.90	67.31	28.89	14.76
	N	6	6	6	6
LDH	Mean	283.2	236.8	433.2	406.7
(U/L)	S.D.	73.19	38.93	402.99	165.11
	N	6	6	6	6
PHOS	Mean	14.8	14.5	14.6	13.8
(mg/dL)	S.D.	1.09	1.61	1.73	1.76
	N	6	6	6	6
TBIL	Mean	0.3	0.2	0.3	0.3
(mg/dL)	S.D.	0.10	0.11	0.12	0.09
	N	6	6	6	6
TP	Mean	6.6	6.4	6.8	6.8
(g/dL)	S.D.	0.38	0.38	0.46	0.32
	N	6	6	6	6
Na	Mean	147.3	145.8	146.2	146.7
(mmol/L)	S.D.	1.63	1.47	2.14	2.34
	N	6	6	6	6
K	Mean	11.0	11.1	12.1	11.7
(mmol/L)	S.D.	1.45	0.72	2.34	2.26
	N	6	6	6	5
Cl	Mean	106.8	106.3	107.0	106.5
(mmol/L)	S.D.	1.94	1.03	0.63	1.05
	N	6	6	6	6

Table L-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Clinical Chemistry
Recovery Male Rats

		Control	1.5 mg/L
ALB	Mean	3.3	3.1*
(g/dL)	S.D.	0.22	0.12
	N	6	6
ALK P	Mean	154.2	152.0
(U/L)	S.D.	40.42	35.70
	N	6	6
ALT	Mean	70.3	67.8
(U/L)	S.D.	25.07	18.56
	N	6	6
AMYL	Mean	1586.7	1561.0
(U/L)	S.D.	137.77	244.92
	N	6	6
AST	Mean	119.5	111.7
(U/L)	S.D.	83.36	53.05
	N	6	6
BUN	Mean	21.3	19.7
(mg/dL)	S.D.	1.03	2.80
	N	6	6
Ca	Mean	11.9	12.2
(mg/dL)	S.D.	0.29	0.25
	N	6	6
CHOL	Mean	74.7	78.0
(mg/dL)	S.D.	8.33	4.34
	N	6	6
CREA	Mean	0.5	0.5
(mg/dL)	S.D.	0.04	0.08
	N	6	6
GLOB	Mean	3.3	3.4
(g/dL)	S.D.	0.19	0.16
	N	6	6
GLU	Mean	249.3	282.3
(mg/dL)	S.D.	30.38	73.50
	N	6	6
LDH	Mean	378.3	293.5
(U/L)	S.D.	175.28	93.46
	N	6	6
PHOS	Mean	13.2	13.0
(mg/dL)	S.D.	1.09	1.28
	N	6	6
TBIL	Mean	0.3	0.2
(mg/dL)	S.D.	0.11	0.05
	N	6	6
TP	Mean	6.6	6.5
(g/dL)	S.D.	0.36	0.08
	N	6	6
Na	Mean	148.8	148.7
(mmol/L)	S.D.	2.32	1.86
	N	6	6
K	Mean	10.2	10.2
(mmol/L)	S.D.	2.14	1.17
	N	6	6
Cl	Mean	104.0	105.0
(mmol/L)	S.D.	1.90	1.10
	N	6	6

* $p < 0.05$

Table L-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Clinical Chemistry
Recovery Female Rats

		Control	1.5 mg/L
ALB	Mean	4.1	3.8
(g/dL)	S.D.	0.29	0.23
	N	6	6
ALK P	Mean	76.3	77.2
(U/L)	S.D.	17.24	18.82
	N	6	6
ALT	Mean	63.8	56.5
(U/L)	S.D.	16.04	12.53
	N	6	6
AMYL	Mean	914.2	971.0
(U/L)	S.D.	74.16	153.87
	N	6	6
AST	Mean	141.5	105.0
(U/L)	S.D.	49.61	12.07
	N	6	6
BUN	Mean	20.3	18.7
(mg/dL)	S.D.	3.14	1.86
	N	6	6
Ca	Mean	12.1	11.8
(mg/dL)	S.D.	0.43	0.36
	N	6	6
CHOL	Mean	81.3	75.7
(mg/dL)	S.D.	14.99	11.45
	N	6	6
CREA	Mean	0.5	0.5
(mg/dL)	S.D.	0.10	0.08
	N	6	6
GLOB	Mean	3.0	2.9
(g/dL)	S.D.	0.19	0.19
	N	6	6
GLU	Mean	156.2	194.5
(mg/dL)	S.D.	76.47	71.87
	N	6	6
LDH	Mean	702.7	388.3
(U/L)	S.D.	550.79	97.63
	N	6	6
PHOS	Mean	12.9	11.9
(mg/dL)	S.D.	1.82	1.82
	N	6	6
TBIL	Mean	0.4	0.3
(mg/dL)	S.D.	0.13	0.08
	N	6	6
TP	Mean	7.0	6.7
(g/dL)	S.D.	0.35	0.39
	N	6	6
Na	Mean	147.5	147.3
(mmol/L)	S.D.	2.88	1.97
	N	6	6
K	Mean	10.8	10.1
(mmol/L)	S.D.	2.05	1.69
	N	6	6
Cl	Mean	107.0	108.3
(mmol/L)	S.D.	0.63	1.51
	N	6	6

Appendix M

Individual and Summary of Hematology Data

Table M-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Hematology
Main Study Male Animals

		WBC	NEU		LYM		MONO		EOS		BASO		RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV
GROUP	ANIMAL ID	(K/uL)	(K/uL)	(%N)	(K/uL)	(%L)	(K/uL)	(%M)	(K/uL)	(%E)	(K/uL)	(%B)	(M/uL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	(%)	(K/uL)	(fL)
Control	550	6.630	0.674	10.200	4.640	70.000	0.413	6.230	0.039	0.589	0.865	13.000	8.48	17.20	48.6	57.3	20.2	35.3	15.6	1560.0	5.64
	552	5.530	0.536	9.700	4.290	77.600	0.293	5.300	0.040	0.726	0.367	6.630	7.72	16.50	47.3	61.3	21.4	35.0	17.4	1227.0	4.63
	553	8.980	0.992	11.000	6.410	71.400	0.717	7.980	0.019	0.212	0.840	9.360	8.43	16.60	49.2	58.4	19.7	33.8	17.1	1318.0	4.55
	560	10.100	0.991	9.830	7.560	75.000	0.799	7.930	0.045	0.444	0.683	6.780	8.54	17.20	50.1	58.7	20.1	34.3	15.9	1194.0	4.43
	566	14.400	0.592	4.120	11.000	76.500	1.200	8.390	0.049	0.343	1.530	10.700	7.56	16.30	45.2	59.8	21.6	36.1	15.5	1150.0	5.68
	579	9.750	0.626	6.410	7.480	76.700	0.732	7.510	0.045	0.461	0.874	8.960	7.55	16.20	46.6	61.7	21.5	34.8	16.0	1195.0	4.59
	Mean	**9.232**	**0.735**	**8.543**	**6.897**	**74.533**	**0.692**	**7.223**	**0.040**	**0.463**	**0.860**	**9.238**	**8.047**	**16.667**	**47.833**	**59.533**	**20.750**	**34.883**	**16.250**	**1274.000**	**4.920**
	S.D.	**3.1070**	**0.2036**	**2.6792**	**2.4389**	**3.1162**	**0.3190**	**1.2001**	**0.0107**	**0.1804**	**0.3805**	**2.4177**	**0.4834**	**0.4367**	**1.8074**	**1.7236**	**0.8408**	**0.7985**	**0.8019**	**150.9689**	**0.5772**
0.1 mg/L	551	15.200	0.707	4.670	12.500	82.300	1.020	6.710	0.049	0.321	0.906	5.970	8.07	16.80	48.6	60.2	20.8	34.6	16.8	1082.0	4.85
	557	14.000	1.480	10.600	11.200	79.700	0.723	5.150	0.081	0.575	0.567	4.040	9.31	19.00	55.9	60.0	20.5	34.1	16.8	745.0	5.08
	571	12.000	1.040	8.710	9.460	79.000	0.789	6.600	0.099	0.828	0.582	4.860	7.38	15.70	44.3	60.0	21.3	35.4	16.8	1187.0	5.04
	572	13.200	1.370	10.400	10.600	80.200	0.667	5.060	0.041	0.311	0.524	3.970	8.69	18.00	50.9	58.6	20.7	35.3	16.8	1286.0	4.86
	573	9.810	0.973	9.920	7.420	75.700	0.608	6.190	0.055	0.563	0.753	7.670	8.53	17.00	49.1	57.6	19.9	34.6	17.8	1319.0	4.60
	582	12.500	0.959	7.650	9.820	78.300	0.874	6.970	0.015	0.118	0.878	7.000	8.46	17.50	51.2	60.5	20.6	34.1	15.3	943.0	4.84
	Mean	**12.785**	**1.088**	**8.658**	**10.167**	**79.200**	**0.780**	**6.113**	**0.057**	**0.453**	**0.702**	**5.585**	**8.407**	**17.333**	**50.000**	**59.483**	**20.633**	**34.683**	**16.717**	**1093.667**	**4.878**
	S.D.	**1.8455**	**0.2865**	**2.2504**	**1.7242**	**2.1891**	**0.1497**	**0.8210**	**0.0298**	**0.2520**	**0.1670**	**1.5504**	**0.6452**	**1.1237**	**3.8032**	**1.1321**	**0.4546**	**0.5636**	**0.8010**	**219.4918**	**0.1714**
0.5 mg/L	554	13.800	0.677	4.900	11.700	84.900	0.605	4.380	0.062	0.446	0.738	5.350	8.51	18.00	51.4	60.4	21.2	35.0	17.2	1319.0	4.75
	555	11.500	0.864	7.500	9.020	78.300	0.499	4.340	0.063	0.546	1.070	9.300	7.85	17.20	49.3	62.9	21.9	34.8	16.8	1102.0	4.79
	561	19.700	1.100	5.600	15.700	79.600	1.280	6.510	0.137	0.699	1.490	7.570	8.74	17.60	50.5	57.8	20.1	34.8	19.3	1283.0	5.16
	569	9.980	0.606	6.070	8.420	84.300	0.463	4.630	0.055	0.548	0.440	4.410	8.49	17.80	51.4	60.6	20.9	34.6	16.1	964.0	4.21
	575	12.700	0.848	6.700	9.420	74.500	1.040	8.200	0.048	0.377	1.300	10.300	8.70	17.30	50.2	57.7	19.8	34.4	17.0	1437.0	4.84
	580	9.950	0.928	9.330	8.030	80.700	0.492	4.940	0.039	0.396	0.461	4.640	7.77	16.50	47.2	60.7	21.2	34.9	17.0	990.0	5.06
	Mean	**12.938**	**0.837**	**6.683**	**10.382**	**80.383**	**0.730**	**5.500**	**0.067**	**0.502**	**0.917**	**6.928**	**8.343**	**17.400**	**50.000**	**60.017**	**20.850**	**34.750**	**17.233**	**1182.500**	**4.802**
	S.D.	**3.6406**	**0.1773**	**1.5749**	**2.9045**	**3.8835**	**0.3451**	**1.5479**	**0.0353**	**0.1207**	**0.4395**	**2.5090**	**0.4257**	**0.5329**	**1.5837**	**1.9773**	**0.7765**	**0.2168**	**1.0820**	**192.2402**	**0.3315**
1.5 mg/L	556	14.400	0.760	5.260	11.200	77.700	1.320	9.110	0.073	0.505	1.080	7.440	7.67	15.90	47.2	61.6	20.8	33.7	16.0	1170.0	4.68
	564	15.300	1.530	9.960	11.400	74.400	1.120	7.290	0.017	0.113	1.270	8.260	8.11	16.90	48.1	59.3	20.9	35.2	16.8	1098.0	4.71
	565	9.510	0.754	7.930	7.580	79.800	0.684	7.200	0.050	0.522	0.436	4.590	8.50	18.30	52.7	62.0	21.6	34.8	16.2	1436.0	5.04
	567	13.400	0.581	4.350	10.600	79.200	1.040	7.770	0.088	0.658	1.070	7.980	8.49	18.00	51.0	60.0	21.2	35.3	16.3	1157.0	5.18
	574	9.550	1.190	12.400	7.260	76.000	0.576	6.030	0.063	0.656	0.463	4.850	8.24	16.40	47.3	57.3	19.9	34.7	18.1	1229.0	4.59
	577	7.950	0.961	12.100	6.270	78.900	0.323	4.060	0.017	0.210	0.375	4.720	7.89	16.60	48.6	61.5	21.0	34.1	16.6	1294.0	4.55
	Mean	**11.685**	**0.963**	**8.667**	**9.052**	**77.667**	**0.844**	**6.910**	**0.051**	**0.444**	**0.782**	**6.307**	**8.150**	**17.017**	**49.150**	**60.283**	**20.900**	**34.633**	**16.667**	**1230.667**	**4.792**
	S.D.	**3.0535**	**0.3475**	**3.4112**	**2.2645**	**2.0916**	**0.3768**	**1.7149**	**0.0294**	**0.2302**	**0.3993**	**1.7599**	**0.3304**	**0.9411**	**2.2206**	**1.7949**	**0.5657**	**0.6250**	**0.7581**	**120.7339**	**0.2572**

Table M-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Hematology
Main Study Female Animals

		WBC	NEU		LYM		MONO		EOS		BASO		RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV
GROUP	ANIMAL ID	(K/uL)	(K/uL)	(%N)	(K/uL)	(%L)	(K/uL)	(%M)	(K/uL)	(%E)	(K/uL)	(%B)	(M/uL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	(%)	(K/uL)	(fL)
Control	586	8.120	0.472	5.820	6.280	77.300	0.761	9.370	0.027	0.328	0.581	7.150	8.51	17.20	48.9	57.5	20.3	35.2	16.8	683.0	5.16
	591	11.300	0.933	8.280	8.680	77.000	0.691	6.130	0.156	1.380	0.819	7.260	7.59	15.20	41.9	55.2	20.1	36.3	16.6	1403.0	5.07
	601	9.610	0.246	2.560	8.110	84.500	0.523	5.440	0.053	0.553	0.671	6.980	7.97	16.30	46.3	58.1	20.4	35.1	16.5	1351.0	4.68
	602	12.600	0.607	4.810	10.300	81.200	0.596	4.730	0.135	1.070	1.030	8.150	7.98	16.20	46.1	57.8	20.3	35.2	16.2	1212.0	4.80
	605	17.100	0.453	2.650	14.700	85.900	0.814	4.760	0.118	0.688	1.030	6.020	8.10	17.00	47.6	58.8	21.1	35.8	16.4	1270.0	5.03
	612	6.860	0.530	7.730	5.260	76.700	0.757	11.000	0.060	0.881	0.250	3.670	8.13	16.50	46.4	57.1	20.2	35.4	16.6	1227.0	5.10
	Mean	**10.932**	**0.540**	**5.308**	**8.888**	**80.433**	**0.690**	**6.905**	**0.092**	**0.817**	**0.730**	**6.538**	**8.047**	**16.400**	**46.200**	**57.417**	**20.400**	**35.500**	**16.517**	**1191.000**	**4.973**
	S.D.	**3.6660**	**0.2270**	**2.4424**	**3.3581**	**4.0633**	**0.1110**	**2.6429**	**0.0517**	**0.3770**	**0.2980**	**1.5610**	**0.2978**	**0.7071**	**2.3580**	**1.2287**	**0.3578**	**0.4648**	**0.2041**	**259.4556**	**0.1895**
0.1 mg/L	595	9.560	0.469	4.900	7.510	78.500	0.970	10.100	0.038	0.403	0.574	6.000	7.91	16.10	46.3	58.6	20.4	34.8	14.6	968.0	4.97
	596	8.200	0.473	5.770	6.600	80.400	0.700	8.540	0.079	0.964	0.353	4.300	7.47	15.40	42.9	57.4	20.6	35.9	16.1	1288.0	4.48
	607	7.380	0.312	4.230	6.110	82.800	0.546	7.410	0.030	0.408	0.379	5.140	8.66	17.20	49.3	56.9	19.9	35.0	15.8	913.0	4.65
	616	7.400	0.741	10.000	5.720	77.300	0.398	5.380	0.052	0.707	0.487	6.590	8.09	16.10	47.0	58.1	19.9	34.3	15.6	1215.0	4.56
	618	5.340	0.383	7.170	4.050	75.800	0.419	7.840	0.040	0.749	0.453	8.480	8.24	16.70	46.9	56.9	20.3	35.6	16.7	1448.0	4.89
	619	9.770	0.583	5.960	7.940	81.300	0.648	6.630	0.091	0.931	0.508	5.190	8.27	16.90	47.1	57.0	20.5	36.0	16.8	1401.0	5.37
	Mean	**7.942**	**0.494**	**6.338**	**6.322**	**79.350**	**0.614**	**7.650**	**0.055**	**0.694**	**0.459**	**5.950**	**8.107**	**16.400**	**46.583**	**57.483**	**20.267**	**35.267**	**15.933**	**1205.500**	**4.820**
	S.D.	**1.6374**	**0.1519**	**2.0533**	**1.3911**	**2.6205**	**0.2119**	**1.6175**	**0.0246**	**0.2444**	**0.0826**	**1.4676**	**0.3987**	**0.6573**	**2.0769**	**0.7139**	**0.3011**	**0.6743**	**0.8091**	**221.7591**	**0.3292**
0.5 mg/L	588	9.060	0.426	4.700	6.760	74.600	0.876	9.660	0.072	0.791	0.928	10.200	8.51	16.80	48.0	56.4	19.7	35.0	16.3	1340.0	5.13
	590	12.800	0.592	4.630	10.000	78.600	0.836	6.540	0.090	0.702	1.220	9.560	8.26	17.80	48.4	58.6	21.5	36.7	14.9	1395.0	4.75
	594	7.150	0.648	9.060	5.090	71.200	0.835	11.700	0.097	1.350	0.480	6.720	7.97	16.50	46.6	58.5	20.7	35.4	16.3	1429.0	5.54
	600	12.000	0.813	6.790	9.810	82.000	0.738	6.170	0.055	0.462	0.545	4.560	8.15	16.40	47.4	58.1	20.1	34.6	15.9	1293.0	5.15
	603	13.500	1.010	7.460	11.200	83.000	0.440	3.250	0.082	0.610	0.765	5.660	7.73	16.10	45.2	58.4	20.9	35.7	16.7	112.0	5.05
	610	5.770	0.506	8.770	4.620	80.000	0.270	4.670	0.008	0.133	0.373	6.460	8.78	18.00	50.2	57.1	20.5	35.8	17.0	1294.0	4.87
	Mean	**10.047**	**0.666**	**6.902**	**7.913**	**78.233**	**0.666**	**6.998**	**0.067**	**0.675**	**0.719**	**7.193**	**8.233**	**16.933**	**47.633**	**57.850**	**20.567**	**35.533**	**16.183**	**1143.833**	**5.082**
	S.D.	**3.1930**	**0.2140**	**1.9226**	**2.7893**	**4.5350**	**0.2509**	**3.1483**	**0.0326**	**0.4033**	**0.3175**	**2.2221**	**0.3757**	**0.7840**	**1.6943**	**0.8961**	**0.6282**	**0.7257**	**0.7333**	**508.4028**	**0.2731**
1.5 mg/L	584	11.500	0.434	3.790	9.790	85.500	0.620	5.410	0.065	0.567	0.543	4.740	8.18	16.60	46.4	56.7	20.3	35.9	16.0	1305.0	4.97
	597	14.300	0.375	2.630	12.700	89.300	0.456	3.200	0.069	0.484	0.623	4.370	7.89	16.90	48.0	60.8	21.5	35.3	16.2	850.0	5.32
	606	12.300	0.729	5.940	10.500	85.500	0.384	3.120	0.046	0.378	0.617	5.020	8.18	16.80	47.9	58.5	20.6	35.1	15.6	1310.0	5.05
	609	9.350	0.281	3.000	8.230	88.100	0.356	3.810	0.054	0.577	0.422	4.520	8.27	16.80	48.4	58.5	20.3	34.6	15.7	1016.0	4.38
	614	10.900	0.352	3.230	9.580	87.900	0.371	3.410	0.038	0.351	0.552	5.070	8.84	18.10	52.2	59.1	20.5	34.8	15.4	773.0	5.17
	615	7.860	0.479	6.100	6.240	79.400	0.504	6.410	0.039	0.490	0.600	7.620	8.50	16.90	48.8	57.4	19.9	34.6	17.2	1007.0	4.88
	Mean	**11.035**	**0.442**	**4.115**	**9.507**	**85.950**	**0.449**	**4.227**	**0.052**	**0.475**	**0.560**	**5.223**	**8.310**	**17.017**	**48.617**	**58.500**	**20.517**	**35.050**	**16.017**	**1043.500**	**4.962**
	S.D.	**2.2545**	**0.1564**	**1.5237**	**2.1712**	**3.5484**	**0.1013**	**1.3628**	**0.0131**	**0.0938**	**0.0751**	**1.2054**	**0.3252**	**0.5419**	**1.9354**	**1.4213**	**0.5382**	**0.5010**	**0.6463**	**224.5464**	**0.3239**

Table M-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Hematology
Recovery Male Animals

		WBC	NEU		LYM		MONO		EOS		BASO		RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV
GROUP	ANIMAL ID	(K/uL)	(K/uL)	(%N)	(K/uL)	(%L)	(K/uL)	(%M)	(K/uL)	(%E)	(K/uL)	(%B)	(M/uL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	(%)	(K/uL)	(fL)
Control	548	24.300	1.660	6.850	17.000	70.000	3.240	13.300	0.210	0.865	2.170	8.960	8.17	17.20	45.8	56.1	21.0	37.5	16.3	1226.0	5.79
	558	17.300	1.300	7.530	13.600	78.400	1.200	6.960	0.119	0.685	1.120	6.470	9.09	16.90	50.4	55.5	18.6	33.6	16.1	953.0	4.88
	559	13.600	2.690	19.700	9.520	70.000	0.819	6.020	0.068	0.499	0.513	3.770	7.69	15.90	45.4	59.1	20.7	35.1	16.6	972.0	4.81
	562	13.400	1.200	8.910	10.200	76.200	0.932	6.940	0.133	0.990	0.936	6.970	7.88	15.80	45.1	57.2	20.1	35.1	16.0	1051.0	5.73
	568	24.700	1.890	7.650	20.700	83.700	1.080	4.360	0.171	0.693	0.882	3.570	7.62	16.90	46.1	60.6	22.1	36.5	16.5	1197.0	4.99
	570	12.700	1.140	8.990	10.400	81.500	0.687	5.400	0.092	0.720	0.428	3.360	8.44	16.50	48.3	57.2	19.6	34.2	17.1	1067.0	4.51
	Mean	**17.667**	**1.647**	**9.938**	**13.570**	**76.633**	**1.326**	**7.163**	**0.132**	**0.742**	**1.008**	**5.517**	**8.148**	**16.533**	**46.850**	**57.617**	**20.350**	**35.333**	**16.433**	**1077.667**	**5.118**
	S.D.	**5.5320**	**0.5873**	**4.8543**	**4.4813**	**5.7434**	**0.9550**	**3.1631**	**0.0519**	**0.1684**	**0.6269**	**2.2965**	**0.5538**	**0.5750**	**2.0753**	**1.9094**	**1.2079**	**1.4459**	**0.3983**	**112.9383**	**0.5222**
1.5 mg/L	549	14.600	1.940	13.300	11.300	77.500	0.661	4.520	0.074	0.509	0.622	4.250	7.97	16.10	46.5	58.4	20.2	34.6	17.1	1007.0	4.68
	563	11.800	0.935	7.910	9.210	77.900	0.887	7.510	0.122	1.030	0.665	5.630	7.57	15.40	42.8	56.5	20.3	35.9	16.8	996.0	4.21
	576	16.000	0.862	5.370	12.400	77.300	1.330	8.290	0.123	0.766	1.330	8.300	8.04	16.20	46.2	57.5	20.2	35.1	15.9	1067.0	5.10
	578	15.700	1.500	9.560	12.700	80.800	0.970	6.160	0.135	0.857	0.420	2.670	7.76	16.10	45.7	58.9	20.8	35.3	16.2	1251.0	5.08
	581	11.700	0.778	6.630	9.930	84.600	0.592	5.050	0.121	1.030	0.315	2.680	7.80	15.50	45.6	58.5	19.9	34.1	15.7	987.0	5.37
	583	21.500	1.480	6.910	16.700	77.800	1.570	7.320	0.140	0.652	1.570	7.290	7.71	15.60	44.0	57.0	20.2	35.4	16.9	1106.0	6.12
	Mean	**15.217**	**1.249**	**8.280**	**12.040**	**79.317**	**1.002**	**6.475**	**0.119**	**0.807**	**0.820**	**5.137**	**7.808**	**15.817**	**45.133**	**57.800**	**20.267**	**35.067**	**16.433**	**1069.000**	**5.093**
	S.D.	**3.5986**	**0.4613**	**2.8300**	**2.6567**	**2.8910**	**0.3818**	**1.4854**	**0.0235**	**0.2081**	**0.5101**	**2.3577**	**0.1724**	**0.3545**	**1.4334**	**0.9466**	**0.2944**	**0.6346**	**0.5785**	**100.3932**	**0.6453**

Table M-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Hematology
Recovery Female Animals

		WBC	NEU		LYM		MONO		EOS		BASO		RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV
GROUP	ANIMAL ID	(K/uL)	(K/uL)	(%N)	(K/uL)	(%L)	(K/uL)	(%M)	(K/uL)	(%E)	(K/uL)	(%B)	(M/uL)	(g/dL)	(%)	(fL)	(pg)	(g/dL)	(%)	(K/uL)	(fL)
Control	585	4.790	0.753	15.700	2.620	54.700	0.648	13.500	0.059	1.230	0.710	14.800	9.78	18.50	53.1	54.3	18.9	34.8	16.8	157.0	6.72
	589	12.400	0.711	5.720	9.830	78.900	0.802	6.440	0.085	0.684	1.020	8.220	8.19	16.30	46.4	56.7	19.8	35.0	14.7	1096.0	4.82
	592	9.220	0.915	9.930	6.550	71.100	1.040	11.300	0.083	0.904	0.628	6.820	8.14	15.70	44.4	54.6	19.2	35.2	16.4	857.0	4.85
	599	10.100	1.020	10.100	7.940	78.700	0.602	5.960	0.106	1.050	0.423	4.190	7.41	15.20	42.3	57.0	20.5	35.9	14.9	851.0	4.56
	604	5.380	1.010	18.800	3.050	56.700	0.783	14.600	0.081	1.500	0.455	8.450	7.63	14.80	41.9	54.9	19.4	35.4	15.5	1121.0	5.14
	611	11.100	0.551	4.970	9.300	83.900	0.375	3.380	0.065	0.584	0.796	7.170	6.99	14.70	40.9	58.6	21.1	36.0	14.5	634.0	4.90
	Mean	**8.832**	**0.827**	**10.870**	**6.548**	**70.667**	**0.708**	**9.197**	**0.080**	**0.992**	**0.672**	**8.275**	**8.023**	**15.867**	**44.833**	**56.017**	**19.817**	**35.383**	**15.467**	**786.000**	**5.165**
	S.D.	**3.0947**	**0.1863**	**5.4594**	**3.0967**	**12.3096**	**0.2238**	**4.5617**	**0.0166**	**0.3427**	**0.2231**	**3.5393**	**0.9722**	**1.4208**	**4.5050**	**1.6916**	**0.8377**	**0.4834**	**0.9480**	**356.7453**	**0.7840**
1.5 mg/L	587	6.010	0.849	14.100	3.270	54.400	0.887	14.800	0.128	2.140	0.877	14.600	7.59	14.00	44.1	58.1	18.5	31.8	16.0	1151.0	6.35
	593	8.280	0.603	7.280	6.500	78.500	0.680	8.220	0.091	1.100	0.403	4.860	7.69	15.40	43.5	56.6	20.1	35.5	14.9	1211.0	4.99
	598	18.700	0.643	3.430	15.200	81.000	1.640	8.750	0.119	0.636	1.160	6.200	7.89	15.50	43.7	55.3	19.7	35.5	16.9	1135.0	4.98
	608	20.000	1.560	7.780	16.000	80.000	1.290	6.430	0.201	1.010	0.958	4.790	6.86	14.60	40.7	59.3	21.2	35.8	15.0	1115.0	4.45
	613	2.880	0.251	8.720	2.170	75.200	0.222	7.710	0.022	0.761	0.220	7.650	7.33	15.10	41.5	56.5	20.6	36.4	15.0	1021.0	4.97
	617	19.000	0.408	2.150	16.700	87.700	0.970	5.110	0.117	0.614	0.843	4.440	6.80	14.50	40.8	60.0	21.4	35.6	15.0	477.0	4.87
	Mean	**12.478**	**0.719**	**7.243**	**9.973**	**76.133**	**0.948**	**8.503**	**0.113**	**1.044**	**0.744**	**7.090**	**7.360**	**14.850**	**42.383**	**57.633**	**20.250**	**35.100**	**15.467**	**1018.333**	**5.102**
	S.D.	**7.6080**	**0.4603**	**4.2419**	**6.7346**	**11.4126**	**0.4897**	**3.3536**	**0.0579**	**0.5722**	**0.3570**	**3.8676**	**0.4488**	**0.5822**	**1.5523**	**1.8107**	**1.0710**	**1.6517**	**0.8140**	**272.2959**	**0.6452**

Table M-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Hematology
Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
WBC	Mean	9.232	12.785	12.938	11.685
(K/uL)	S.D.	3.1070	1.8455	3.6406	3.0535
	N	6	6	6	6
NEU	Mean	8.543	8.658	6.683	8.667
(%N)	S.D.	2.6792	2.2504	1.5749	3.4112
	N	6	6	6	6
LYM	Mean	74.533	79.200	80.383*	77.667
(%L)	S.D.	3.1162	2.1891	3.8835	2.0916
	N	6	6	6	6
MONO	Mean	7.223	6.113	5.500	6.910
(%M)	S.D.	1.2001	0.8210	1.5479	1.7149
	N	6	6	6	6
EOS	Mean	0.463	0.453	0.502	0.444
(%E)	S.D.	0.1804	0.2520	0.1207	0.2302
	N	6	6	6	6
BASO	Mean	9.238	5.585*	6.928	6.307
(%B)	S.D.	2.4177	1.5504	2.5090	1.7599
	N	6	6	6	6
RBC	Mean	8.047	8.407	8.343	8.150
(M/uL)	S.D.	0.4834	0.6452	0.4257	0.3304
	N	6	6	6	6
HGB	Mean	16.667	17.333	17.400	17.017
(g/dL)	S.D.	0.4367	1.1237	0.5329	0.9411
	N	6	6	6	6
HCT	Mean	47.833	50.000	50.000	49.150
(%)	S.D.	1.8074	3.8032	1.5837	2.2206
	N	6	6	6	6
MCV	Mean	59.533	59.483	60.017	60.283
(fL)	S.D.	1.7236	1.1321	1.9773	1.7949
	N	6	6	6	6
MCH	Mean	20.750	20.633	20.850	20.900
(pg)	S.D.	0.8408	0.4546	0.7765	0.5657
	N	6	6	6	6
MCHC	Mean	34.883	34.683	34.750	34.633
(g/dL)	S.D.	0.7985	0.5636	0.2168	0.6250
	N	6	6	6	6
RDW	Mean	16.250	16.717	17.233	16.667
(%)	S.D.	0.8019	0.8010	1.0820	0.7581
	N	6	6	6	6
PLT	Mean	1274.000	1093.667	1182.500	1230.667
(K/uL)	S.D.	150.9689	219.4918	192.2402	120.7339
	N	6	6	6	6
MPV	Mean	4.920	4.878	4.802	4.792
(fL)	S.D.	0.5772	0.1714	0.3315	0.2572
	N	6	6	6	6

* $p < 0.05$

Table M-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Hematology
Main Study Female Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
WBC	Mean	10.932	7.942	10.047	11.035
(K/uL)	S.D.	3.6660	1.6374	3.1930	2.2545
	N	6	6	6	6
NEU	Mean	5.308	6.338	6.902	4.115
(%N)	S.D.	2.4424	2.0533	1.9226	1.5237
	N	6	6	6	6
LYM	Mean	80.433	79.350	78.233	85.950
(%L)	S.D.	4.0633	2.6205	4.5350	3.5484
	N	6	6	6	6
MONO	Mean	6.905	7.650	6.998	4.227
(%M)	S.D.	2.6429	1.6175	3.1483	1.3628
	N	6	6	6	6
EOS	Mean	0.817	0.694	0.675	0.475
(%E)	S.D.	0.3770	0.2444	0.4033	0.0938
	N	6	6	6	6
BASO	Mean	6.538	5.950	7.193	5.223
(%B)	S.D.	1.5610	1.4676	2.2221	1.2054
	N	6	6	6	6
RBC	Mean	8.047	8.107	8.233	8.310
(M/uL)	S.D.	0.2978	0.3987	0.3757	0.3252
	N	6	6	6	6
HGB	Mean	16.400	16.400	16.933	17.017
(g/dL)	S.D.	0.7071	0.6573	0.7840	0.5419
	N	6	6	6	6
HCT	Mean	46.200	46.583	47.633	48.617
(%)	S.D.	2.3580	2.0769	1.6943	1.9354
	N	6	6	6	6
MCV	Mean	57.417	57.483	57.850	58.500
(fL)	S.D.	1.2287	0.7139	0.8961	1.4213
	N	6	6	6	6
MCH	Mean	20.400	20.267	20.567	20.517
(pg)	S.D.	0.3578	0.3011	0.6282	0.5382
	N	6	6	6	6
MCHC	Mean	35.500	35.267	35.533	35.050
(g/dL)	S.D.	0.4648	0.6743	0.7257	0.5010
	N	6	6	6	6
RDW	Mean	16.517	15.933	16.183	16.017
(%)	S.D.	0.2041	0.8091	0.7333	0.6463
	N	6	6	6	6
PLT	Mean	1191.000	1205.500	1143.833	1043.500
(K/uL)	S.D.	259.4556	221.7591	508.4028	224.5464
	N	6	6	6	6
MPV	Mean	4.973	4.820	5.082	4.962
(fL)	S.D.	0.1895	0.3292	0.2731	0.3239
	N	6	6	6	6

Table M-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Hematology
Recovery Male Rats

		Control	1.5 mg/L
WBC	Mean	17.667	15.217
(K/uL)	S.D.	5.5320	3.5986
	N	6	6
NEU	Mean	9.938	8.280
(%N)	S.D.	4.8543	2.8300
	N	6	6
LYM	Mean	76.633	79.317
(%L)	S.D.	5.7434	2.8910
	N	6	6
MONO	Mean	7.163	6.475
(%M)	S.D.	3.1631	1.4854
	N	6	6
EOS	Mean	0.742	0.807
(%E)	S.D.	0.1684	0.2081
	N	6	6
BASO	Mean	5.517	5.137
(%B)	S.D.	2.2965	2.3577
	N	6	6
RBC	Mean	8.148	7.808
(M/uL)	S.D.	0.5538	0.1724
	N	6	6
HGB	Mean	16.533	15.817*
(g/dL)	S.D.	0.5750	0.3545
	N	6	6
HCT	Mean	46.850	45.133
(%)	S.D.	2.0753	1.4334
	N	6	6
MCV	Mean	57.617	57.800
(fL)	S.D.	1.9094	0.9466
	N	6	6
MCH	Mean	20.350	20.267
(pg)	S.D.	1.2079	0.2944
	N	6	6
MCHC	Mean	35.333	35.067
(g/dL)	S.D.	1.4459	0.6346
	N	6	6
RDW	Mean	16.433	16.433
(%)	S.D.	0.3983	0.5785
	N	6	6
PLT	Mean	1077.667	1069.000
(K/uL)	S.D.	112.9383	100.3932
	N	6	6
MPV	Mean	5.118	5.093
(fL)	S.D.	0.5222	0.6453
	N	6	6

* $p < 0.05$

Table M-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Hematology
Recovery Female Rats

		Control	1.5 mg/L
WBC	Mean	8.832	12.478
(K/uL)	S.D.	3.0947	7.6080
	N	6	6
NEU	Mean	10.870	7.243
(%N)	S.D.	5.4594	4.2419
	N	6	6
LYM	Mean	70.667	76.133
(%L)	S.D.	12.3096	11.4126
	N	6	6
MONO	Mean	9.197	8.503
(%M)	S.D.	4.5617	3.3536
	N	6	6
EOS	Mean	0.992	1.044
(%E)	S.D.	0.3427	0.5722
	N	6	6
BASO	Mean	8.275	7.090
(%B)	S.D.	3.5393	3.8676
	N	6	6
RBC	Mean	8.023	7.360
(M/uL)	S.D.	0.9722	0.4488
	N	6	6
HGB	Mean	15.867	14.850
(g/dL)	S.D.	1.4208	0.5822
	N	6	6
HCT	Mean	44.833	42.383
(%)	S.D.	4.5050	1.5523
	N	6	6
MCV	Mean	56.017	57.633
(fL)	S.D.	1.6916	1.8107
	N	6	6
MCH	Mean	19.817	20.250
(pg)	S.D.	0.8377	1.0710
	N	6	6
MCHC	Mean	35.383	35.100
(g/dL)	S.D.	0.4834	1.6517
	N	6	6
RDW	Mean	15.467	15.467
(%)	S.D.	0.9480	0.8140
	N	6	6
PLT	Mean	786.000	1018.333
(K/uL)	S.D.	356.7453	272.2959
	N	6	6
MPV	Mean	5.165	5.102
(fL)	S.D.	0.7840	0.6452
	N	6	6

Appendix N

Individual and Summary of Prothrombin Time Data

Table N-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Prothrombin Time
Main Study Male Animals

GROUP	ANIMAL ID	Average Prothrombin Time
Control	550	9.6
	552	9.8
	553	9.4
	560	9.3
	566	9.4
	579	9.4
	Mean	**9.48**
	S.D.	**0.167**
0.1 mg/L	551	10.2
	557	9.5
	571	9.6
	572	9.9
	573	9.3
	582	9.2
	Mean	**9.60**
	S.D.	**0.338**
0.5 mg/L	554	9.1
	555	9.2
	561	9.5
	569	9.7
	575	9.2
	580	9.7
	Mean	**9.37**
	S.D.	**0.232**
1.5 mg/L	556	9.3
	564	8.9
	565	9.3
	567	9.2
	574	9.5
	577	9.1
	Mean	**9.20**
	S.D.	**0.189**

Table N-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Prothrombin Time
Main Study Female Animals

GROUP	ANIMAL ID	Average Prothrombin Time
Control	586	8.8
	591	9.4
	601	9.0
	602	8.5
	605	8.6
	612	8.3
	Mean	**8.75**
	S.D.	**0.400**
0.1 mg/L	595	8.8
	596	9.0
	607	9.3
	616	8.7
	618	8.9
	619	9.0
	Mean	**8.93**
	S.D.	**0.209**
0.5 mg/L	588	9.1
	590	8.5
	594	8.6
	600	8.7
	603	ND
	610	8.6
	Mean	**8.67**
	S.D.	**0.225**
1.5 mg/L	584	9.1
	597	10.0
	606	9.5
	609	8.5
	614	9.1
	615	8.4
	Mean	**9.08**
	S.D.	**0.625**

ND = No data

Table N-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Prothrombin Time
Recovery Male Animals

GROUP	ANIMAL ID	Average Prothrombin Time
Control	548	9.1
	558	9.1
	559	8.8
	562	8.9
	568	8.4
	570	8.9
	Mean	**8.84**
	S.D.	**0.271**
1.5 mg/L	549	8.8
	563	9.1
	576	9.4
	578	8.9
	581	8.9
	583	8.5
	Mean	**8.93**
	S.D.	**0.301**

Table N-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Prothrombin Time
Recovery Female Animals

GROUP	ANIMAL ID	Average Prothrombin Time
Control	585	9.3
	589	9.1
	592	8.7
	599	9.1
	604	8.7
	611	8.7
	Mean	**8.92**
	S.D.	**0.284**
1.5 mg/L	587	8.6
	593	9.2
	598	9.2
	608	9.4
	613	9.0
	617	ND
	Mean	**9.06**
	S.D.	**0.295**

ND = No data

Table N-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Prothrombin Times

Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Average PT	Mean	9.48	9.60	9.37	9.20
	S.D.	0.167	0.338	0.232	0.189
	N	6	6	6	6

Main Study Female Rats

		Corn Oil	Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Average PT	Mean	8.75	8.93	8.67	9.08
	S.D.	0.400	0.209	0.225	0.625
	N	6	6	5	6

Recovery Male Rats

		Control	1.5 mg/L
Average PT	Mean	8.84	8.93
	S.D.	0.271	0.301
	N	6	6

Recovery Female Rats

		Control	1.5 mg/L
Average PT	Mean	8.92	9.06
	S.D.	0.284	0.295
	N	6	5

Appendix O

Gross Pathology Observations

Table O-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Gross Observations
Main Study and Recovery Male Animals

Control	550	NGLR
	552	White focal areas in right caudal lobe of lung
	553	NGLR
	560	Right lung has dark spots
	566	NGLR
	579	Right pulmonary lobe has dark focal area
	548	NGLR
	558	NGLR
	559	NGLR
	562	NGLR
	568	NGLR
	570	Liver has reticular pattern
0.1 mg/L	551	Liver dark in color; Dark focal area of right caudal lobe of lung; Right lobe of liver has 1 cm mass
	557	NGLR
	571	Right-middle pulmonary lobe has dark focal area
	572	NGLR
	573	Yellow mass (1 cm) on caudal lobe of liver; Right-middle pulmonary lobe of lung has focal dark area
	582	NGLR
0.5 mg/L	554	Lungs appear dark in color
	555	Dark white material in bladder
	561	Lungs appear dark in color; Liver slightly pale
	569	Liver is mildly dark; Left pulmonary lobe cranial aspect appears darker
	575	Lungs show diffuse dark areas
	580	Liver is moderately pale
1.5 mg/L	556	Liver dark in color; Spleen is mildly dark; Right pulmonary lobe has dark focal area
	564	Right pulmonary lobe has dark focal area; Left lobe of lung is dark in color
	565	Liver slightly dark; Entire right lung has dark spots
	567	Liver is mildly dark; Multifocal to coalescing darkened areas of lungs
	574	Dark white material in bladder
	577	Liver appears moderately dark; Left lobe of liver has small hard mass (1 cm)
	549	NGLR
	563	Right lung is blotchy
	576	Dark spots on right side of lung
	578	Both testes about half normal size
	581	NGLR
	583	NGLR

NGLR = No gross lesions recognized

Table O-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Gross Observations
Main Study and Recovery Female Animals

Control	586	NGLR
	591	Right pulmonary lobe has dark focal area
	601	NGLR
	602	Liver mildly pale
	605	NGLR
	612	Dry red material around right eye; Liver is moderately pale; Lungs show multifocal to coalescing dark and light areas
	585	NGLR
	589	NGLR
	592	NGLR
	599	NGLR
	604	NGLR
	611	Liver slightly pale
0.1 mg/L	595	NGLR
	596	Red blanching areas throughout lungs
	607	NGLR
	616	Liver is mildly pale; Orange/red material in ileum portion of G.I. tract; Right cranial lobe has white focal areas
	618	Multifocal to coalescing moderately darkened areas of lungs
	619	Orange/red material in ileum; Right caudal lobe has dark focal area
0.5 mg/L	588	Lungs appear dark in color; Pale liver
	590	NGLR
	594	NGLR
	600	NGLR
	603	Liver mildly dark; Right middle pulmonary lobe has dark focal areas
	610	Liver is moderately pale; Right caudal lobe has small dark focal areas
1.5 mg/L	584	Liver moderately dark; Right lung has dark focal areas
	597	Lungs appear dark in color
	606	Spotting on right lung
	609	NGLR
	614	Spleen moderately dark; Urogenital system stained light pink; White regions on cranial aspects of both lobes; Multifocal to coalescing areas covering lungs
	615	NGLR
	587	NGLR
	593	NGLR
	598	NGLR
	608	NGLR
	613	Uterus appears to be in proestrus
	617	NGLR

NGLR = No gross lesions recognized

Appendix P

Individual and Summary of Organ Mass and Mass Ratio Data

Table P-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ Mass (grams)
Main Study Male Animals

GROUP	ANIMAL ID	BODY MASS[1]	BODY MASS[2]	ADRENALS	BRAIN	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	550	338.2	306.8	0.052	1.888	1.012	2.336	0.683	11.397	4.080	0.458	3.253	0.412
	552	329.4	303.9	0.060	1.916	1.333	2.302	0.593	12.384	3.749	0.518	2.292	0.368
	553	339.5	315.7	0.044	2.026	1.315	2.425	0.644	12.175	4.548	0.595	3.046	0.639
	560	329.1	310.0	0.069	2.027	1.164	2.224	0.684	11.404	4.475	0.493	3.113	0.483
	566	320.7	300.3	0.057	1.929	1.156	2.288	0.712	10.877	3.573	0.697	3.050	0.468
	579	338.1	316.6	0.075	2.095	1.429	2.628	0.665	11.173	4.695	0.970	3.462	0.668
	Mean	**332.500**	**308.883**	**0.060**	**1.980**	**1.235**	**2.367**	**0.664**	**11.568**	**4.187**	**0.622**	**3.036**	**0.506**
	S.D.	**7.3927**	**6.4824**	**0.0113**	**0.0809**	**0.1514**	**0.1438**	**0.0412**	**0.5872**	**0.4586**	**0.1907**	**0.3971**	**0.1215**
0.1 mg/L	551	361.2	335.9	0.077	1.868	1.295	2.662	0.697	12.900	4.640	0.779	2.949	0.534
	557	330.3	302.9	0.059	1.981	1.206	2.448	0.704	11.064	4.058	0.748	3.219	0.443
	571	328.2	297.0	0.047	2.107	1.205	2.235	0.685	10.901	3.863	0.591	2.951	0.367
	572	356.7	328.9	0.071	1.959	1.499	2.611	0.595	12.306	4.207	0.669	3.075	0.797
	573	324.0	305.0	0.066	1.899	1.088	2.414	0.645	10.412	4.445	0.597	3.373	0.549
	582	331.6	299.5	0.076	1.998	1.312	2.284	0.713	9.668	5.501	0.639	3.379	0.550
	Mean	**338.667**	**311.533**	**0.066**	**1.969**	**1.268**	**2.442**	**0.673**	**11.209**	**4.452**	**0.671**	**3.158**	**0.540**
	S.D.	**15.9847**	**16.5443**	**0.0115**	**0.0839**	**0.1387**	**0.1706**	**0.0451**	**1.1991**	**0.5827**	**0.0781**	**0.1961**	**0.1453**
0.5 mg/L	554	296.0	265.2	0.067	1.841	1.216	1.845	0.733	9.096	3.355	0.527	3.248	0.428
	555	307.8	282.3	0.045	1.917	1.125	2.069	0.637	10.836	3.970	0.671	3.037	0.396
	561	326.0	297.6	0.055	1.975	1.072	2.104	0.567	11.066	4.152	0.489	2.981	0.354
	569	313.2	286.4	0.074	1.966	1.335	2.535	0.659	11.577	3.614	0.540	3.207	0.458
	575	357.6	336.4	0.089	2.065	1.196	2.716	0.669	12.112	4.371	0.585	3.441	0.474
	580	331.8	308.6	0.069	2.009	1.355	2.403	0.478	10.907	3.806	0.493	2.881	0.333
	Mean	**322.067**	**296.083**	**0.067**	**1.962**	**1.217**	**2.279**	**0.624**	**10.932**	**3.878**	**0.551**	**3.133**	**0.407**
	S.D.	**21.6077**	**24.5843**	**0.0153**	**0.0770**	**0.1122**	**0.3271**	**0.0893**	**1.0205**	**0.3674**	**0.0685**	**0.2046**	**0.0565**
1.5 mg/L	556	327.3	296.7	0.069	1.939	1.350	2.328	0.600	12.370	3.616	0.967	3.020	0.409
	564	330.4	295.4	0.065	2.012	1.250	2.419	0.675	9.686	4.081	0.607	3.350	0.489
	565	359.6	327.9	0.066	2.047	1.206	2.805	0.794	13.277	5.482	0.813	3.196	0.409
	567	349.0	328.9	0.064	2.090	1.172	2.757	0.581	11.690	5.497	0.818	2.962	0.695
	574	318.4	297.8	0.059	2.043	1.249	2.404	0.635	11.337	3.423	0.526	2.959	0.459
	577	311.5	286.9	0.071	1.960	1.240	2.171	0.620	10.205	3.952	0.508	3.122	0.565
	Mean	**332.700**	**305.600**	**0.066**	**2.015**	**1.245**	**2.481**	**0.651**	**11.428**	**4.342**	**0.707**	**3.102**	**0.504**
	S.D.	**18.3176**	**18.0774**	**0.0042**	**0.0570**	**0.0599**	**0.2492**	**0.0771**	**1.3352**	**0.9193**	**0.1863**	**0.1533**	**0.1100**

[1] Non-fasted Body Mass
[2] Fasted Body Mass
* Outlier

Table P-2
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ Mass (grams)
Main Study Female Animals

GROUP	ANIMAL ID	BODY MASS[1]	BODY MASS[2]	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	586	200.6	184.8	0.052	1.936	0.729	1.366	6.115	3.326	0.122	0.434	0.237	0.384
	591	224.4	212.0	0.062	1.894	0.865	1.658	6.414	3.310	0.102	0.403	0.435	0.439
	601	236.3	218.6	0.064	1.943	0.832	1.716	7.896	3.364	0.133	0.472	0.401	0.441
	602	249.5	236.4	0.067	1.893	0.984	1.894	9.114	3.499	0.152	0.532	0.566	0.422
	605	214.0	205.6	0.067	1.819	0.804	1.689	7.326	3.022	0.120	0.452	0.458	0.325
	612	224.5	212.4	0.041	1.812	0.933	1.514	7.991	3.588	0.109	0.466	0.477	0.526
	Mean	**224.883**	**211.633**	**0.059**	**1.883**	**0.858**	**1.640**	**7.476**	**3.352**	**0.123**	**0.460**	**0.429**	**0.423**
	S.D.	**16.9990**	**16.8468**	**0.0103**	**0.0562**	**0.0914**	**0.1811**	**1.1070**	**0.1943**	**0.0178**	**0.0433**	**0.1092**	**0.0668**
0.1 mg/L	595	229.9	211.6	0.068	1.865	0.887	1.694	7.973	3.452	0.108	0.494	0.401	0.527
	596	250.0	227.1	0.063	1.918	0.909	1.810	7.767	3.218	0.131	0.462	0.513	0.527
	607	191.7	171.0	0.051	1.781	0.792	1.444	5.768	2.642	0.078	0.424	0.476	0.802
	616	219.9	207.0	0.077	1.857	0.945	1.747	6.883	3.585	0.108	0.416	0.540	0.364
	618	213.4	206.1	0.072	1.887	0.778	1.683	7.972	3.276	0.107	0.431	0.470	0.459
	619	225.4	212.4	0.057	1.933	0.954	1.973	6.832	3.098	0.116	0.395	0.605	0.397
	Mean	**221.717**	**205.867**	**0.065**	**1.874**	**0.878**	**1.725**	**7.199**	**3.212**	**0.108**	**0.437**	**0.501**	**0.513**
	S.D.	**19.2559**	**18.6732**	**0.0096**	**0.0540**	**0.0758**	**0.1737**	**0.8720**	**0.3283**	**0.0173**	**0.0355**	**0.0694**	**0.1565**
0.5 mg/L	588	216.8	197.3	0.071	2.000	0.798	1.562	7.053	3.019	0.118	0.367	0.367	0.453
	590	230.3	208.5	0.059	2.007	0.912	1.635	8.323	3.034	0.120	0.449	0.391	0.557
	594	199.5	182.6	0.048	1.833	0.839	1.513	6.840	2.989	0.125	0.379	0.327	0.468
	600	201.8	186.1	0.054	1.742	0.825	1.369	6.725	3.231	0.083	0.362	0.494	0.498
	603	253.1	239.2	0.077	1.904	0.975	1.618	7.249	3.329	0.103	0.479	0.592	0.366
	610	225.7	212.8	0.061	1.979	0.938	1.564	7.525	3.723	0.118	0.379	0.414	0.442
	Mean	**221.200**	**204.417**	**0.062**	**1.911**	**0.881**	**1.544**	**7.286**	**3.221**	**0.111**	**0.403**	**0.431**	**0.464**
	S.D.	**19.9363**	**20.7795**	**0.0107**	**0.1063**	**0.0705**	**0.0960**	**0.5834**	**0.2805**	**0.0156**	**0.0490**	**0.0966**	**0.0633**
1.5 mg/L	584	229.3	213.7	0.069	1.946	0.925	1.579	7.165	3.426	0.111	0.380	0.593	0.364
	597	229.3	213.8	0.072	1.904	0.913	1.676	8.002	3.394	0.166	0.414	0.471	0.511
	606	201.2	189.3	0.056	1.912	0.752	1.523	6.872	3.216	0.138	0.514	0.291	0.353
	609	225.3	211.8	0.065	1.940	0.887	1.672	7.183	4.176	0.092	0.479	0.422	0.367
	614	249.3	233.1	ND	2.223	0.981	1.872	8.176	4.305	0.137	0.556	0.559	0.321
	615	216.0	203.2	0.079	1.910	0.877	1.552	7.182	3.453	0.115	0.462	0.325	0.401
	Mean	**225.067**	**210.817**	**0.068**	**1.973**	**0.889**	**1.646**	**7.430**	**3.662**	**0.127**	**0.468**	**0.444**	**0.386**
	S.D.	**15.9686**	**14.3924**	**0.0085**	**0.1239**	**0.0765**	**0.1274**	**0.5268**	**0.4578**	**0.0259**	**0.0643**	**0.1218**	**0.0663**

[1] Non-fasted Body Mass
[2] Fasted Body Mass
* Outlier
ND = No data

Table P-3
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ Mass (grams)
Recovery Male Animals

GROUP	ANIMAL ID	BODY MASS[1]	BODY MASS[2]	ADRENALS	BRAIN	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	548	507.4	476.2	0.054	2.173	1.789	2.979	1.283	16.214	5.121	1.045	3.445	0.488
	558	491.1	453.7	0.065	2.272	1.399	3.028	1.154	15.632	5.816	0.681	3.336	0.432
	559	507.9	470.1	0.074	2.283	2.085	3.057	1.196	16.697	5.748	0.979	3.439	0.449
	562	447.0	424.4	0.066	2.247	1.453	2.491	1.112	15.058	6.275	0.718	3.000	0.234
	568	527.9	502.5	0.094	2.191	1.838	3.067	1.164	18.021	7.897	0.803	3.836	0.539
	570	498.9	462.9	0.075	2.204	1.601	3.028	1.094	14.547	5.973	0.703	3.341	0.626
	Mean	**496.700**	**464.967**	**0.071**	**2.228**	**1.694**	**2.942**	**1.167**	**16.028**	**6.138**	**0.822**	**3.400**	**0.461**
	S.D.	**27.2751**	**25.8386**	**0.0134**	**0.0454**	**0.2594**	**0.2229**	**0.0676**	**1.2446**	**0.9413**	**0.1547**	**0.2688**	**0.1316**
1.5 mg/L	549	512.6	487.0	0.066	2.177	1.591	3.422	1.118	18.044	5.896	0.758	3.287	0.635
	563	488.6	466.3	0.071	2.075	1.676	2.848	1.178	15.446	6.606	0.781	3.230	0.613
	576	542.3	521.3	0.071	2.310	1.996	3.820	1.173	20.228	7.530	0.958	3.346	0.455
	578	470.4	456.3	0.079	2.143	1.557	2.973	0.607	16.000	8.830	0.650	0.991	0.778
	581	471.6	447.3	0.071	2.141	1.816	2.886	1.326	15.530	5.937	0.777	3.394	0.458
	583	443.3	417.7	0.055	2.186	1.871	2.684	1.123	13.932	6.506	1.070	3.282	0.669
	Mean	**488.133**	**465.983**	**0.069**	**2.172**	**1.751**	**3.106**	**1.088**	**16.530**	**6.884**	**0.832**	**2.922**	**0.601**
	S.D.	**35.0163**	**35.4284**	**0.0080**	**0.0781**	**0.1718**	**0.4290**	**0.2472**	**2.2438**	**1.1223**	**0.1528**	**0.9475**	**0.1257**

[1] Non-fasted Body Mass
[2] Fasted Body Mass
* Outlier

Table P-4
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ Mass (grams)
Recovery Female Animals

GROUP	ANIMAL ID	BODY MASS[1]	BODY MASS[2]	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	585	239.4	225.0	0.065	1.914	0.915	1.632	7.457	3.658	0.123	0.445	0.479	0.663
	589	272.4	258.6	0.070	2.036	0.909	1.946	8.183	4.438	0.119	0.570	0.374	0.536
	592	251.8	237.4	0.062	2.014	0.914	1.736	8.112	ND	0.163	0.451	0.228	0.513
	599	275.6	256.2	0.070	2.012	1.127	2.061	7.847	3.994	0.123	0.625	0.381	0.547
	604	291.2	273.8	0.081	2.151	1.141	2.224	9.270	4.430	0.196	0.555	0.430	1.241
	611	277.1	258.3	0.061	2.016	0.958	1.651	7.303	3.628	0.082	0.546	0.367	0.421
	Mean	**267.917**	**251.550**	**0.068**	**2.024**	**0.994**	**1.875**	**8.029**	**4.030**	**0.134**	**0.532**	**0.377**	**0.654**
	S.D.	**18.8602**	**17.4188**	**0.0074**	**0.0757**	**0.1100**	**0.2408**	**0.7012**	**0.3962**	**0.0396**	**0.0706**	**0.0843**	**0.2981**
1.5 mg/L	587	285.1	278.3	0.070	2.134	1.144	1.928	9.040	4.443	0.181	0.525	0.319	0.541
	593	242.7	227.3	0.070	2.015	0.833	1.606	6.810	4.188	0.114	0.435	0.268	0.607
	598	269.9	259.3	0.064	2.072	0.989	1.823	7.931	3.679	0.122	0.555	0.370	0.534
	608	241.8	218.9	0.059	2.130	0.983	1.814	7.348	3.578	0.133	0.490	0.380	0.775
	613	249.2	234.6	0.071	2.147	0.848	1.556	7.582	3.856	0.123	0.484	0.246	1.192
	617	291.0	269.3	0.078	1.942	1.069	1.817	8.516	3.750	0.137	0.636	0.430	ND
	Mean	**263.283**	**247.950**	**0.069**	**2.073**	**0.978**	**1.757**	**7.871**	**3.916**	**0.135**	**0.521**	**0.336**	**0.730**
	S.D.	**21.7785**	**24.3077**	**0.0065**	**0.0812**	**0.1216**	**0.1440**	**0.8086**	**0.3327**	**0.0240**	**0.0695**	**0.0706**	**0.2760**

[1] Non-fasted Body Mass
[2] Fasted Body Mass
* Outlier
ND = No data

Table P-5
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Body Mass
Main Study Male Animals

GROUP	ANIMAL ID	ADRENALS	BRAIN	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	550	0.0002	0.0062	0.0033	0.0076	0.0022	0.0371	0.0133	0.0015	0.0106	0.0013
	552	0.0002	0.0063	0.0044	0.0076	0.0020	0.0408	0.0123	0.0017	0.0075	0.0012
	553	0.0001	0.0064	0.0042	0.0077	0.0020	0.0386	0.0144	0.0019	0.0096	0.0020
	560	0.0002	0.0065	0.0038	0.0072	0.0022	0.0368	0.0144	0.0016	0.0100	0.0016
	566	0.0002	0.0064	0.0038	0.0076	0.0024	0.0362	0.0119	0.0023	0.0102	0.0016
	579	0.0002	0.0066	0.0045	0.0083	0.0021	0.0353	0.0148	0.0031	0.0109	0.0021
	Mean	**0.0002**	**0.0064**	**0.0040**	**0.0077**	**0.0022**	**0.0375**	**0.0135**	**0.0020**	**0.0098**	**0.0016**
	S.D.	**0.00004**	**0.00014**	**0.00045**	**0.00036**	**0.00015**	**0.00196**	**0.00121**	**0.00060**	**0.00121**	**0.00036**
0.1 mg/L	551	0.0002	0.0056	0.0039	0.0079	0.0021	0.0384	0.0138	0.0023	0.0088	0.0016
	557	0.0002	0.0065	0.0040	0.0081	0.0023	0.0365	0.0134	0.0025	0.0106	0.0015
	571	0.0002	0.0071	0.0041	0.0075	0.0023	0.0367	0.0130	0.0020	0.0099	0.0012
	572	0.0002	0.006	0.0046	0.0079	0.0018	0.0374	0.0128	0.0020	0.0093	0.0024
	573	0.0002	0.0062	0.0036	0.0079	0.0021	0.0341	0.0146	0.0020	0.0111	0.0018
	582	0.0003	0.0067	0.0044	0.0076	0.0024	0.0323	0.0184	0.0021	0.0113	0.0018
	Mean	**0.0002**	**0.0064**	**0.0041**	**0.0078**	**0.0022**	**0.0359**	**0.0143**	**0.0022**	**0.0102**	**0.0017**
	S.D.	**0.00004**	**0.00053**	**0.00036**	**0.00022**	**0.00022**	**0.00227**	**0.00209**	**0.00021**	**0.00100**	**0.00040**
0.5 mg/L	554	0.0003	0.0069	0.0046	0.0070	0.0028	0.0343	0.0127	0.0020	0.0122	0.0016
	555	0.0002	0.0068	0.0040	0.0073	0.0023	0.0384	0.0141	0.0024	0.0108	0.0014
	561	0.0002	0.0066	0.0036	0.0071	0.0019	0.0372	0.0140	0.0016	0.0100	0.0012
	569	0.0003	0.0069	0.0047	0.0089	0.0023	0.0404	0.0126	0.0019	0.0112	0.0016
	575	0.0003	0.0061	0.0036	0.0081	0.0020	0.0360	0.0130	0.0017	0.0102	0.0014
	580	0.0002	0.0065	0.0044	0.0078	0.0015	0.0353	0.0123	0.0016	0.0093	0.0011
	Mean	**0.0003**	**0.0066**	**0.0042**	**0.0077**	**0.0021**	**0.0369**	**0.0131**	**0.0019**	**0.0106**	**0.0014**
	S.D.	**0.00005**	**0.00031**	**0.00049**	**0.00072**	**0.00044**	**0.00222**	**0.00076**	**0.00031**	**0.00102**	**0.00020**
1.5 mg/L	556	0.0002	0.0065	0.0046	0.0078	0.0020	0.0417	0.0122	0.0033	0.0102	0.0014
	564	0.0002	0.0068	0.0042	0.0082	0.0023	0.0328	0.0138	0.0021	0.0113	0.0017
	565	0.0002	0.0062	0.0037	0.0086	0.0024	0.0405	0.0167	0.0025	0.0097	0.0012
	567	0.0002	0.0064	0.0036	0.0084	0.0018	0.0355	0.0167	0.0025	0.0090	0.0021
	574	0.0002	0.0069	0.0042	0.0081	0.0021	0.0381	0.0115	0.0018	0.0099	0.0015
	577	0.0002	0.0068	0.0043	0.0076	0.0022	0.0356	0.0138	0.0018	0.0109	0.0020
	Mean	**0.0002**	**0.0066**	**0.0041**	**0.0081**	**0.0021**	**0.0374**	**0.0141**	**0.0023**	**0.0102**	**0.0017**
	S.D.	**0.00000**	**0.00028**	**0.00038**	**0.00037**	**0.00022**	**0.00336**	**0.00219**	**0.00057**	**0.00083**	**0.00035**

* Outlier
ND = No data

Table P-6
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Body Mass
Main Study Female Animals

GROUP	ANIMAL ID	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	586	0.0003	0.0105	0.0039	0.0074	0.0331	0.0180	0.0007	0.0023	0.0013	0.0021
	591	0.0003	0.0089	0.0041	0.0078	0.0303	0.0156	0.0005	0.0019	0.0021	0.0021
	601	0.0003	0.0089	0.0038	0.0078	0.0361	0.0154	0.0006	0.0022	0.0018	0.0020
	602	0.0003	0.0080	0.0042	0.0080	0.0386	0.0148	0.0006	0.0023	0.0024	0.0018
	605	0.0003	0.0088	0.0039	0.0082	0.0356	0.0147	0.0006	0.0022	0.0022	0.0016
	612	0.0002	0.0085	0.0044	0.0071	0.0376	0.0169	0.0005	0.0022	0.0022	0.0025
	Mean	**0.0003**	**0.0089**	**0.0041**	**0.0077**	**0.0352**	**0.0159**	**0.0006**	**0.0022**	**0.0020**	**0.0020**
	S.D.	**0.00004**	**0.00084**	**0.00023**	**0.00040**	**0.00306**	**0.00130**	**0.00008**	**0.00015**	**0.00039**	**0.00031**
0.1 mg/L	595	0.0003	0.0088	0.0042	0.0080	0.0377	0.0163	0.0005	0.0023	0.0019	0.0025
	596	0.0003	0.0084	0.0040	0.0080	0.0342	0.0142	0.0006	0.0020	0.0023	0.0023
	607	0.0003	0.0104	0.0046	0.0084	0.0337	0.0155	0.0005	0.0025	0.0028	0.0047
	616	0.0004	0.0090	0.0046	0.0084	0.0333	0.0173	0.0005	0.0020	0.0026	0.0018
	618	0.0003	0.0092	0.0038	0.0082	0.0387	0.0159	0.0005	0.0021	0.0023	0.0022
	619	0.0003	0.0091	0.0045	0.0093	0.0322	0.0146	0.0005	0.0019	0.0028	0.0019
	Mean	**0.0003**	**0.0092**	**0.0043**	**0.0084**	**0.0350**	**0.0156**	**0.0005**	**0.0021**	**0.0025**	**0.0026**
	S.D.	**0.00004**	**0.00067**	**0.00034**	**0.00048**	**0.00261**	**0.00113**	**0.00004**	**0.00023**	**0.00035**	**0.00108**
0.5 mg/L	588	0.0004	0.0101	0.0040	0.0079	0.0357	0.0153	0.0006	0.0019	0.0019	0.0023
	590	0.0003	0.0096	0.0044	0.0078	0.0399	0.0146	0.0006	0.0022	0.0019	0.0027
	594	0.0003	0.0100	0.0046	0.0083	0.0375	0.0164	0.0007	0.0021	0.0018	0.0026
	600	0.0003	0.0094	0.0044	0.0074	0.0361	0.0174	0.0004	0.0019	0.0027	0.0027
	603	0.0003	0.0080	0.0041	0.0068	0.0303	0.0139	0.0004	0.0020	0.0025	0.0015
	610	0.0003	0.0093	0.0044	0.0073	0.0354	0.0175	0.0006	0.0018	0.0019	0.0021
	Mean	**0.0003**	**0.0094**	**0.0043**	**0.0076**	**0.0358**	**0.0159**	**0.0006**	**0.0020**	**0.0021**	**0.0023**
	S.D.	**0.00004**	**0.00076**	**0.00022**	**0.00053**	**0.00317**	**0.00149**	**0.00012**	**0.00015**	**0.00038**	**0.00047**
1.5 mg/L	584	0.0003	0.0091	0.0043	0.0074	0.0335	0.0160	0.0005	0.0018	0.0028	0.0017
	597	0.0003	0.0089	0.0043	0.0078	0.0374	0.0159	0.0008	0.0019	0.0022	0.0024
	606	0.0003	0.0101	0.0040	0.0080	0.0363	0.0170	0.0007	0.0027	0.0015	0.0019
	609	0.0003	0.0092	0.0042	0.0079	0.0339	0.0197	0.0004	0.0023	0.0020	0.0017
	614	ND	0.0095	0.0042	0.0080	0.0351	0.0185	0.0006	0.0024	0.0024	0.0014
	615	0.0004	0.0094	0.0043	0.0076	0.0353	0.0170	0.0006	0.0023	0.0016	0.0020
	Mean	**0.0003**	**0.0094**	**0.0042**	**0.0078**	**0.0353**	**0.0174**	**0.0006**	**0.0022**	**0.0021**	**0.0019**
	S.D.	**0.00004**	**0.00042**	**0.00012**	**0.00024**	**0.00146**	**0.00148**	**0.00014**	**0.00033**	**0.00049**	**0.00034**

* Outlier
ND = No data

Table P-7
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Body Mass
Recovery Male Animals

GROUP	ANIMAL ID	ADRENALS	BRAIN	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	548	0.0001	0.0046	0.0038	0.0063	0.0027	0.0340	0.0108	0.0022	0.0072	0.0010
	558	0.0001	0.0050	0.0031	0.0067	0.0025	0.0345	0.0128	0.0015	0.0074	0.0010
	559	0.0002	0.0049	0.0044	0.0065	0.0025	0.0355	0.0122	0.0021	0.0073	0.0010
	562	0.0002	0.0053	0.0034	0.0059	0.0026	0.0355	0.0148	0.0017	0.0071	0.0006
	568	0.0002	0.0044	0.0037	0.0061	0.0023	0.0359	0.0157	0.0016	0.0076	0.0011
	570	0.0002	0.0048	0.0035	0.0065	0.0024	0.0314	0.0129	0.0015	0.0072	0.0014
	Mean	**0.0002**	**0.0048**	**0.0036**	**0.0063**	**0.0025**	**0.0345**	**0.0132**	**0.0018**	**0.0073**	**0.0010**
	S.D.	**0.00002**	**0.00033**	**0.00046**	**0.00030**	**0.00015**	**0.00164**	**0.00179**	**0.00030**	**0.00019**	**0.00026**
1.5 mg/L	549	0.0001	0.0045	0.0033	0.0070	0.0023	0.0371	0.0121	0.0016	0.0067	0.0013
	563	0.0002	0.0044	0.0036	0.0061	0.0025	0.0331	0.0142	0.0017	0.0069	0.0013
	576	0.0001	0.0044	0.0038	0.0073	0.0023	0.0388	0.0144	0.0018	0.0064	0.0009
	578	0.0002	0.0047	0.0034	0.0065	0.0013	0.0351	0.0194	0.0014	0.0022	0.0017
	581	0.0002	0.0048	0.0041	0.0065	0.0030	0.0347	0.0133	0.0017	0.0076	0.0010
	583	0.0001	0.0052	0.0045	0.0064	0.0027	0.0334	0.0156	0.0026	0.0079	0.0016
	Mean	**0.0002**	**0.0047**	**0.0038**	**0.0066**	**0.0024**	**0.0354**	**0.0148**	**0.0018**	**0.0063**	**0.0013**
	S.D.	**0.00005**	**0.00031**	**0.00045**	**0.00044**	**0.00058**	**0.00221**	**0.00252**	**0.00041**	**0.00208**	**0.00032**

* Outlier
ND = No data

Table P-8
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Body Mass
Recovery Female Animals

GROUP	ANIMAL ID	ADRENALS	BRAIN	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	585	0.0003	0.0085	0.0041	0.0073	0.0331	0.0163	0.0005	0.0020	0.0021	0.0029
	589	0.0003	0.0079	0.0035	0.0075	0.0316	0.0172	0.0005	0.0022	0.0014	0.0021
	592	0.0003	0.0085	0.0039	0.0073	0.0342	ND	0.0007	0.0019	0.0010	0.0022
	599	0.0003	0.0079	0.0044	0.0080	0.0306	0.0156	0.0005	0.0024	0.0015	0.0021
	604	0.0003	0.0079	0.0042	0.0081	0.0339	0.0162	0.0007	0.0020	0.0016	0.0045
	611	0.0002	0.0078	0.0037	0.0064	0.0283	0.0140	0.0003	0.0021	0.0014	0.0016
	Mean	**0.0003**	**0.0081**	**0.0040**	**0.0074**	**0.0320**	**0.0159**	**0.0005**	**0.0021**	**0.0015**	**0.0026**
	S.D.	**0.00004**	**0.00033**	**0.00033**	**0.00061**	**0.00226**	**0.00119**	**0.00015**	**0.00018**	**0.00036**	**0.00103**
1.5 mg/L	587	0.0003	0.0077	0.0041	0.0069	0.0325	0.0160	0.0007	0.0019	0.0011	0.0019
	593	0.0003	0.0089	0.0037	0.0071	0.0300	0.0184	0.0005	0.0019	0.0012	0.0027
	598	0.0002	0.0080	0.0038	0.0070	0.0306	0.0142	0.0005	0.0021	0.0014	0.0021
	608	0.0003	0.0097	0.0045	0.0083	0.0336	0.0163	0.0006	0.0022	0.0017	0.0035
	613	0.0003	0.0092	0.0036	0.0066	0.0323	0.0164	0.0005	0.0021	0.0010	0.0051
	617	0.0003	0.0072	0.0040	0.0067	0.0316	0.0139	0.0005	0.0024	0.0016	ND
	Mean	**0.0003**	**0.0085**	**0.0040**	**0.0071**	**0.0318**	**0.0159**	**0.0006**	**0.0021**	**0.0013**	**0.0031**
	S.D.	**0.00004**	**0.00096**	**0.00033**	**0.00062**	**0.00132**	**0.00165**	**0.00008**	**0.00019**	**0.00028**	**0.00130**

* Outlier
ND = No data

Table P-9
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Brain Mass
Main Study Male Animals

GROUP	ANIMAL ID	ADRENALS	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	550	0.0275	0.5360	1.2373	0.3618	6.0365	2.1610	0.2426	1.7230	0.2182
	552	0.0313	0.6957	1.2015	0.3095	6.4635	1.9567	0.2704	1.1962	0.1921
	553	0.0217	0.6491	1.1969	0.3179	6.0094	2.2448	0.2937	1.5035	0.3154
	560	0.034	0.5742	1.0972	0.3374	5.6260	2.2077	0.2432	1.5358	0.2383
	566	0.0295	0.5993	1.1861	0.3691	5.6387	1.8523	0.3613	1.5811	0.2426
	579	0.0358	0.6821	1.2544	0.3174	5.3332	2.2411	0.4630	1.6525	0.3189
	Mean	**0.0300**	**0.6227**	**1.1956**	**0.3355**	**5.8512**	**2.1106**	**0.3124**	**1.5320**	**0.2543**
	S.D.	**0.00503**	**0.06320**	**0.05478**	**0.02505**	**0.39962**	**0.16578**	**0.08584**	**0.18276**	**0.05191**
0.1 mg/L	551	0.0412	0.6933	1.4251	0.3731	6.9058	2.4839	0.4170	1.5787	0.2859
	557	0.0298	0.6088	1.2357	0.3554	5.5851	2.0485	0.3776	1.6249	0.2236
	571	0.0223	0.5719	1.0607	0.3251	5.1737	1.8334	0.2805	1.4006	0.1742
	572	0.0362	0.7652	1.3328	0.3037	6.2818	2.1475	0.3415	1.5697	0.4068
	573	0.0348	0.5729	1.2712	0.3397	5.4829	2.3407	0.3144	1.7762	0.2891
	582	0.038	0.6567	1.1431	0.3569	4.8388	2.7533	0.3198	1.6912	0.2753
	Mean	**0.0337**	**0.6448**	**1.2448**	**0.3423**	**5.7114**	**2.2679**	**0.3418**	**1.6069**	**0.2758**
	S.D.	**0.00674**	**0.07586**	**0.13059**	**0.02500**	**0.75772**	**0.32833**	**0.04885**	**0.12715**	**0.07809**
0.5 mg/L	554	0.0364	0.6605	1.0022	0.3982	4.9408	1.8224	0.2863	1.7643	0.2325
	555	0.0235	0.5869	1.0793	0.3323	5.6526	2.0709	0.3500	1.5842	0.2066
	561	0.0278	0.5428	1.0653	0.2871	5.6030	2.1023	0.2476	1.5094	0.1792
	569	0.0376	0.6790	1.2894	0.3352	5.8886	1.8383	0.2747	1.6312	0.2330
	575	0.0431	0.5792	1.3153	0.3240	5.8654	2.1167	0.2833	1.6663	0.2295
	580	0.0343	0.6745	1.1961	0.2379	5.4291	1.8945	0.2454	1.4340	0.1658
	Mean	**0.0338**	**0.6205**	**1.1579**	**0.3191**	**5.5633**	**1.9742**	**0.2812**	**1.5982**	**0.2078**
	S.D.	**0.00707**	**0.05798**	**0.12847**	**0.05354**	**0.34990**	**0.13706**	**0.03799**	**0.11693**	**0.02932**
1.5 mg/L	556	0.0356	0.6962	1.2006	0.3094	6.3796	1.8649	0.4987	1.5575	0.2109
	564	0.0323	0.6213	1.2023	0.3355	4.8141	2.0283	0.3017	1.6650	0.2430
	565	0.0322	0.5892	1.3703	0.3879	6.4861	2.6781	0.3972	1.5613	0.1998
	567	0.0306	0.5608	1.3191	0.2780	5.5933	2.6301	0.3914	1.4172	0.3325
	574	0.0289	0.6114	1.1767	0.3108	5.5492	1.6755	0.2575	1.4484	0.2247
	577	0.0362	0.6327	1.1077	0.3163	5.2066	2.0163	0.2592	1.5929	0.2883
	Mean	**0.0326**	**0.6186**	**1.2295**	**0.3230**	**5.6715**	**2.1489**	**0.3510**	**1.5404**	**0.2499**
	S.D.	**0.00282**	**0.04579**	**0.09701**	**0.03680**	**0.65381**	**0.41195**	**0.09506**	**0.09236**	**0.05101**

* Outlier
ND = No data

Table P-10
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Brain Mass
Main Study Female Animals

GROUP	ANIMAL ID	ADRENALS	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	586	0.0269	0.3765	0.7056	3.1586	1.7180	0.0630	0.2242	0.1224	0.1983
	591	0.0327	0.4567	0.8754	3.3865	1.7476	0.0539	0.2128	0.2297	0.2318
	601	0.0329	0.4282	0.8832	4.0638	1.7313	0.0685	0.2429	0.2064	0.2270
	602	0.0354	0.5198	1.0005	4.8146	1.8484	0.0803	0.2810	0.2990	0.2229
	605	0.0368	0.4420	0.9285	4.0275	1.6614	0.0660	0.2485	0.2518	0.1787
	612	0.0226	0.5149	0.8355	4.4100	1.9801	0.0602	0.2572	0.2632	0.2903
	Mean	**0.0312**	**0.4564**	**0.8715**	**3.9768**	**1.7811**	**0.0653**	**0.2444**	**0.2288**	**0.2248**
	S.D.	**0.00541**	**0.05446**	**0.09885**	**0.61929**	**0.11493**	**0.00891**	**0.02420**	**0.06077**	**0.03788**
0.1 mg/L	595	0.0365	0.4756	0.9083	4.2751	1.8509	0.0579	0.2649	0.2150	0.2826
	596	0.0328	0.4739	0.9437	4.0495	1.6778	0.0683	0.2409	0.2675	0.2748
	607	0.0286	0.4447	0.8108	3.2386	1.4834	0.0438	0.2381	0.2673	0.4503
	616	0.0415	0.5089	0.9408	3.7065	1.9305	0.0582	0.2240	0.2908	0.1960
	618	0.0382	0.4123	0.8919	4.2247	1.7361	0.0567	0.2284	0.2491	0.2432
	619	0.0295	0.4935	1.0207	3.5344	1.6027	0.0600	0.2043	0.3130	0.2054
	Mean	**0.0345**	**0.4682**	**0.9194**	**3.8381**	**1.7136**	**0.0575**	**0.2334**	**0.2671**	**0.2754**
	S.D.	**0.00509**	**0.03482**	**0.06926**	**0.41330**	**0.16308**	**0.00790**	**0.02015**	**0.03378**	**0.09261**
0.5 mg/L	588	0.0355	0.3990	0.7810	3.5265	1.5095	0.0590	0.1835	0.1835	0.2265
	590	0.0294	0.4544	0.8146	4.1470	1.5117	0.0598	0.2237	0.1948	0.2775
	594	0.0262	0.4577	0.8254	3.7316	1.6307	0.0682	0.2068	0.1784	0.2553
	600	0.031	0.4736	0.7859	3.8605	1.8548	0.0476	0.2078	0.2836	0.2859
	603	0.0404	0.5121	0.8498	3.8072	1.7484	0.0541	0.2516	0.3109	0.1922
	610	0.0308	0.4740	0.7903	3.8024	1.8813	0.0596	0.1915	0.2092	0.2233
	Mean	**0.0322**	**0.4618**	**0.8078**	**3.8125**	**1.6894**	**0.0581**	**0.2108**	**0.2267**	**0.2435**
	S.D.	**0.00501**	**0.03697**	**0.02692**	**0.20133**	**0.16435**	**0.00684**	**0.02439**	**0.05630**	**0.03584**
1.5 mg/L	584	0.0355	0.4753	0.8114	3.6819	1.7605	0.0570	0.1953	0.3047	0.1871
	597	0.0378	0.4795	0.8803	4.2027	1.7826	0.0872	0.2174	0.2474	0.2684
	606	0.0293	0.3933	0.7965	3.5941	1.6820	0.0722	0.2688	0.1522	0.1846
	609	0.0335	0.4572	0.8619	3.7026	2.1526	0.0474	0.2469	0.2175	0.1892
	614	ND	0.4413	0.8421	3.6779	1.9366	0.0616	0.2501	0.2515	0.1444
	615	0.0414	0.4592	0.8126	3.7602	1.8079	0.0602	0.2419	0.1702	0.2099
	Mean	**0.0355**	**0.4510**	**0.8341**	**3.7699**	**1.8537**	**0.0643**	**0.2367**	**0.2239**	**0.1973**
	S.D.	**0.00454**	**0.03141**	**0.03275**	**0.21866**	**0.16825**	**0.01378**	**0.02618**	**0.05641**	**0.04085**

* Outlier
ND = No data

Table P-11
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Brain Mass
Recovery Male Animals

GROUP	ANIMAL ID	ADRENALS	HEART	KIDNEYS	EPIDIDYMIDES	LIVER	LUNGS	SPLEEN	TESTES	THYMUS
Control	548	0.0249	0.8233	1.3709	0.5904	7.4616	2.3566	0.4809	1.5854	0.2246
	558	0.0286	0.6158	1.3327	0.5079	6.8803	2.5599	0.2997	1.4683	0.1901
	559	0.0324	0.9133	1.3390	0.5239	7.3136	2.5177	0.4288	1.5064	0.1967
	562	0.0294	0.6466	1.1086	0.4949	6.7014	2.7926	0.3195	1.3351	0.1041
	568	0.0429	0.8389	1.3998	0.5313	8.2250	3.6043	0.3665	1.7508	0.2460
	570	0.0340	0.7264	1.3739	0.4964	6.6003	2.7101	0.3190	1.5159	0.2840
	Mean	**0.0320**	**0.7607**	**1.3208**	**0.5241**	**7.1970**	**2.7569**	**0.3691**	**1.5270**	**0.2076**
	S.D.	**0.00619**	**0.11706**	**0.10684**	**0.03558**	**0.60702**	**0.44223**	**0.07191**	**0.13734**	**0.06122**
1.5 mg/L	549	0.0303	0.7308	1.5719	0.5136	8.2885	2.7083	0.3482	1.5099	0.2917
	563	0.0342	0.8077	1.3725	0.5677	7.4439	3.1836	0.3764	1.5566	0.2954
	576	0.0307	0.8641	1.6537	0.5078	8.7567	3.2597	0.4147	1.4485	0.1970
	578	0.0369	0.7266	1.3873	0.2832	7.4662	4.1204	0.3033	0.4624	0.3630
	581	0.0332	0.8482	1.3480	0.6193	7.2536	2.7730	0.3629	1.5852	0.2139
	583	0.0252	0.8559	1.2278	0.5137	6.3733	2.9762	0.4895	1.5014	0.3060
	Mean	**0.0318**	**0.8056**	**1.4269**	**0.5009**	**7.5970**	**3.1702**	**0.3825**	**1.3440**	**0.2778**
	S.D.	**0.00402**	**0.06262**	**0.15675**	**0.11511**	**0.83415**	**0.51378**	**0.06381**	**0.43447**	**0.06192**

* Outlier
ND = No data

Table P-12
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Individual Organ to Brain Mass
Recovery Female Animals

GROUP	ANIMAL ID	ADRENALS	HEART	KIDNEYS	LIVER	LUNGS	OVARIES	SPLEEN	THYMUS	UTERUS
Control	585	0.034	0.4781	0.8527	3.8960	1.9112	0.0643	0.2325	0.2503	0.3464
	589	0.0344	0.4465	0.9558	4.0192	2.1798	0.0584	0.2800	0.1837	0.2633
	592	0.0308	0.4538	0.8620	4.0278	ND	0.0809	0.2239	0.1132	0.2547
	599	0.0348	0.5601	1.0244	3.9001	1.9851	0.0611	0.3106	0.1894	0.2719
	604	0.0377	0.5305	1.0339	4.3096	2.0595	0.0911	0.2580	0.1999	0.5769
	611	0.0303	0.4752	0.8189	3.6225	1.7996	0.0407	0.2708	0.1820	0.2088
	Mean	**0.0337**	**0.4907**	**0.9246**	**3.9625**	**1.9870**	**0.0661**	**0.2626**	**0.1864**	**0.3203**
	S.D.	**0.00275**	**0.04498**	**0.09289**	**0.22444**	**0.14431**	**0.01776**	**0.03193**	**0.04395**	**0.13331**
1.5 mg/L	587	0.0328	0.5361	0.9035	4.2362	2.0820	0.0848	0.2460	0.1495	0.2535
	593	0.0347	0.4134	0.7970	3.3797	2.0784	0.0566	0.2159	0.1330	0.3012
	598	0.0309	0.4773	0.8798	3.8277	1.7756	0.0589	0.2679	0.1786	0.2577
	608	0.0277	0.4615	0.8516	3.4498	1.6798	0.0624	0.2300	0.1784	0.3638
	613	0.0331	0.3950	0.7247	3.5314	1.7960	0.0573	0.2254	0.1146	0.5552
	617	0.0402	0.5505	0.9356	4.3852	1.9310	0.0705	0.3275	0.2214	ND
	Mean	**0.0332**	**0.4723**	**0.8487**	**3.8017**	**1.8905**	**0.0651**	**0.2521**	**0.1626**	**0.3463**
	S.D.	**0.00417**	**0.06288**	**0.07691**	**0.42542**	**0.16742**	**0.01092**	**0.04119**	**0.03825**	**0.12494**

* Outlier
ND = No data

Table P-13
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Absolute Organ Mass (grams)
Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Body Mass[1]	Mean	332.500	338.667	322.067	332.700
	S.D.	7.3927	15.9847	21.6077	18.3176
	N	6	6	6	6
Body Mass[2]	Mean	308.883	311.533	296.083	305.600
	S.D.	6.4824	16.5443	24.5843	18.0774
	N	6	6	6	6
Adrenals	Mean	0.060	0.066	0.067	0.066
	S.D.	0.0113	0.0115	0.0153	0.0042
	N	6	6	6	6
Brain	Mean	1.980	1.969	1.962	2.015
	S.D.	0.0809	0.0839	0.0770	0.0570
	N	6	6	6	6
Heart	Mean	1.235	1.268	1.217	1.245
	S.D.	0.1514	0.1387	0.1122	0.0599
	N	6	6	6	6
Kidneys	Mean	2.367	2.442	2.279	2.481
	S.D.	0.1438	0.1706	0.3271	0.2492
	N	6	6	6	6
Epididymides	Mean	0.664	0.673	0.624	0.651
	S.D.	0.0412	0.0451	0.0893	0.0771
	N	6	6	6	6
Liver	Mean	11.568	11.209	10.932	11.428
	S.D.	0.5872	1.1991	1.0205	1.3352
	N	6	6	6	6
Lungs	Mean	4.187	4.452	3.878	4.342
	S.D.	0.4586	0.5827	0.3674	0.9193
	N	6	6	6	6
Spleen	Mean	0.622	0.671	0.551	0.707
	S.D.	0.1907	0.0781	0.0685	0.1863
	N	6	6	6	6
Testes	Mean	3.036	3.158	3.133	3.102
	S.D.	0.3971	0.1961	0.2046	0.1533
	N	6	6	6	6
Thymus	Mean	0.506	0.540	0.407	0.504
	S.D.	0.1215	0.1453	0.0565	0.1100
	N	6	6	6	6

Table P-14
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Absolute Organ Mass (grams)
Main Study Female Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Body Mass[1]	Mean	224.883	221.717	221.200	225.067
	S.D.	16.9990	19.2559	19.9363	15.9686
	N	6	6	6	6
Body Mass[2]	Mean	211.633	205.867	204.417	210.817
	S.D.	16.8468	18.6732	20.7795	14.3924
	N	6	6	6	6
Adrenals	Mean	0.059	0.065	0.062	0.068
	S.D.	0.0103	0.0096	0.0107	0.0085
	N	6	6	6	5
Brain	Mean	1.883	1.874	1.911	1.973
	S.D.	0.0562	0.0540	0.1063	0.1239
	N	6	6	6	6
Heart	Mean	0.858	0.878	0.881	0.889
	S.D.	0.0914	0.0758	0.0705	0.0765
	N	6	6	6	6
Kidneys	Mean	1.640	1.725	1.544	1.646
	S.D.	0.1811	0.1737	0.0960	0.1274
	N	6	6	6	6
Liver	Mean	7.476	7.199	7.286	7.430
	S.D.	1.1070	0.8720	0.5834	0.5268
	N	6	6	6	6
Lungs	Mean	3.352	3.212	3.221	3.662
	S.D.	0.1943	0.3283	0.2805	0.4578
	N	6	6	6	6
Ovaries	Mean	0.123	0.108	0.111	0.127
	S.D.	0.0178	0.0173	0.0156	0.0259
	N	6	6	6	6
Spleen	Mean	0.460	0.437	0.403	0.468
	S.D.	0.0433	0.0355	0.0490	0.0643
	N	6	6	6	6
Thymus	Mean	0.429	0.501	0.431	0.444
	S.D.	0.1092	0.0694	0.0966	0.1218
	N	6	6	6	6
Uterus	Mean	0.423	0.513	0.464	0.386
	S.D.	0.0668	0.1565	0.0633	0.0663
	N	6	6	6	6

Table P-15
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Absolute Organ Mass (grams)
Recovery Male Rats

		Control	1.5 mg/L
Body Mass[1]	Mean	496.700	488.133
	S.D.	27.2751	35.0163
	N	6	6
Body Mass[2]	Mean	464.967	465.983
	S.D.	25.8386	35.4284
	N	6	6
Adrenals	Mean	0.071	0.069
	S.D.	0.0134	0.0080
	N	6	6
Brain	Mean	2.228	2.172
	S.D.	0.0454	0.0781
	N	6	6
Heart	Mean	1.694	1.751
	S.D.	0.2594	0.1718
	N	6	6
Kidneys	Mean	2.942	3.106
	S.D.	0.2229	0.4290
	N	6	6
Epididymides	Mean	1.167	1.088
	S.D.	0.0676	0.2472
	N	6	6
Liver	Mean	16.028	16.530
	S.D.	1.2446	2.2438
	N	6	6
Lungs	Mean	6.138	6.884
	S.D.	0.9413	1.1223
	N	6	6
Spleen	Mean	0.822	0.832
	S.D.	0.1547	0.1528
	N	6	6
Testes	Mean	3.400	2.922
	S.D.	0.2688	0.9475
	N	6	6
Thymus	Mean	0.461	0.601
	S.D.	0.1316	0.1257
	N	6	6

Table P-16
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Absolute Organ Mass (grams)
Recovery Female Rats

		Control	1.5 mg/L
Body Mass[1]	Mean	267.917	263.283
	S.D.	18.8602	21.7785
	N	6	6
Body Mass[2]	Mean	251.550	247.950
	S.D.	17.4188	24.3077
	N	6	6
Adrenals	Mean	0.068	0.069
	S.D.	0.0074	0.0065
	N	6	6
Brain	Mean	2.024	2.073
	S.D.	0.0757	0.0812
	N	6	6
Heart	Mean	0.994	0.978
	S.D.	0.1100	0.1216
	N	6	6
Kidneys	Mean	1.875	1.757
	S.D.	0.2408	0.1440
	N	6	6
Liver	Mean	8.029	7.871
	S.D.	0.7012	0.8086
	N	6	6
Lungs	Mean	4.030	3.916
	S.D.	0.3962	0.3327
	N	5	6
Ovaries	Mean	0.134	0.135
	S.D.	0.0396	0.0240
	N	6	6
Spleen	Mean	0.532	0.521
	S.D.	0.0706	0.0695
	N	6	6
Thymus	Mean	0.377	0.336
	S.D.	0.0843	0.0706
	N	6	6
Uterus	Mean	0.654	0.730
	S.D.	0.2981	0.2760
	N	6	5

Table P-17
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Body Mass
Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Adrenals	Mean	0.0002	0.0002	0.0003	0.0002
	S.D.	0.00004	0.00004	0.00005	0.00000
	N	6	6	6	6
Brain	Mean	0.0064	0.0064	0.0066	0.0066
	S.D.	0.00014	0.00053	0.00031	0.00028
	N	6	6	6	6
Heart	Mean	0.0040	0.0041	0.0042	0.0041
	S.D.	0.00045	0.00036	0.00049	0.00038
	N	6	6	6	6
Kidneys	Mean	0.0077	0.0078	0.0077	0.0081
	S.D.	0.00036	0.00022	0.00072	0.00037
	N	6	6	6	6
Epididymides	Mean	0.0022	0.0022	0.0021	0.0021
	S.D.	0.00015	0.00022	0.00044	0.00022
	N	6	6	6	6
Liver	Mean	0.0375	0.0359	0.0369	0.0374
	S.D.	0.00196	0.00227	0.00222	0.00336
	N	6	6	6	6
Lungs	Mean	0.0135	0.0143	0.0131	0.0141
	S.D.	0.00121	0.00209	0.00076	0.00219
	N	6	6	6	6
Spleen	Mean	0.0020	0.0022	0.0019	0.0023
	S.D.	0.00060	0.00021	0.00031	0.00057
	N	6	6	6	6
Testes	Mean	0.0098	0.0102	0.0106	0.0102
	S.D.	0.00121	0.00100	0.00102	0.00083
	N	6	6	6	6
Thymus	Mean	0.0016	0.0017	0.0014	0.0017
	S.D.	0.00036	0.00040	0.00020	0.00035
	N	6	6	6	6

Table P-18
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Body Mass
Main Study Female Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Adrenals	Mean	0.0003	0.0003	0.0003	0.0003
	S.D.	0.00004	0.00004	0.00004	0.00004
	N	6	6	6	5
Brain	Mean	0.0089	0.0092	0.0094	0.0094
	S.D.	0.00084	0.00067	0.00076	0.00042
	N	6	6	6	6
Heart	Mean	0.0041	0.0043	0.0043	0.0042
	S.D.	0.00023	0.00034	0.00022	0.00012
	N	6	6	6	6
Kidneys	Mean	0.0077	0.0084	0.0076	0.0078
	S.D.	0.00040	0.00048	0.00053	0.00024
	N	6	6	6	6
Liver	Mean	0.0352	0.0350	0.0358	0.0353
	S.D.	0.00306	0.00261	0.00317	0.00146
	N	6	6	6	6
Lungs	Mean	0.0159	0.0156	0.0159	0.0174
	S.D.	0.00130	0.00113	0.00149	0.00148
	N	6	6	6	6
Ovaries	Mean	0.0006	0.0005	0.0006	0.0006
	S.D.	0.00008	0.00004	0.00012	0.00014
	N	6	6	6	6
Spleen	Mean	0.0022	0.0021	0.0020	0.0022
	S.D.	0.00015	0.00023	0.00015	0.00033
	N	6	6	6	6
Thymus	Mean	0.0020	0.0025	0.0021	0.0021
	S.D.	0.00039	0.00035	0.00038	0.00049
	N	6	6	6	6
Uterus	Mean	0.0020	0.0026	0.0023	0.0019
	S.D.	0.00031	0.00108	0.00047	0.00034
	N	6	6	6	6

Table P-19
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Body Mass
Recovery Male Rats

		Control	1.5 mg/L
Adrenals	Mean	0.0002	0.0002
	S.D.	0.00002	0.00005
	N	6	6
Brain	Mean	0.0048	0.0047
	S.D.	0.00033	0.00031
	N	6	6
Heart	Mean	0.0036	0.0038
	S.D.	0.00046	0.00045
	N	6	6
Kidneys	Mean	0.0063	0.0066
	S.D.	0.00030	0.00044
	N	6	6
Epididymides	Mean	0.0025	0.0024
	S.D.	0.00015	0.00058
	N	6	6
Liver	Mean	0.0345	0.0354
	S.D.	0.00164	0.00221
	N	6	6
Lungs	Mean	0.0132	0.0148
	S.D.	0.00179	0.00252
	N	6	6
Spleen	Mean	0.0018	0.0018
	S.D.	0.00030	0.00041
	N	6	6
Testes	Mean	0.0073	0.0063
	S.D.	0.00019	0.00208
	N	6	6
Thymus	Mean	0.0010	0.0013
	S.D.	0.00026	0.00032
	N	6	6

Table P-20
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Body Mass
Recovery Female Rats

		Control	1.5 mg/L
Adrenals	Mean	0.0003	0.0003
	S.D.	0.00004	0.00004
	N	6	6
Brain	Mean	0.0081	0.0085
	S.D.	0.00033	0.00096
	N	6	6
Heart	Mean	0.0040	0.0040
	S.D.	0.00033	0.00033
	N	6	6
Kidneys	Mean	0.0074	0.0071
	S.D.	0.00061	0.00062
	N	6	6
Liver	Mean	0.0320	0.0318
	S.D.	0.00226	0.00132
	N	6	6
Lungs	Mean	0.0159	0.0159
	S.D.	0.00119	0.00165
	N	5	6
Ovaries	Mean	0.0005	0.0006
	S.D.	0.00015	0.00008
	N	6	6
Spleen	Mean	0.0021	0.0021
	S.D.	0.00018	0.00019
	N	6	6
Thymus	Mean	0.0015	0.0013
	S.D.	0.00036	0.00028
	N	6	6
Uterus	Mean	0.0026	0.0031
	S.D.	0.00103	0.00130
	N	6	5

Table P-21
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Brain Mass
Main Study Male Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Adrenals	Mean	0.0300	0.0337	0.0338	0.0326
	S.D.	0.00503	0.00674	0.00707	0.00282
	N	6	6	6	6
Heart	Mean	0.6227	0.6448	0.6205	0.6186
	S.D.	0.06320	0.07586	0.05798	0.04579
	N	6	6	6	6
Kidneys	Mean	1.1956	1.2448	1.1579	1.2295
	S.D.	0.05478	0.13059	0.12847	0.09701
	N	6	6	6	6
Epididymides	Mean	0.3355	0.3423	0.3191	0.3230
	S.D.	0.02505	0.02500	0.05354	0.03680
	N	6	6	6	6
Liver	Mean	5.8512	5.7114	5.5633	5.6715
	S.D.	0.39962	0.75772	0.34990	0.65381
	N	6	6	6	6
Lungs	Mean	2.1106	2.2679	1.9742	2.1489
	S.D.	0.16578	0.32833	0.13706	0.41195
	N	6	6	6	6
Spleen	Mean	0.3124	0.3418	0.2812	0.3510
	S.D.	0.08584	0.04885	0.03799	0.09506
	N	6	6	6	6
Testes	Mean	1.5320	1.6069	1.5982	1.5404
	S.D.	0.18276	0.12715	0.11693	0.09236
	N	6	6	6	6
Thymus	Mean	0.2543	0.2758	0.2078	0.2499
	S.D.	0.05191	0.07809	0.02932	0.05101
	N	6	6	6	6

Table P-22
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Brain Mass
Main Study Female Rats

			Red Smoke Exposed		
		Control	0.1 mg/L	0.5 mg/L	1.5 mg/L
Adrenals	Mean	0.0312	0.0345	0.0322	0.0355
	S.D.	0.00541	0.00509	0.00501	0.00454
	N	6	6	6	5
Heart	Mean	0.4564	0.4682	0.4618	0.4510
	S.D.	0.05446	0.03482	0.03697	0.03141
	N	6	6	6	6
Kidneys	Mean	0.8715	0.9194	0.8078	0.8341
	S.D.	0.09885	0.06926	0.02692	0.03275
	N	6	6	6	6
Liver	Mean	3.9768	3.8381	3.8125	3.7699
	S.D.	0.61929	0.41330	0.20133	0.21866
	N	6	6	6	6
Lungs	Mean	1.7811	1.7136	1.6894	1.8537
	S.D.	0.11493	0.16308	0.16435	0.16825
	N	6	6	6	6
Ovaries	Mean	0.0653	0.0575	0.0581	0.0643
	S.D.	0.00891	0.00790	0.00684	0.01378
	N	6	6	6	6
Spleen	Mean	0.2444	0.2334	0.2108	0.2367
	S.D.	0.02420	0.02015	0.02439	0.02618
	N	6	6	6	6
Thymus	Mean	0.2288	0.2671	0.2267	0.2239
	S.D.	0.06077	0.03378	0.05630	0.05641
	N	6	6	6	6
Uterus	Mean	0.2248	0.2754	0.2435	0.1973
	S.D.	0.03788	0.09261	0.03584	0.04085
	N	6	6	6	6

Table P-23
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Brain Mass
Recovery Male Rats

		Control	1.5 mg/L
Adrenals	Mean	0.0320	0.0318
	S.D.	0.00619	0.00402
	N	6	6
Heart	Mean	0.7607	0.8056
	S.D.	0.11706	0.06262
	N	6	6
Kidneys	Mean	1.3208	1.4269
	S.D.	0.10684	0.15675
	N	6	6
Epididymides	Mean	0.5241	0.5009
	S.D.	0.03558	0.11511
	N	6	6
Liver	Mean	7.1970	7.5970
	S.D.	0.60702	0.83415
	N	6	6
Lungs	Mean	2.7569	3.1702
	S.D.	0.44223	0.51378
	N	6	6
Spleen	Mean	0.3691	0.3825
	S.D.	0.07191	0.06381
	N	6	6
Testes	Mean	1.5270	1.3440
	S.D.	0.13734	0.43447
	N	6	6
Thymus	Mean	0.2076	0.2778
	S.D.	0.06122	0.06192
	N	6	6

Table P-24
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Summary of Organ to Body Mass
Recovery Female Rats

		Control	1.5 mg/L
Adrenals	Mean	0.0337	0.0332
	S.D.	0.00275	0.00417
	N	6	6
Heart	Mean	0.4907	0.4723
	S.D.	0.04498	0.06288
	N	6	6
Kidneys	Mean	0.9246	0.8487
	S.D.	0.09289	0.07691
	N	6	6
Liver	Mean	3.9625	3.8017
	S.D.	0.22444	0.42542
	N	6	6
Lungs	Mean	1.9870	1.8905
	S.D.	0.14431	0.16742
	N	5	6
Ovaries	Mean	0.0661	0.0651
	S.D.	0.01776	0.01092
	N	6	6
Spleen	Mean	0.2626	0.2521
	S.D.	0.03193	0.04119
	N	6	6
Thymus	Mean	0.1864	0.1626
	S.D.	0.04395	0.03825
	N	6	6
Uterus	Mean	0.3203	0.3463
	S.D.	0.13331	0.12494
	N	6	5

Appendix Q

Pathology Report

Pathology Report for

35-15-01-01

Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke

26 May, 2016

Prepared by;

Erica E. Carroll, DVM, PhD, Diplomate, ACVP

LTC, VC

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GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This pathology investigation was conducted in a manner consistent with the principles of the United States Environmental Protection Agency (USEPA) Good Laboratory Practice regulations of the Toxic Substances Control Act (TSCA), as detailed in 40 CFR Part 792, plus amendments.

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20 May, 2016

Erica E. Carroll, DVM, PhD, Diplomate ACVP
LTC, VC
Study Pathologist
Toxicology Portfolio
U.S. Army Public Health Center

Date

QUALITY ASSURANCE STATEMENT

For the Pathology Report for Protocol No. 35-15-01-01 entitled "Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke", the following critical phases were audited by the APHC Quality Systems and Regulatory Compliance Office (QSARC), Laboratory and Toxicology Accreditation and Compliance Office (LTACO):

Critical Phase Inspected/Audited	Date Inspected/Audited	Date Reported to Management/SD
Pathology Contributing Scientist Inspection-QA audit of statistician's report and Excel Entered Data	04/25/2016	05/18/2016
Pathology Contributing Scientist Inspection - Summary Data and Summary Table Review	04/28/2016	05/18/2016
Pathology Contributing Scientist Inspection -Interim Pathology Report GLP Standard Regulation Review	05/17/2016	05/18/2016
Pathology Contributing Scientist Inspection- Final Pathology Report GLP Standard Regulation Review	06/14/2016	06/15/2016

Note 1 All findings were made known to the Study Director and the Program Manager at the time of the audit/inspection. If there were no findings during the inspection, the inspection was reported to Management and the Study Director on the date shown in the table.

Note 2 In addition to the study specific critical phase inspections listed here, general facility and process based inspections not specifically related to this study are done monthly or annually in accordance with QSARC, LTACO Standing Operating Procedures.

Note 3 This report has been audited by the Quality Assurance Unit (QSARC, LTACO) and is considered to be an accurate account of the data generated and of the procedures followed

15 - June -2016

_____ _____

Michael P. Kefauver
Quality Assurance Specialist, QSARC

Date

INTRODUCTION

The purpose of this study is to determine the inhalation toxicity of a pyrotechnically disseminated red smoke formulation used by the military. Head only inhalation exposures of the test atmosphere were conducted in rats with a single dose (acute study; one 30-minute exposure), repeat-dose with immediate necropsy (2-week (subacute) study; ten 30-minute exposures) and repeat-dose with four week recovery period prior to euthanasia. The acute study entailed three experiments, each using five male and five female rats with exposure at 2mg/L, 1.7mg/L and a third at 0.6mg/L, respectively. Acute study rats were humanely euthanized, necropsied to observe any gross lesions, and lungs were formalin-fixed for histopathologic examination. The subacute study was then conducted using groups of male and female rats exposed to Red Smoke at 1.5mg/L, 0.5 mg/L or 0.1 mg/L. The remainder of the study was conducted similar to the acute study.At the conclusion of the ten exposures of the subacute study, all rats and sham-exposed control animals were humanely euthanized, necropsied and a complete set of tissue specimens examined, weighed and fixed (in accordance with the protocol) for histologic analysis.

METHODS

Collected tissue specimens were preserved in neutral buffered formalin or modified Davidson's, in accordance with the protocol, trimmed into cassettes, processed through a series of dehydration and rehydration steps in xylene and ethanol using an automated processor, embedded in paraffin, sectioned on a microtome to 4um, stained with hematoxylin and eosin (or periodic acid-Schiff for the testes) and cover-slipped for microscopic examination. Histologic scoring criteria were: ''0' = virtually no lesion (<1% of the tissue affected; '1' = minimal (affecting 1-5% of the tissue); '2' = mild (6-15% of tissue affected); '3' = moderate (16-30% of the tissue affected; '4' = marked (affects > 30% of the sampled tissue).

Statistical analysis was performed on the histologic scores of animals in the Subacute study using Fisher's Exact Test, comparing the number of animals of a given exposure group with a non-zero score (i.e., with a given lesion) to the number of control animals with a non-zero score. Given the small sample size, the initial statistical question asked was simply 'is the lesion present?' with a comparison of exposed versus control groups.

RESULTS

ACUTE STUDY

ACUTE STUDY GROSS OBSERVATIONS

Verbatim comments made by the prosector of this study (not the author) are in Appendix A. All animals in the 2mg/L group were euthanized two weeks after one exposure. Of five male rats exposed to 2mg/L of Red Smoke, numbered 0525-0529, all lungs had dark patches and some appeared atelectatic. One rat (0527) also had dark kidneys and liver. Five females (0530-0534) exposed to 2 mg/L Red Smoke exhibited dark patches on the lungs, occasional areas described as 'white.' Four rats in this group were described as having possible 'dead or dying' pulmonary tissue (0530, 0532, 0533, and 0534). The airways of the lungs of this group were inadvertently perfused with water. All others were formalin-filled at necropsy.

Five males (0732-0736) and five females (0737-0741) were exposed to 1.7 mg/L Red Smoke. 0732, 0733, 0734, 0737, 0738, and 0739 were euthanized one day after exposure. Although four of the five males had 'pale pink' lungs, male 0734 exhibited multifocal to coalescing dark brown to red regions on the ventral surface of both lungs. The caudal left lung was described as having a 'reticular' pattern. Females 737, 738 had pink lung (presumably grossly normal) but 737

had a focal brown area on right side and 0738 had 'outer edge' that was described as 'white.' (Rat 739 has no necropsy sheet.)

Males 0735 and 0736 and females 0740 and 0741 were administered 1.7 mg/L and euthanized fourteen days post-exposure. No gross lesions were reported.

Males (0780-0784) and females (0785-0789) were exposed to 0.6 mg/L Red Smoke. Rat 0780, euthanized one day post-exposure, had multifocal dark brown areas on ventral pulmonary surface. Female rat 0787, euthanized one day post-exposure, was described as having bilateral multifocal brown spots. Female rat 0787, euthanized one day post-exposure had 'mildly dark' liver and a 1 mm white focal lesion on the left kidney. Male rats 0783, 0784 and female rats 0788 and 0789 were euthanized 2 weeks following exposure. Male 0783 exhibited scattered, pale, slightly raised areas, in distal right caudal and left lobes. Male 0784 lung had 'whitish pink' parenchyma peripheral to central 'dark red' discoloration.

ACUTE STUDY HISTOLOGY RESULTS

Lungs from 30 rats exposed to a single dose (2mg/L, 1.7mg/L or 0.6mg/L) of Red Smoke were examined microscopically. Summaries of histologic changes are available in Appendix B. Individual animal scores are in Appendix D. Lungs from air-exposed control rats of the Subacute study were used as age-matched controls for the acute study. It should be noted that control animals were sham-exposed (to air) ten times to match the Red Smoke-exposed Subacute Study animals whereas Acute Study animals were exposed once, then euthanized one day or 14 days later.

The only statistically significant findings in acute study lungs were increased alveolar septal congestion in female rats with all five rats affected compared to zero of six control females at the high exposure ($p= 0.002$) and at 1.7mg/L four of five female rats were affected compared to zero of six controls ($p=0.015$) (Figure 1). Of the males four of five high-exposure males compared to one of six control males ($p=0.08$) and four of five 1.7mg/L males compared to one of six controls ($p=0.08$) exhibited alveolar septal congestion. At 0.6mg/L five of five males compared to one of six controls had alveolar septal congestion ($p=0.15$). This makes a total of 13 of 15 exposed males are affected versus 1/6 unexposed males. Venous congestion was also present in four of five males in 1.7mg/L and 0.6 mg/L group and in four of five females in 1.7mg/L and 0.6mg/L exposure groups (Figure 2). Other lesions were either common background lesions or incidental findings but not linked to exposure to the test article.

SUBACUTE STUDY

SUBACUTE STUDY GROSS OBSERVATIONS

Gross observations were made by a prosector (not the author) are summarized in Table A. They consisted predominantly of discoloration of lungs and liver. All recovery animals had grossly normal lungs. Lungs from four of twelve control animals had a few dark or lighter-colored areas, suggesting that discoloration may have been partly due to perimortem hemorrhage commonly observed in rodents euthanized by carbon dioxide asphyxiation.

Table A. Red Smoke Subacute Inhalation Study Summary of Gross Findings

RED SMOKE SUBACUTE INHALATION STUDY SUMMARY OF GROSS FINDINGS												
Each column represents one treatment group and contains n= 6 rats												
	Controls		1.5		0.5		0.1		1.5-Treated/ Recovered		Recovery Control	
LUNG	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females	Males	Females
Dark patches	2	2	4	4	4	3	3	2	2			
Light Patches	1			1				1				
LIVER												
Dark			4	1		1	1				1R	
Pale		2			2	2		1				1
Mass			1				1					
URINARY BLADDER												
"Dark white" contents			1		1							
ILEUM: Orange Contents								1				
TESTES -Small									1			
UTERUS - Distended										1		
No Gross Lesions Reported	3	3	0	2	0	3	3	2	3	5*	5	5
R - indicates Reticular pattern												
* - Prosector reported one 1.5-Treated/Recovered Female "appeared to be in proestrus."												

SUBACUTE STUDY HISTOLOGY RESULTS

Nasal Turbinates: The only histologic findings that are most likely associated with Red Smoke exposure are lesions in the nasal turbinates. Incidence summaries of histologic lesions observed in the subacute Red Smoke Study are available as Appendix C. Individual rat scores are in Appendix E. Six of six high-exposure male rats exhibited transitional epithelial hyperplasia in level 1 (T1, Figure 3, p=0.02) with varying amounts of neutrophilic or lymphocytic infiltrates and moderate mucosal degeneration (Figure 4) in two of six male rats. Lesions were also present in the 0.5 mg/L exposure males. Five of five 1.5 mg/L-exposed females had minimal to mild transitional epithelial hyperplasia at T1 (p=0.008), occasionally with mucosal degeneration. Transitional epithelial hyperplasia was observed in 0.5mg/L-exposure female rats (p=0.029) and in 0.1mg/L-exposed females (p=0.029).

At Level 2 (T2) goblet cell hyperplasia and respiratory epithelial hyperplasia were common in exposed and control male rats but granulocytic infiltrate (five of six, P=0.015) prevailed in exposed male turbinates. Mucosal degeneration was only present in exposed males (three of six, p=0.182) (Figure 5) and did not occur with every incidence of transitional epithelial hyperplasia (Figure 6). Four of five female rats exposed to 0.1mg/L Red Smoke exhibited granulocytic infiltrates at Level 2 (p=0.048) and lymphocytic infiltrates in four of five rats (p=0.206).

At level 3 male rats exposed to 0.1mg/kg Red Smoke exhibited more respiratory epithelial hyperplasia than controls (p=0.029) but this finding was common in both exposed and the older recovery control female rats (Figure 7).

Lung: Red Smoke-exposed male rats exposed ten times over two weeks exhibited no clearly important lung lesions. Three 1.5mg/L-exposed males had minimal to moderate alveolar septal congestion compared to one of six controls. In 0.5mg/L-exposed rats, five of six were affected (p=0.08). Five high-exposure rats had minimal or mild alveolar atelectasis compared to two of six controls. There were no biologically or statistically important lesions in Red Smoke-

exposed female lungs: Minimal pulmonary venous congestion (four of six 1.5 mg/L females versus one of six controls, p=0.242), more tracheal globular leukocytes (four of six) than controls (one of six, p=0.242).

In the fourteen week-old recovery groups, five of six rats in both treated and untreated recovering females had increased fluid in proximal tubules. This was not apparent in male rats. Three high-exposure females had minimal renal lymphocytic interstitial infiltrates and two had a few cystic tubules compared to zero control females. Three high-exposure males had minimal renal lymphocytic interstitial infiltrates compared to zero control males. Other observed histologic changes were known background lesions (e.g., micro-foci of hepatic histiocytic infiltrates) or processing artifacts (e.g., pulmonary atelectasis).

DISCUSSION

ACUTE STUDY:

Control rat lung tissue from the Subacute study was compared to exposed animals in the Acute study because control tissues from the acute study were not preserved. The age of control and treated rats was comparable but Subacute Control rats were exposed to air (vehicle) ten times and euthanized 24 hours after the last exposure, compared to a single exposure of Acute Study rats followed by euthanasia one or fourteen days later. This is noted in the off-chance that the Subacute control rats endured more stress or other factors than acute rats, which could be reflected in blood values or histology.

For this study 'alveolar hemorrhage' had to be carefully defined. Rats euthanized by numerous means, especially carbon dioxide asphyxiation and cardiac venipuncture are commonly found to have intra-alveolar extravasated erythrocytes. Those euthanized with carbon dioxide often have subpleural edema as well. Due to the perimortem nature of this finding, it is considered an insignificant background lesion. It must be distinguished from antemortem hemorrhage, which usually has corroborative histologic evidence such as increased numbers of macrophages, macrophages with more cytoplasm, 'foamy' cytoplasm (interpreted as reactive), intracytoplasmic erythrocytes (erythrophagocytosis), intra-alveolar fibrin, alveolar septal wall injury, and, if enough time has elapsed, neutrophils or other leukocytes. In the absence of corroborative evidence, a few extravasated erythrocytes are not coded. They are interpreted as necropsy-related and not 'pathology.'

Alveolar septal and venous congestion, with scattered perimortem alveolar hemorrhage, may be test article-related. The finding is not statistically significant at every exposure level due, in part, to small sample size. Lungs of Acute Study high-exposure males and females were inadvertently filled with water instead of formalin. This introduced artifacts which may have obscured findings. The presence of artifact is suggested by the presence of venous congestion in four of five animals in lower-exposure groups but not in controls or high-dose males and females. High-dose rat lungs had alveolar septal congestion but not venous congestion. However, it is difficult to imagine how instilling water in airways could produce this effect. In the acute study, all high-exposure males and females were described grossly as having dark patches on the lungs. Untreated control animals were not necropsied for comparison. This pathologist suspects the absence of control tissues at necropsy affected the descriptions of the Red Smoke-exposed lungs by the non-pathologist prosector who may be unfamiliar with the postmortem collapse and darkening of all rodent lungs within minutes of exposure to air. Histologic examination did not corroborate gross descriptions of the lungs in some aspects. Histologically observed perimortem hemorrhage consisted of a few erythrocytes in many alveoli, as opposed to patches of hemorrhage that would be observed grossly. Necrosis was not observed histologically. Venous and alveolar septal congestion, minimal to moderate in males and females, may explain the gross finding of 'dark patches.' The venous and alveolar septal congestion is probably passive congestion because veins were distended, not the arteries. Left side cardiac insufficiency (i.e., weakened contractions of the left atrium and/or ventricle) is a known cause of passive

pulmonary congestion. Terminal phlebotomy resulting in hypovolemia would most likely lead to quickening, weak cardiac contractions, but not usually passive congestion which usually occurs over time. Leaky vessels, or pulmonary hypertension would more likely produce diffuse, minimal alveolar hemorrhage, as seen in these rats (and in controls) but there was no histologic evidence of antemortem hypertension (e.g., vascular smooth muscle hypertrophy). Evidence of antemortem passive congestion usually includes hemosiderin-laden, or enlarged alveolar macrophages, but none were seen in these rats. The mechanism and cause of alveolar septal and venous congestion in Red Smoke-exposed rats are therefore unclear.

Artifacts are not generally recorded. Highest-exposure acute study rat lungs all had somewhat dilated alveolar septa that most likely is due to the perfusion with water instead of formalin at necropsy. This is mentioned because the artifact may have obscured pathology (Figure 8). Additionally, one does not normally record histologic atelectasis because it is often associated with insufficient post-mortem perfusion of the lung. In this study, however, its increased presence in Red Smoke-exposed lungs compared to control lungs raised the suspicion of a test article effect; therefore the incidence and severity of atelectasis were recorded.

SUBACUTE STUDY:

The primary lesion associated with ten thirty-minute head-only exposures to Red Smoke was nasal turbinate injury in the anterior areas, Levels 1 and 2 of rat nasal passages. Level 1 had transitional epithelial hyperplasia in males and females at all three exposure levels affecting the nasoturbinate, lateral wall of the lateral meatus and the maxilloturbinates (Figure 3). Mucosal degeneration (characterized by cytoplasmic vacuoles with low numbers of necrotic cells) was evident in Level 1 and 2 of males (Figure 4) and in Level 1 of females. At level 2, mucosal degeneration affected transitional or respiratory epithelium in males (Figures 5). Not every incidence of transitional epithelial hyperplasia was accompanied by degeneration, however (Figure 6). Respiratory epithelial hyperplasia was only clearly associated with Red Smoke exposure in low-exposure males at Level 3 although it was seen at other anatomic levels and other exposure levels (Figure 7). Subepithelial granulocytes (generally neutrophils) were present in high-exposure males and females at Levels 1 and 2 (Figure 6). Lymphocytes were not a key feature of the female nasal turbinate lesion at any exposure level but were occasionally present in high-exposure males. Small sample size may have obscured the significance of leukocyte types at a given level. Epithelial metaplasia was not appreciated in this study with the possible exception of a few rats (e.g., male 15-574 and female 15-597) that appeared to have transitional epithelial hyperplasia in an area normally occupied by respiratory epithelium. It is most often reported in studies of longer duration. Figure 9 illustrates in a diagram the location of the predominant nasal lesions.

In this study only transitional and respiratory, not olfactory, squamous or lymphoepithelial tissues exhibited appreciable lesions. Lesions observed in inhalation studies are often site-specific, depending on the regional dose of the inhaled chemical and the sensitivity of that tissue to the toxicant. (Harkema et al, 2006). State-of-the-art toxicological examination requires nasal mapping of lesions, since sensitivity to test articles may depend on airflow-driven deposition of the test article, local dose and regional tissue sensitivity. Mucus flow and blood flow in an area may also play a role in regional and systemic toxicity. Mapping enables more precise understanding of individual cell-type sensitivity which can improve extrapolation to humans, given their slightly different anatomy and tissue distribution. Unlike humans, laboratory rodents have no hairs in the nasal vestibule near the nares, which could block ingress of some particulates. However, laboratory rodents have complex maxilloturbinates (levels 1 (T1)and 2 (T2)) which provide better protection of the lower respiratory system than the simple middle and inferior turbinates found in humans. Level 3 in rodents is complex, presumably to increase surface area lined by olfactory epithelium for the critical survival skill of olfaction (Harkema et al, 2006).

There are five types of nasal epithelium. Transitional epithelium is found between the stratified squamous epithelium lining the nares and vestibule and the ciliated pseudostratified columnar epithelium lining the rest of the conducting portion of the respiratory tract. Transitional epithelium is characterized by one or two layers of non-ciliated cuboidal to columnar cells overlying basal cells, with few goblet (mucous) cells. Transitional epithelial cells have abundant smooth endoplasmic reticulum (SER), known to contain xenobiotic metabolizing-enzymes such as cytochromes P-450 (Harkema et al, 2006). Transitional epithelium covers the ventral tip of nasoturbinates and the dorsal tip of the maxilloturbinates at Level 1 and 2, which appear to be locations where inhaled substances would first make contact with the animal. Transitional epithelial hyperplasia of these areas was present in every exposure level of both genders of rats. Concomitant transitional mucosal degeneration was often but inconsistently observed. Additionally, mucosal degeneration at T1 in females was not observed but transitional epithelium in several rats appeared to extend into an area normally occupied by respiratory epithelium. Thus far, it is unclear whether Red Smoke presents a physical irritant (to which the tissue responds by hyperplasia) or a primary toxicant, or one that is metabolized to an active form by enzymes in the transitional epithelium. Ozone causes transitional epithelial hyperplasia with mucous cell metaplasia, hypothesized to be related to the influx of neutrophils. Mucous cell metaplasia was not present in this study although neutrophils were present in low numbers in exposed rats. This pathologist suspects this 14-day study concluded prior to the development of additional or metaplastic lesions as many of the described lesions occurred after much longer studies (Hardisty et al, 1999; Renne et al, 2007). Mucous (goblet) cells were plentiful and robust in Red Smoke-exposed rats in this study but some control rats also exhibited what appeared to be 'mild' increase in goblet cells over other control rats at T1 and T2 (Figure 10). A longer duration study may clarify a treatment effect on goblet cells and reactive mucus production.

Respiratory epithelium makes up 46% of the nasal cavity in a F344 rat (Harkema et al, 2006). It differs from respiratory epithelium lining the rest of the respiratory system in that it consists of six cell types; mucous, ciliated, nonciliated columnar, cuboidal, brush, and basal. Nasal respiratory epithelium is normally over-lain by a layer of mucus which is removed in tissue processing and therefore visualized with special processing and stains. The cilia propel inhaled particulates distally to the oropharynx where they are swallowed. Mucus, secreted by mucous cells lining the proximal septum and nasopharynx is known to be a strong anti-oxidant agent (Cross et al., 1984). Serous cells are the primary secretory cells in the remainder of the respiratory tract. These have abundant SER and may have metabolic activity for certain xenobiotic agents (Harkema et al, 2006). Locations of respiratory epithelial degeneration observed in this study were identical in Level 2 to those exhibiting transitional epithelial degeneration in Level 1, suggesting a correlation with airflow or points of first contact. Studies have demonstrated the presence of carboxylesterase, aldehyde dehydrogenase, cytochrome P-450, epoxide hydrolase, and glutathione S-transferases in respiratory epithelium. Degenerate respiratory epithelium at level 2 was present in three of six high-dose males (no females) suggesting irritation or biochemical injury similar to that observed at Level 1. Additionally, mucus was either insufficiently protective against Red Smoke injury or the injury did not involve oxidation.

Superficial injury to respiratory epithelium is often reversible (Harkema et al, 2006) Recovered high-exposure male rats continued to exhibit respiratory epithelial hyperplasia at insignificant numbers and no other lesions, suggesting reversibility of lesions caused by 1.5mg/L Red Smoke for ten exposures. Females had even fewer lesions.

Olfactory epithelium has higher levels of cytochromes p450 than transitional and respiratory epithelium. It also has carboxyl esterases and aldehyde dehydrogenases which hydrolyze esters (Renne et al, 2007). The lack of lesions in olfactory epithelium in this study suggests the injury was not induced by metabolism of xenobiotics.

A few rats (one Recovery control male (15-562) and one 0.1mg/L female) had a few large pale vacuoles that span two cells in width in transitional or respiratory epithelium of anterior nasal passages, that do not resemble the commonly reported eosinophilic droplets (Harkema et al, 2006). This may represent an aging change, degeneration or an incidental finding.

During necropsy, grossly observed dark patches on lungs were reported for many rats. No specific histologic finding correlated with dark patches. Alveolar septal congestion, venous congestion, perivascular or peribronchiolar hemorrhage or hemorrhage immediate prior to death (or erythrocyte extravasation postmortem) could all account for the grossly observed dark patches but none of the histologic lesions were severe. Most were minimal to mild. None of the lesions had evidence of having occurred earlier than immediately prior to euthanasia. The liver was reported to be 'dark' in a few rats. This is judged to be within normal limits as there were no histologic findings that would correlate with dark color. Female rat uterus was reported to 'appear to be in proestrus' which was corroborated histologically. Male rat 15-578 had grossly half-normal sized testes. This was corroborated by marked degeneration or atrophy of seminiferous tubules. Male rat 15-551 was reported to have a 1 cm hepatic mass which was unable to be confirmed histologically as the trimmed liver specimen did not contain the mass. Male 15-573 had a 1 cm hepatic mass which was identified histologically as a resolving torsed liver lobe. The entire lobe exhibited coagulative necrosis with surrounding granulomatous inflammation, fibrosis, biliary hyperplasia with mineral and pigment (bile or hemosiderin), which was observed extracellularly and within macrophage cytoplasm.

Additional background or incidental lesions consisted of one pulmonary osteoma and numerous eosinophilic globules in the respiratory epithelium of the trachea (globule leukocytes) of many rats. Many rats had minimal pulmonary alveolar hemorrhage that is commonly observed in rats euthanized with carbon dioxide (Renne et al, 2009). Fourteen-week-old recovery female rats may have a higher glomerular filtration rate or slightly more protein in their tubules, as five of six rats in both treated and untreated recovering female groups had increased fluid in proximal tubules relative to younger controls and to males of either age. This is unexpected because male rats and not female rats secrete the protein alpha 2_u- globulin.

Rodents exposed to water-soluble, gaseous irritants most often have lesions in the surface epithelium lining the lateral meatus, i.e., the lateral margins of the naso- and maxilloturbinate and on the lateral wall. (Harkema et al, 2006; Renne et al, 2007) The location of lesions in this study match this description. Relative locations of respiratory epithelial degeneration matched those of the transitional epithelium, suggesting an air-flow driven site specificity but could also reflect tissue sensitivity. The former is similar to the effects of cigarette smoke or formaldehyde, the latter similar to the effects of ozone (urban smog) (Harkema et al,2006).

The average particle size of the high concentration exposures was 2.4 microns, 2.33 microns for the intermediate concentration exposures, and 2.3 microns for the low concentration exposures, in a mono-dispersed dust-like aerosol. One-to-10 micron particles are deposited in the upper nasopharyngeal region and in the first five generations of the conducting airways (Leikauf, 2013). The small size of Red Smoke particles enables passage into the lower respiratory track and deposition in alveoli. Red Smoke contains a number of ingredients, not the least of which are aldehydes, including acrolein (a component of smog and tobacco smoke) and formic acid. The toxicity of aldehydes is incompletely understood but involves the formation of DNA adducts. Aldehydes often cause eye and respiratory tract irritation, are highly reactive and may be carcinogenic. Acrolein, in particular, causes increased air flow resistance mediated by C-fibers and central cholinergic reflexes and thus is a sensory irritant. It also cross-links proteins, much like formaldehyde (Costa et al, 2013). Formic acid inhibits mitochondrial cytochrome oxidase leading to 'histotoxic hypoxia.' (Liesivuori et al, 1991). Formic acid is oxidized to carbon dioxide and water, partly excreted unchanged in the urine, and partly metabolized in tissues (Thompson M, 1992). After two weeks of inhalational exposure to formic acid (at concentrations between 62.5 – 500 parts per million) F344/N rats exhibited squamous metaplasia of the nasal respiratory epithelium, inflammation and necrosis. Red Smoke, however, is a mixture. Exposure of Sprague-Dawley rats to Red Smoke over a

comparable period of time had a reduced effect compared to that of pure formic acid, possibly due to lower concentrations of formic acid or mitigation of its effects by interference of the other ingredients.

In this study ten thirty-minute inhalational exposures to Red Smoke was associated only with injury to those initial tissues (nasal turbinates and epithelia) with which it came into contact, therefore Red Smoke may be an irritant. Histologic evidence lacks in this study for other forms of toxicity.

FINAL REPORT APPROVAL

15 June, 2016

Erica E. Carroll, DVM, PhD, Diplomate ACVP
LTC, VC
Study Pathologist
Toxicology Portfolio
U.S. Army Public Health Center

Date

PHOTOMICROGRAPHS

Figure 1. Acute Study. Female rat 15-740 was exposed one time to 1.7mg/L of Red Smoke and euthanized two weeks later. There is moderate alveolar septal congestion (arrows) and venous congestion. 20X

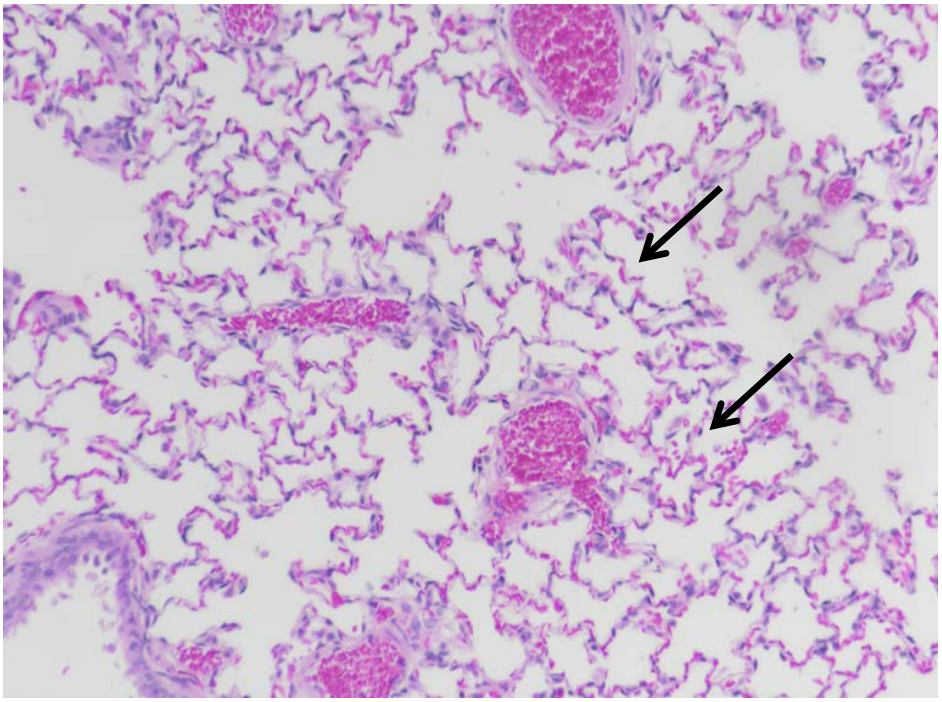
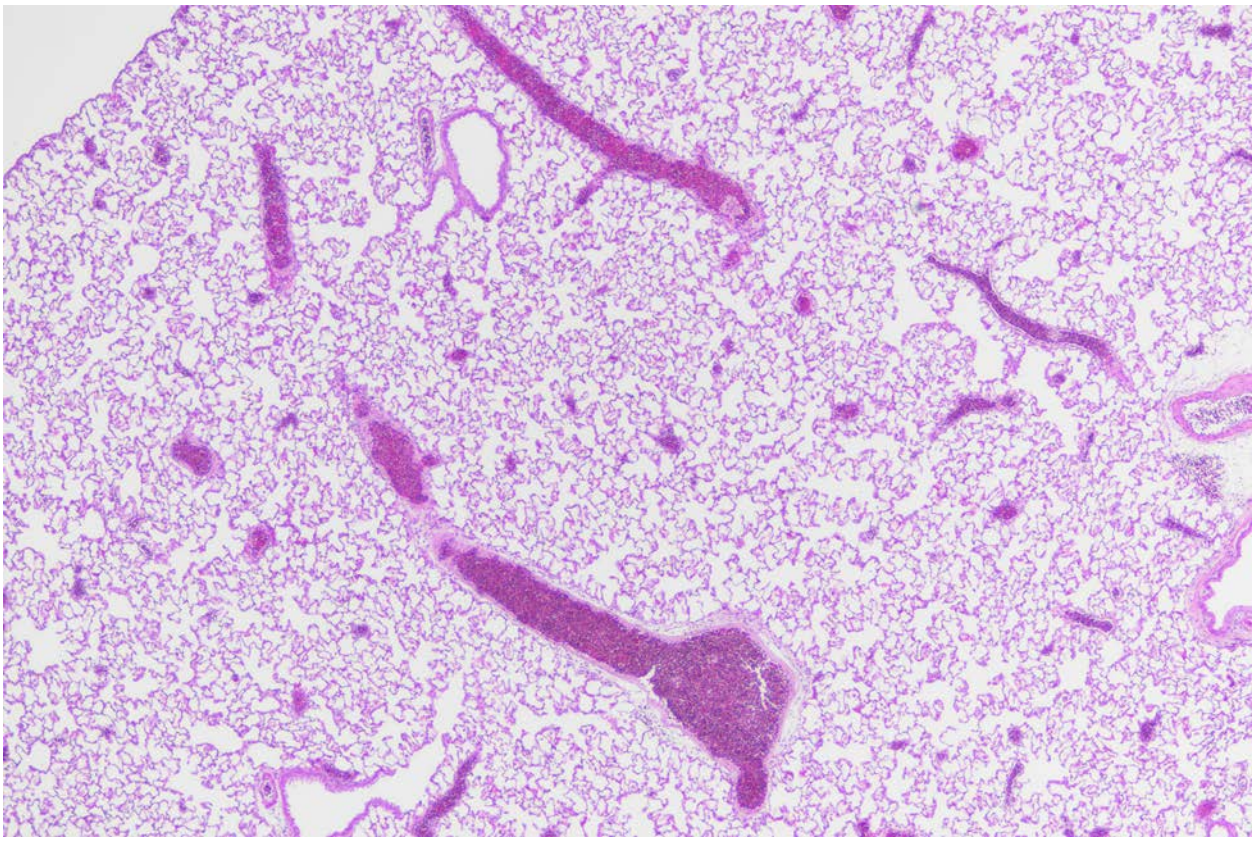


Figure 2. Acute study. Male rat (15-0734) exposed to 1.7mg/L Red Smoke. Lung. Moderate venous congestion 4X



SUBACUTE STUDY FIGURES

Figure 3. Subacute study. Male rat (15-565) exposed to 1.5mg/L Red Smoke. Nasal turbinates, level 1. Moderate transitional epithelial hyperplasia 5-6 cells thick (3A). Compare with (3B) normal control 15-552, both at 4X. At higher magnification the transitional epithelium of 552 is six-seven cells thick (3C) compared to normal (3D) in which it is cuboidal to columnar and 1-2 cells thick. 20X

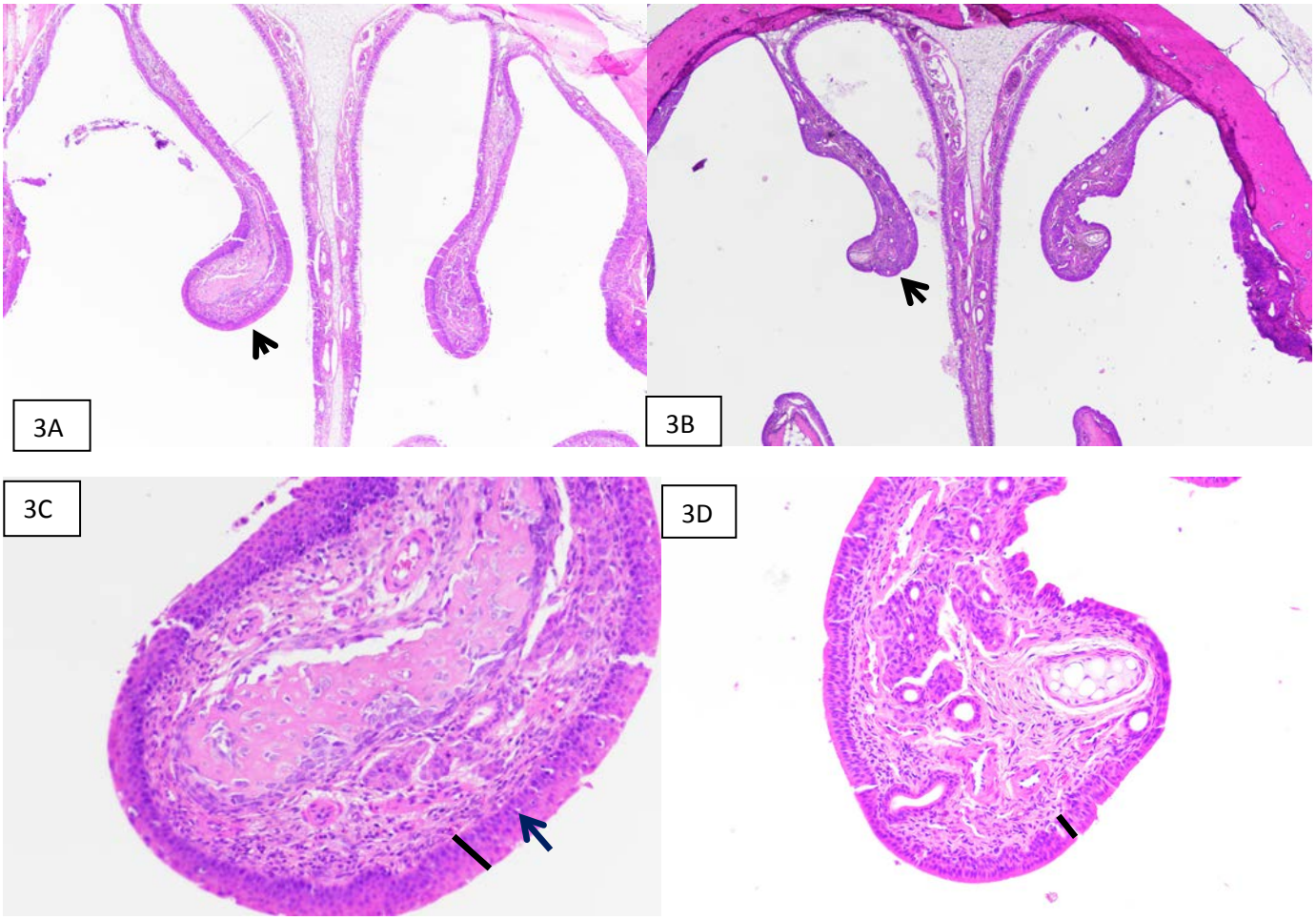


Figure 4. Subacute study.Turbinate level 1 (T1) mucosal degeneration in 1.5 mg/L Red Smoke-exposed male rat (15-556) nasoturbinate (4A) and lateral wall of the lateral meatus (4B). Transitional epithelial hypertrophy with several vacuolated, necrotic or sloughing epithelial cells and few subepithelial granulocytes. 40X

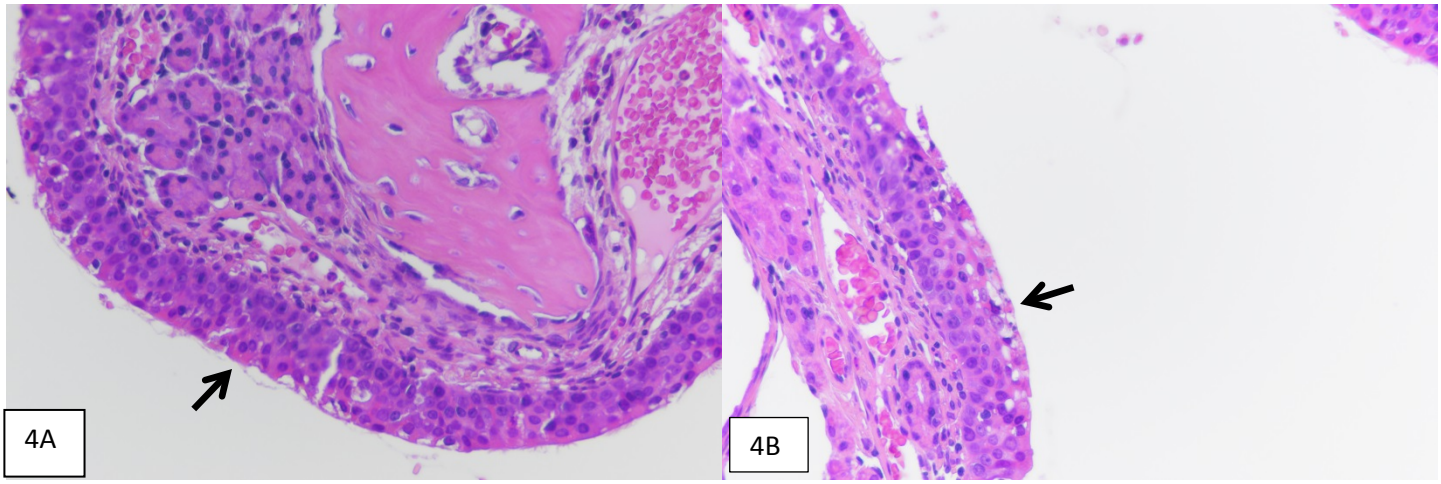
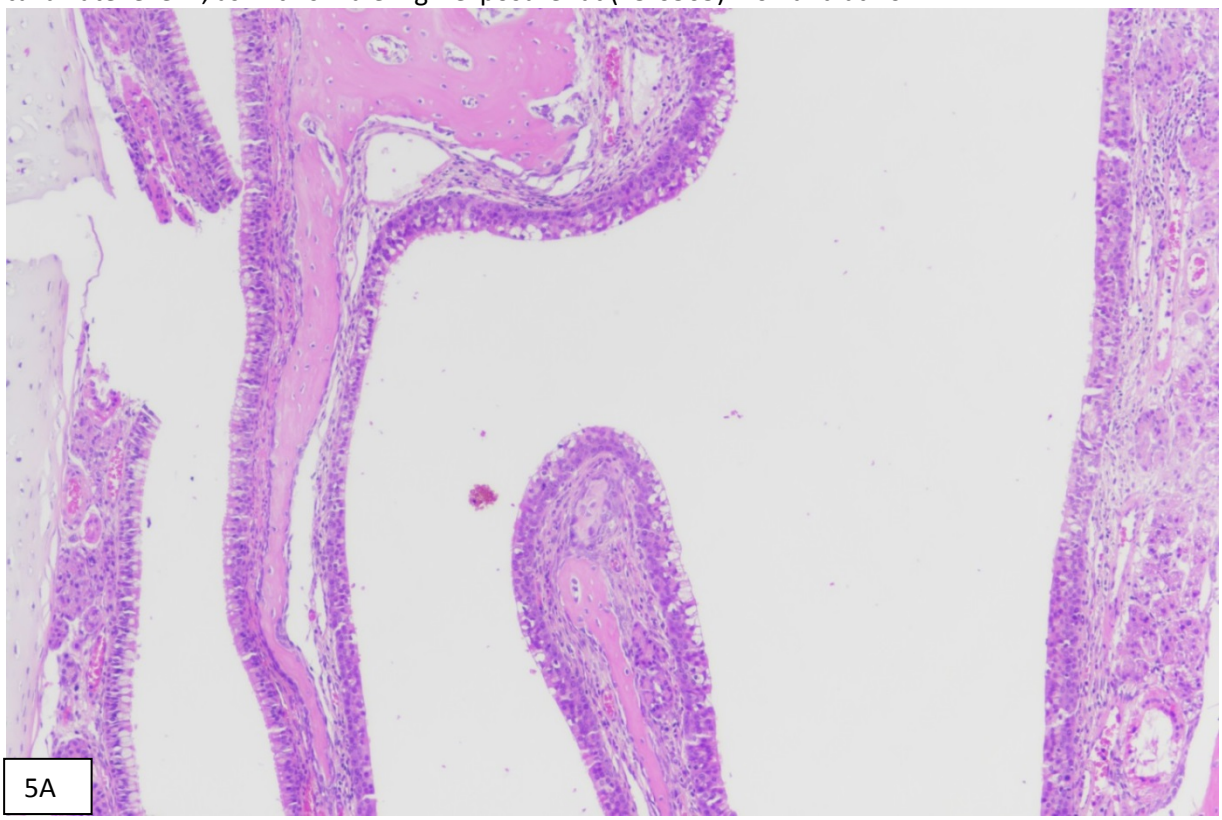


Figure 5. Subacute study. Red Smoke-associated mucosal degeneration occasionally affected respiratory epithelium of turbinate level 2, as in this male high-exposure rat (15-0565). 10X and at 20X.



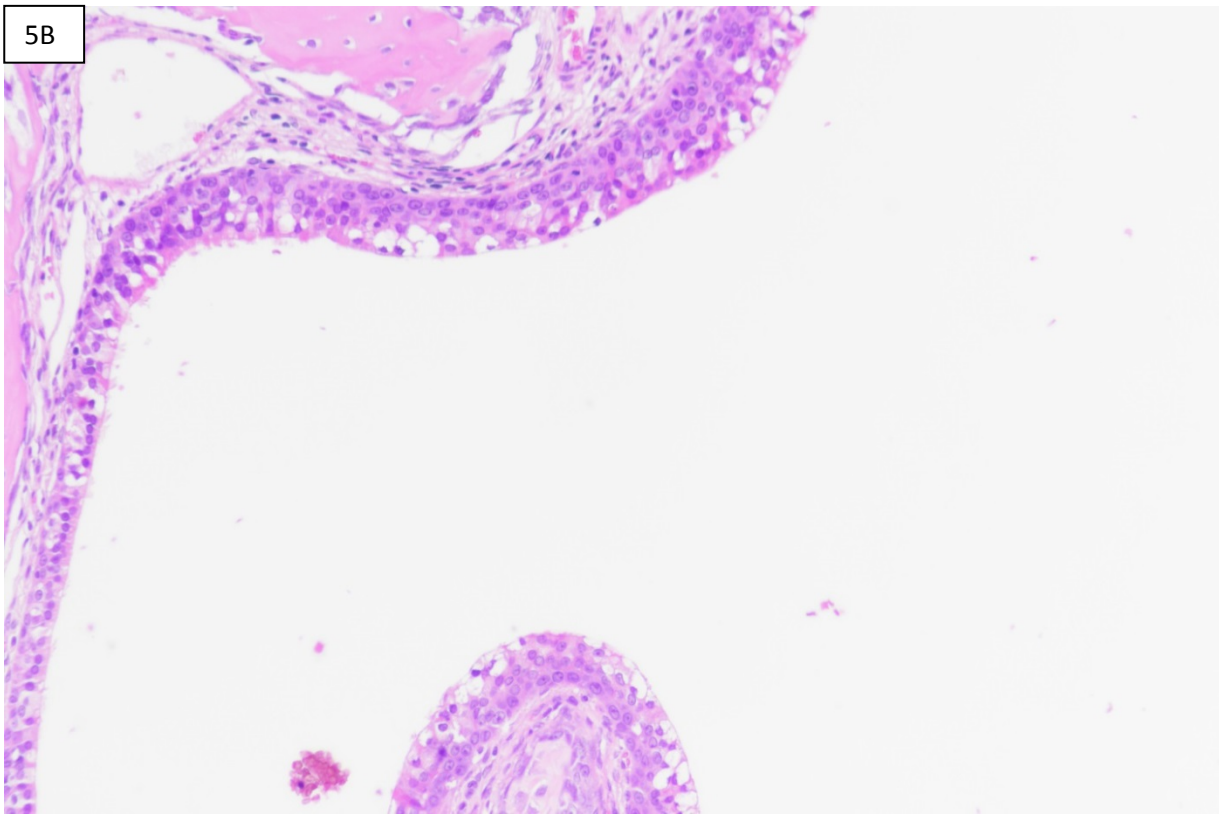


Figure 6. Subacute study. High-exposure male (15-574) level 2 variably displayed transitional epithelial hyperplasia (arrows) with subepithelial granulocytes (yellow arrowheads). 20X

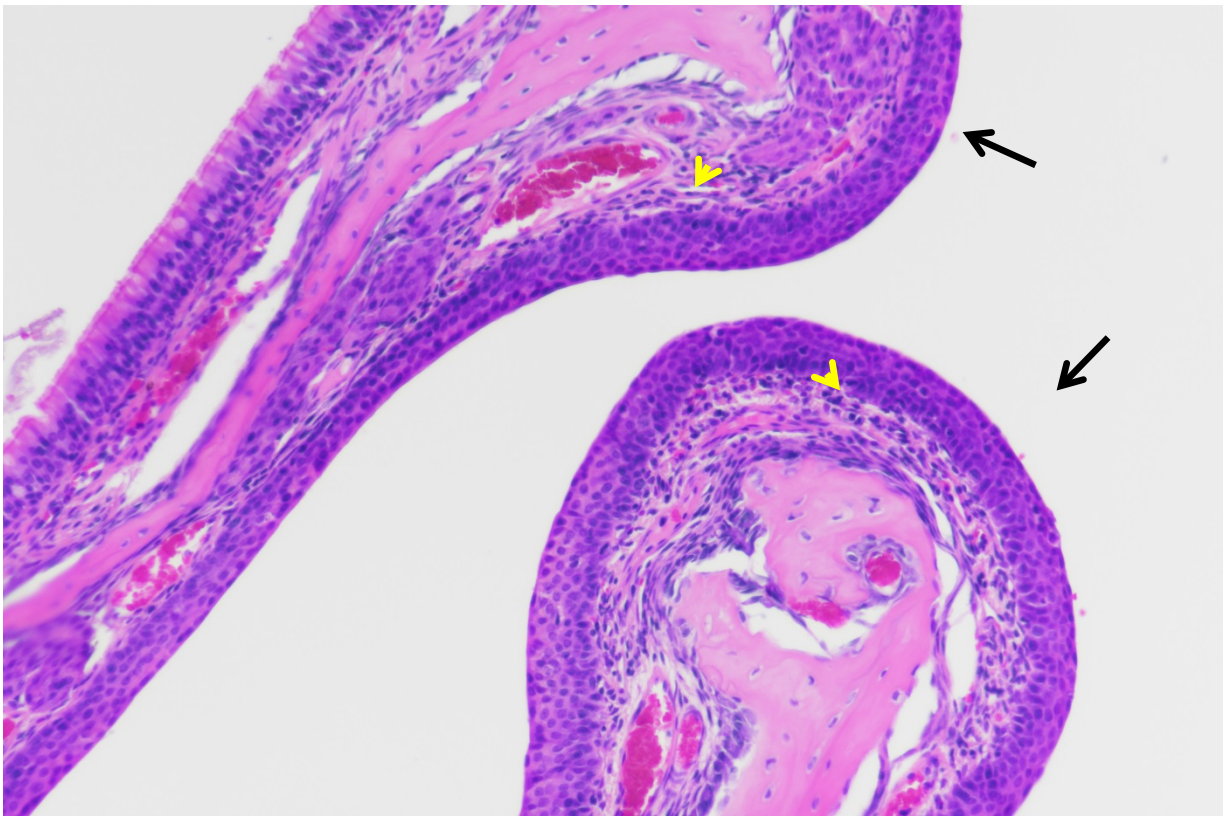
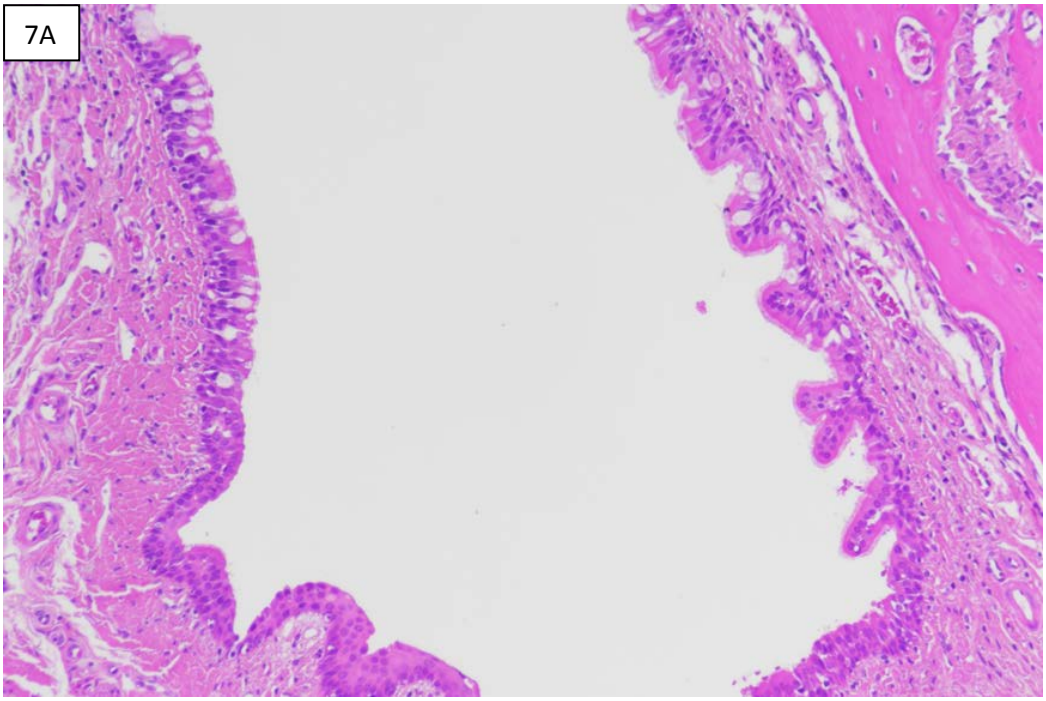
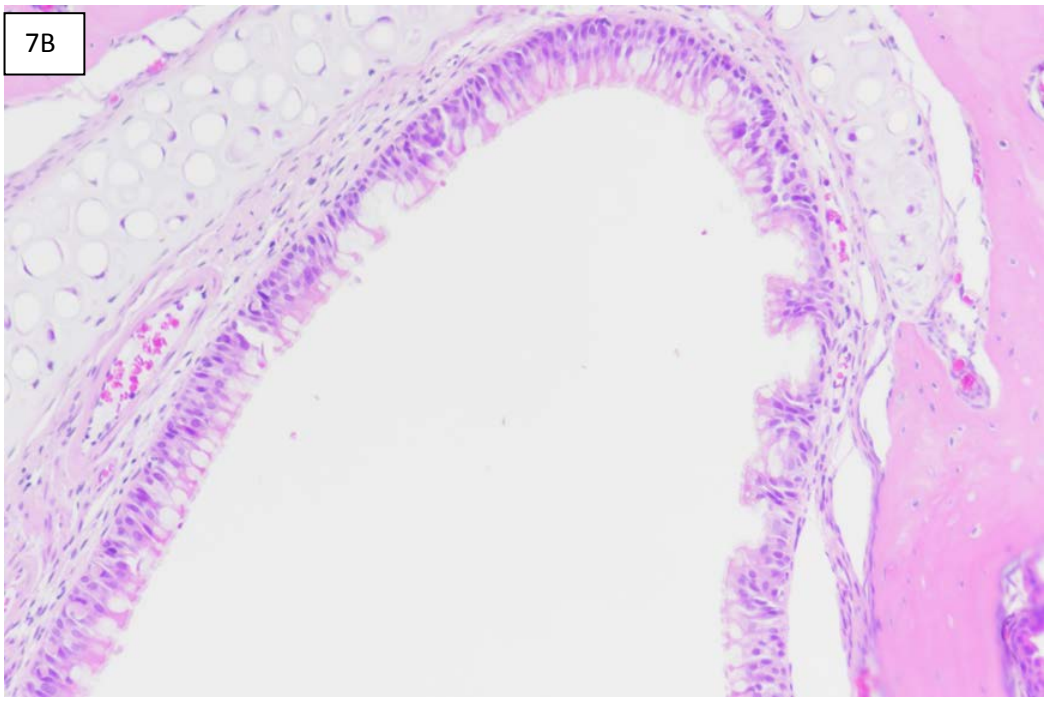


Figure 7. Subacute study. Epithelial hyperplasia was common in Red Smoke-exposed rats but also in older recovery controls. Female 15-615 exposed to 1.5mg/L Red Smoke had respiratory epithelial hyperplasia in the ventral meatus of nasal level 2(7A). 20X. Rat 15-594 (0.5mg/L exposure) had respiratory epithelial hyperplasia in the dorsal meatus. 20X (7B). Fourteen week-old Recovery control female (15-585) also had level 1 dorsal meatus respiratory epithelial hyperplasia. 20X (7C)

7A



7B



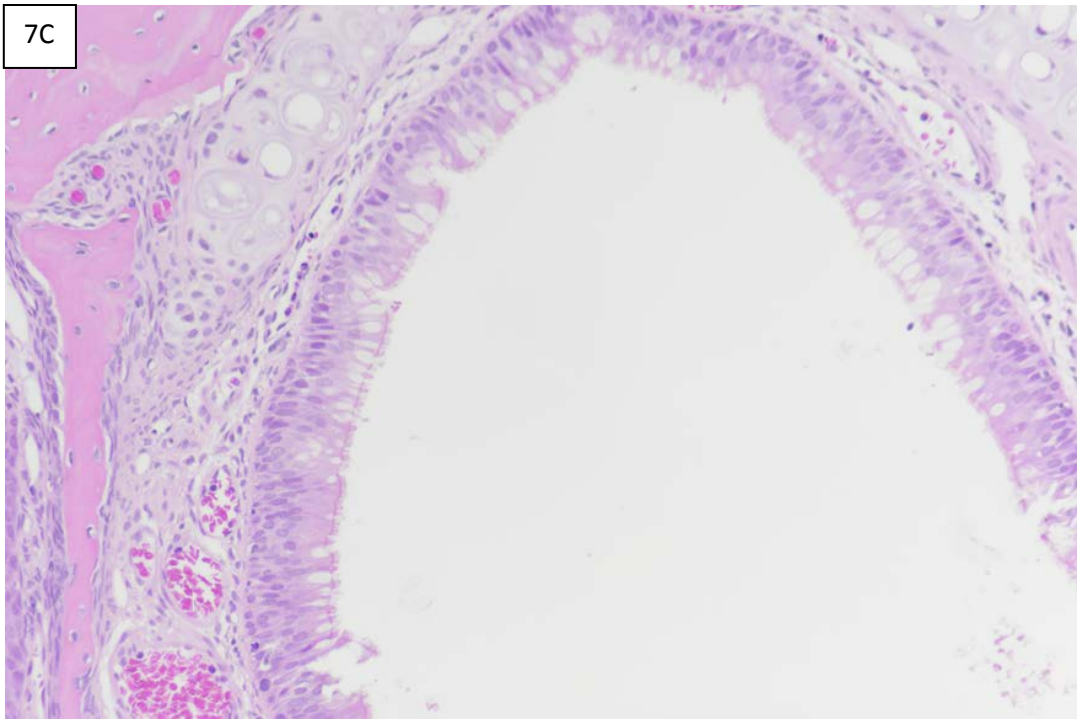


Figure 8. Acute study. Female rat (15-0531) exposed to 2mg/L Red Smoke. Lung. Dilated alveolar septa and poorly visible erythrocytes interpreted to be an artifact of water-perfused lung (8A). Compare to 15-586 female control lung (8B). HE 40X

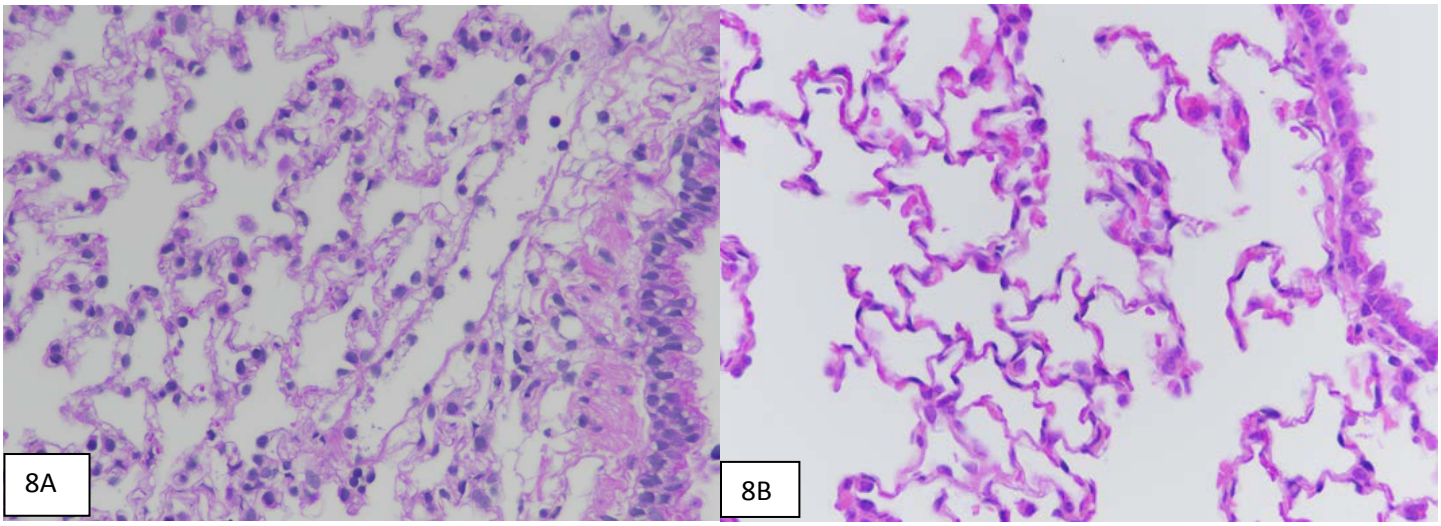


Figure 9. Subacute study. Diagram of most common nasal lesions associated with Red Smoke exposure. Level 1 (9A) most often exhibited transitional epithelial degeneration or hyperplasia affecting ventral and lateral surfaces of the nasoturbinates, dorsolateral surfaces of the maxilloturbinates and the adjacent lateral wall of the lateral meatus. Level 2 often exhibited degeneration or hyperplasia of the same prominences that are covered by respiratory epithelium (9B). Blue ink delineates most often affected areas.

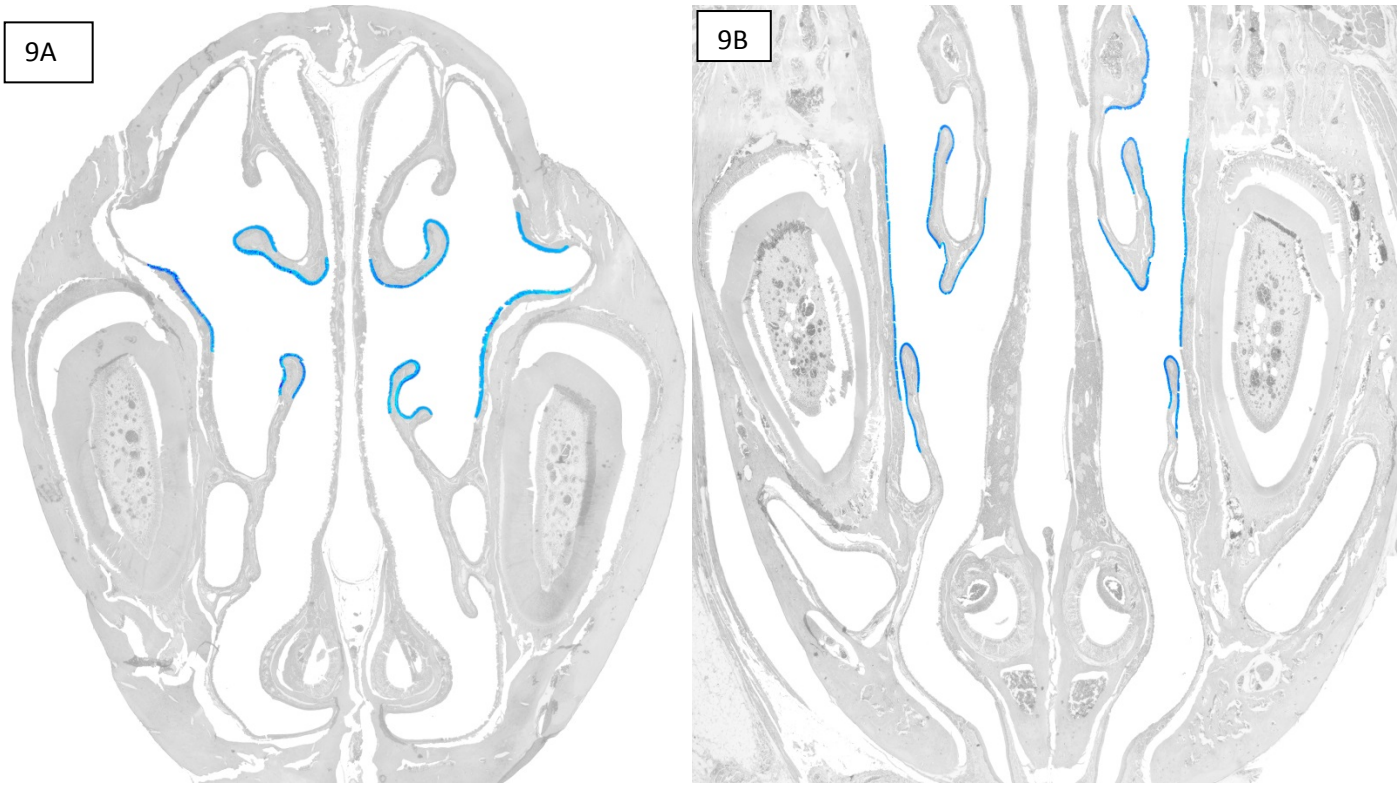
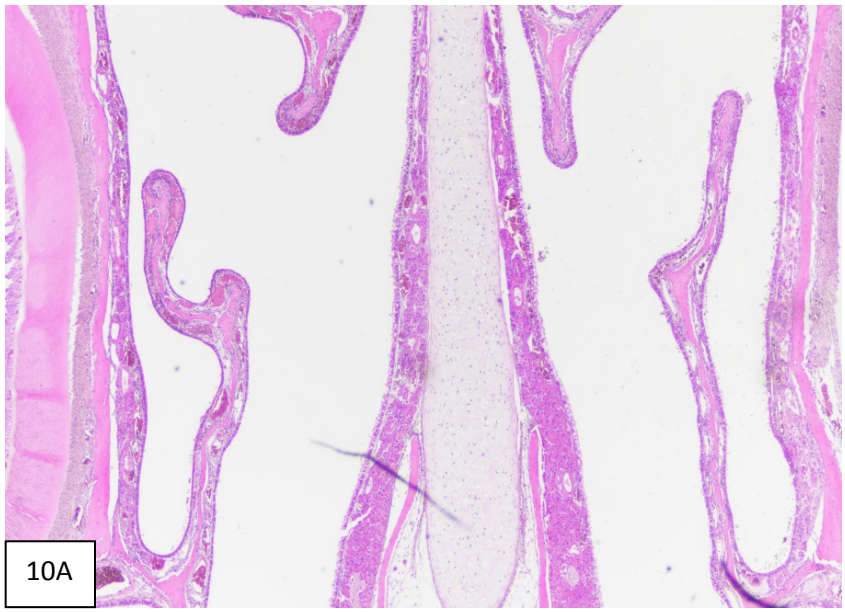
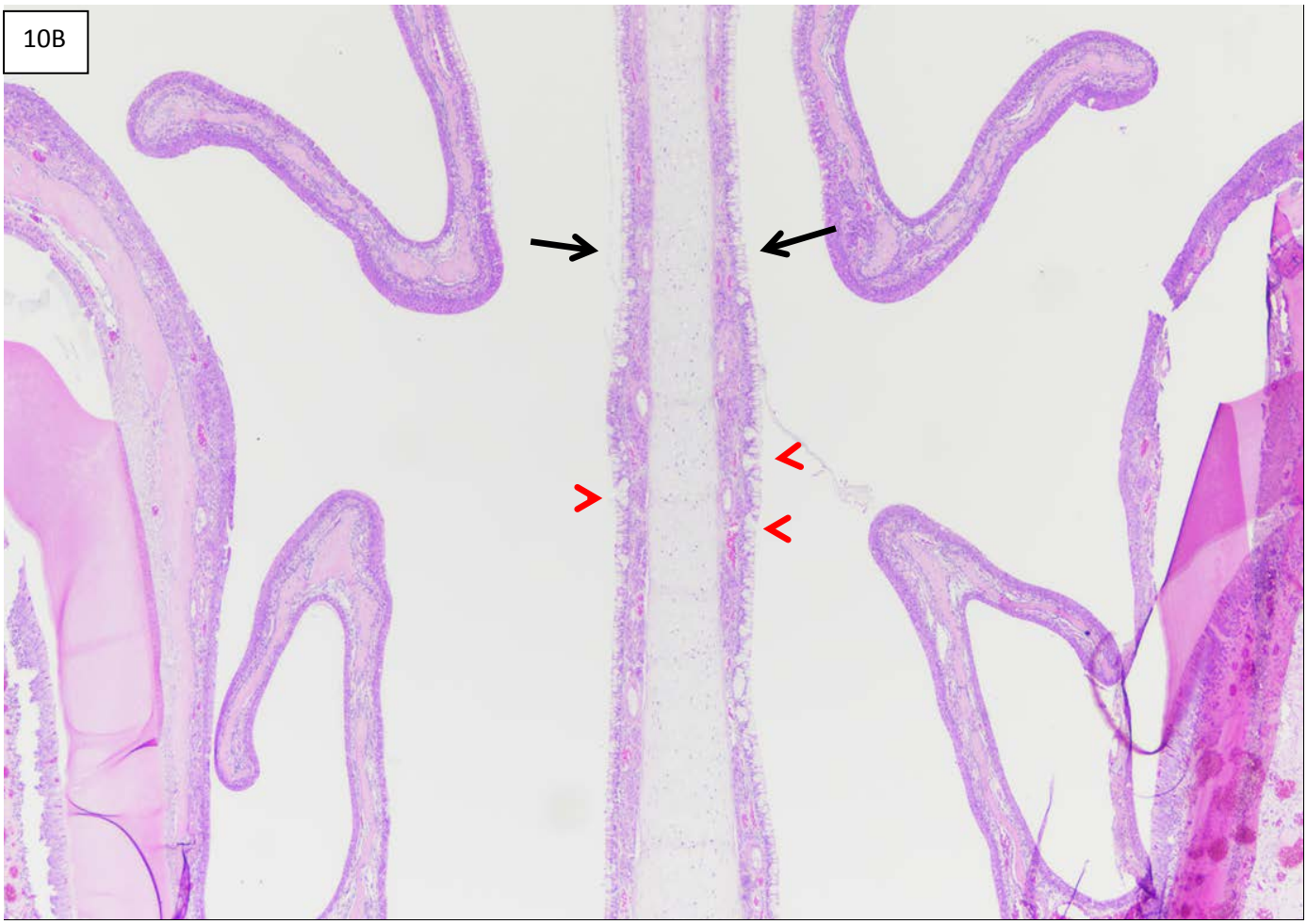


Figure 10. Ten week-old male control rat (15-550) Level 1 nasal septum is lined by normal respiratory epithelium (10A, arrows). High-exposure male ten week-old rat (15-577) Level 1 nasal septum is lined by increased numbers of mucus-secreting goblet cells (goblet cell hyperplasia, arrows) and folding respiratory epithelium (hyperplasia, red arrowheads).

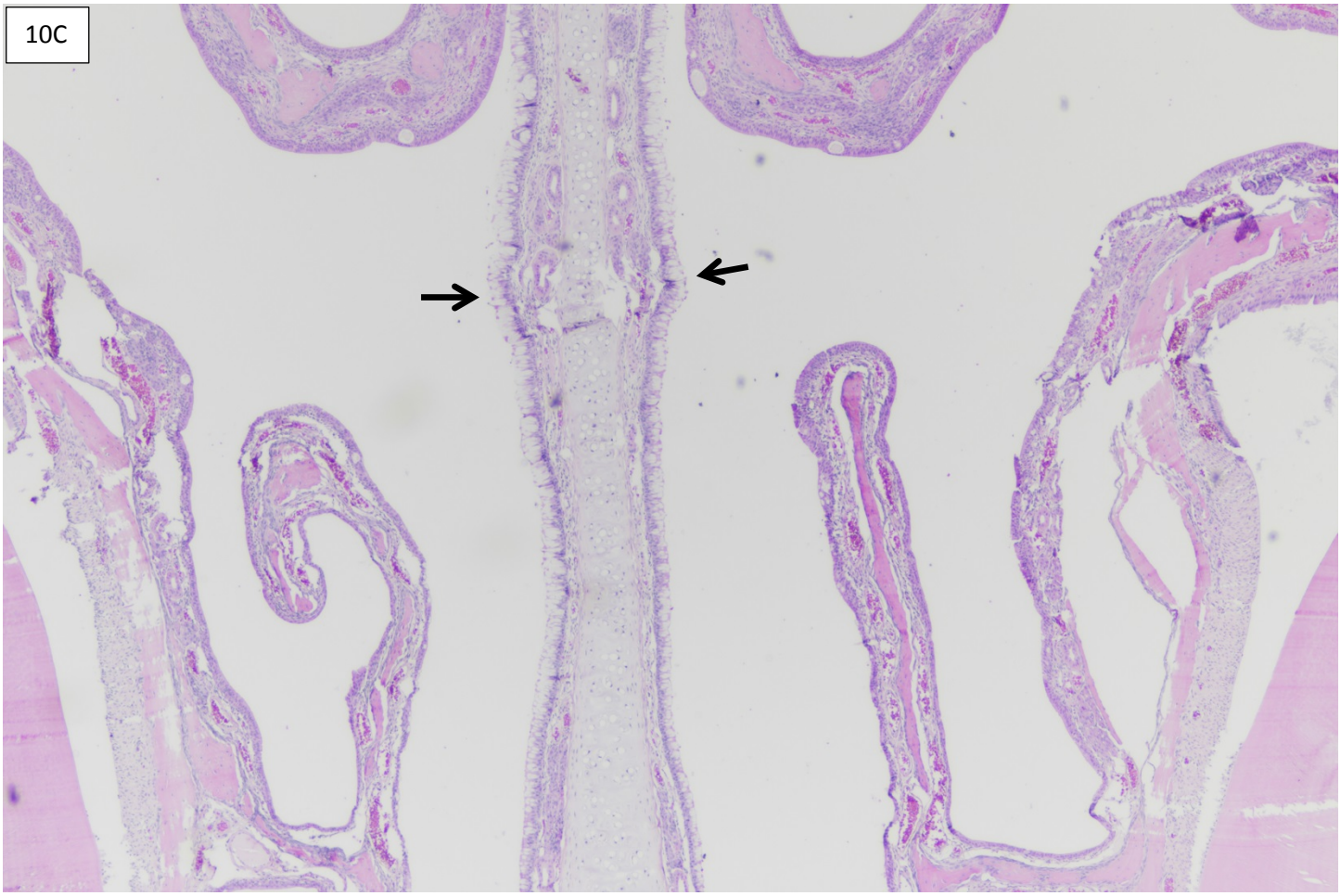
Transitional epithelial hyperplasia is also evident (10B). 14-week-old Recovery Control male (15-562) Level 1 nasal septum is lined by myriad goblet cells (goblet cell hyperplasia) that focally replace respiratory epithelium (10C) 4X



10A



10B



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APPENDIX A -GROSS OBSERVATIONS OF ACUTE STUDY ANIMALS

The lungs of the first group of acute study rats were inadvertently inflated with water. The second and third exposure groups were inflated with formalin. Below is more specific information, verbatim by the prosector:

Acute #1 - Males(0525-0529) Females (0530-0534) - all inflated with water- 2 mg/L exposure level

All animals euthanized 2 weeks following exposure

0525-Edges of right and left lung lobes appear dark in color and collapsed.

0526-Left caudal lobe appears dark in color and collapsed.

0527-Left and right lung appears dark in color with dark spots, Kidneys dark in color, Liver dark in color.

0528-Parts of left and right lung have what appears to be dead or dying tissue and dark patches.

0529- Parts of left and right lung have what appears to be dead or dying tissue and dark patches.

0530- Parts of left and right lung have what appears to be dead or dying tissue and dark patches.

0531-Minimal white patches throughout the lungs.

0532- Parts of left and right lung have what appears to be dead or dying tissue and dark patches.

0533-Possible necrotic areas on fringes of middle pulmonary lobe and accessory pulmonary lobe.

0534- Parts of left and right lung have what appears to be dead or dying tissue and dark patches.

Acute #2 - Males (0732-0736) Females (0737-0741) - all inflated with formalin - 1.7 mg/L exposure level

0732, 0733, 0734, 0737, 0738, and 0739 were euthanized the day after exposure

0732-Cranial aspect of both lungs are pale pink.

0733- Cranial aspect of both lungs are pale pink.

0734-Diffuse multifocal to coalescing dark brown to red regions on front of both lungs, Cranial most aspect of both lungs are pale pink, Caudal left lung has reticular pattern.

0737-Focal dark brown region on cranial lobe of right lung, Cranial aspect of left lung pale pink.

0738-Outer edge of all lung lobes white and both lungs pale pink.

0739-No necropsy sheet.

0735, 0736, 0740, and 0741 were euthanized 2 weeks following exposure

0735-NGLR

0736-NGLR

0740-NGLR

0741-NGLR

Acute #3 - Males (0780-0784) Females (0785-0789) - all inflated with formalin – 0.6 mg/L exposure level

0780, 0781, 0782, 0785, 0786, and 0787 were euthanized the day after exposure

0780-Anterior portion of right and left lung appear to have dark brown focal regions.

0781-Anterior portion of the left lung is pale pink.

782-NGLR

0785-NGLR

0786-Right anterior portion of lung is pale pink.

0787-Liver is mildly dark, Anterior portions of right and left lung have focal brown spots, Outer edges of anterior portion of lung are pale pink, Left kidney has white focal area 1 mm in diameter.

0783, 0784, 0788, and 0789 were euthanized 2 weeks following exposure

0783-Diffuse whitish, slightly raised areas, in distal region of right caudal and left pulmonary lobes.

0784-Left pulmonary lobe is whitish pink around edges with dark red center.

0788-NGLR

0789-Hydronecrosis [*sic*] of right kidney.

APPENDIX B - INCIDENCE SUMMARIES OF ACUTE RED SMOKE STUDY IN RATS

ACUTE STUDY HISTOLOGIC FINDINGS IN (2 mg/L) RED SMOKE-EXPOSED FEMALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS

TISSUE	LESION or HISTOLOGIC CHANGE	Control*	2 mg/L*	Fisher's Exact Test P-value	Conclusion
Lung	Congestion, alveolar septal	0/6	5/5	0.002	2mg/L > Control
Lung	Congestion, venous	1/6	0/5	1.000	No significant difference
Lung	Erythrocyte extravasation, alveolar	1/6	2/5	0.545	No significant difference
Lung	Erythrophagocytosis	0/6	0/5	1.000	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	3/6	1/5	0.545	No significant difference
Lung	Edema, perivascular	0/6	2/5	0.182	No significant difference
Lung	Ateletasis, alveolar	2/6	3/5	0.567	No significant difference
Lung	Histiocytosis, alveolar	0/6	1/5	0.454	No significant difference
Lung	Infiltrate, granulocytic	2/6	1/5	1.000	No significant difference
Lung	Edema, subpleural	0/6	3/5	0.061	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	0/5	1.000	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	0/5	1.000	No significant difference

Fisher's Exact Test p-value < .05 was considered statistically significant

* Number of animals with the finding out of the total number in the group.

ACUTE STUDY HISTOLOGIC FINDINGS IN (1.7 mg/L)-RED SMOKE-EXPOSED FEMALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS

TISSUE	LESION or HISTOLOGIC CHANGE	Control*	1.7 mg/L*	Fisher's Exact Test P-value	Conclusion
Lung	Congestion, alveolar septal	0/6	4/5	0.015	1.7 mg/L > Control
Lung	Congestion, venous	1/6	4/5	0.080	No significant difference
Lung	Erythrocyte extravasation, alveolar	1/6	1/5	1.000	No significant difference
Lung	Erythrophagocytosis	0/6	0/5	1.000	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	3/6	2/5	1.000	No significant difference
Lung	Edema, perivascular	0/6	0/5	1.000	No significant difference
Lung	Ateletasis, alveolar α	2/6	2/5	1.000	No significant difference
Lung	Histiocytosis, alveolar	0/6	0/5	1.000	No significant difference
Lung	Infiltrate, granulocytic	2/6	1/5	1.000	No significant difference
Lung	Edema, subpleural	0/6	0/5	1.000	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	0/5	1.000	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	0/5	1.000	No significant difference

Fisher's Exact Test p-value < .05 was considered statistically significant

* Number of animals with the finding out of the total number in the group.

ACUTE STUDY HISTOLOGIC FINDINGS IN (0.6 mg/L)-RED SMOKE-EXPOSED FEMALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS					
TISSUE	**LESION or HISTOLOGIC CHANGE**	**Control***	**0.6 mg/L***	**Fisher's Exact Test P-value**	**Conclusion**
Lung	Congestion, alveolar septal	0/6	2/5	0.185	No significant difference
Lung	Congestion, venous	1/6	4/5	0.080	No significant difference
Lung	Erythrocyte extravasation, alveolar	1/6	3/5	0.242	No significant difference
Lung	Erythrophagocytosis	0/6	1/5	0.454	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	3/6	4/5	0.545	No significant difference
Lung	Edema, perivascular	0/6	1/5	0.454	No significant difference
Lung	Ateletasis, alveolar α	2/6	0/5	0.455	No significant difference
Lung	Histiocytosis, alveolar	0/6	0/5	1.000	No significant difference
Lung	Infiltrate, granulocytic	2/6	4/5	0.242	No significant difference
Lung	Edema, subpleural	0/6	0/5	1.000	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	0/5	1.000	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	0/5	1.000	No significant difference
Fisher's Exact Test p-value < .05 was considered statistically significant					
* Number of animals with the finding out of the total number in the group.					

ACUTE STUDY - SEVERITY SCORES for FEMALE RATS EXPOSED to RED SMOKE at: 2 mg/L, 1.7 mg/L, 0.6 mg/L and AIR CONTROL

TISSUE	HISTOLOGIC FINDING and score*						
Lung	Congestion, alveolar septal						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	0	2	.	.	.	2
	1.7	1	2	1	1	.	5
	0.6	3	.	.	2	.	5
Lung	Congestion, venous						
		0	1	2	3	4	Total
	Control	5	.	1	.	.	6
	2	5	.	.	.	.	5
	1.7	1	3	1	.	.	5
	0.6	1	2	.	2	.	5
Lung	Erythrocyte extravasation, alveolar						
		0	1	2	3	4	Total
	Control	5	1	.	.	.	6
	2	3	2	.	.	.	5
	1.7	4	.	1	.	.	5
	0.6	2	1	1	1	.	5
Lung	Erythrophagocytosis						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	5	.	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	4	1	.	.	.	5

Lung	Hemorrhage, perivascular or peribronchiolar						
		0	1	2	3	4	Total
	Control	3	3	.	.	.	6
	2	4	1	.	.	.	5
	1.7	3	2	.	.	.	5
	0.6	1	3	1	.	.	5

Lung	Edema, perivascular						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	3	2	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	4	1	.	.	.	5

Lung	Ateletasis, alveolar						
		0	1	2	3	4	Total
	Control	4	2	.	.	.	6
	2	2	2	1	.	.	5
	1.7	3	1	.	1	.	5
	0.6	5	.	.	.	.	5

Lung	Histiocytosis, alveolar						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	4	1	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	5	.	.	.	.	5

Lung	Infiltrate, granulocytic						
		0	1	2	3	4	Total
	Control	4	1	1	.	.	6
	2	4	1	.	.	.	5
	1.7	4	1	.	.	.	5
	0.6	1	4	.	.	.	5

Lung	Edema, subpleural						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	2	2	1	.	.	5
	1.7	5	.	.	.	.	5
	0.6	5	.	.	.	.	5

Lung	Fibrosis, alveolar, focal						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	5	.	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	5	.	.	.	.	5

Lung	Crystals, eosinophilic, alveolar						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	5	.	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	5	.	.	.	.	5

* Scores: 1= minimal (<5% of the tissue is affected); 2 = mild (6-15%); 3 =moderate (16-30%); 4 = marked (>30%).

ACUTE STUDY HISTOLOGIC FINDINGS IN (2 mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS

TISSUE	LESION or HISTOLOGIC CHANGE	Control*	2 mg/L*	Fisher's Exact Test P-value	Conclusion
Lung	Congestion, alveolar septal	1/6	4/5	0.080	No significant difference
Lung	Congestion, venous	2/6	1/5	1.000	No significant difference
Lung	Erythrocyte extravasation, alveolar	4/6	4/5	1.000	No significant difference
Lung	Erythrophagocytosis	1/6	0/5	1.000	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	4/6	2/5	0.567	No significant difference
Lung	Edema, perivascular	0/6	2/5	0.182	No significant difference
Lung	Ateletasis, alveolar	2/6	4/5	0.242	No significant difference
Lung	Histiocytosis, alveolar	1/6	4/5	0.080	No significant difference
Lung	Infiltrate, granulocytic	0/6	2/5	0.185	No significant difference
Lung	Edema, subpleural	0/6	3/5	0.061	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	1/5	0.454	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	0/5	1.000	No significant difference

Fisher's Exact Test p-value < .05 was considered statistically significant

* Number of animals with the finding out of the total number in the group.

ACUTE STUDY HISTOLOGIC FINDINGS IN (1.7 mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS

TISSUE	LESION or HISTOLOGIC CHANGE	Control*	1.7 mg/L*	Fisher's Exact Test P-value	Conclusion
Lung	Congestion, alveolar septal	1/6	4/5	0.080	No significant difference
Lung	Congestion, venous	2/6	4/5	0.242	No significant difference
Lung	Erythrocyte extravasation, alveolar	4/6	5/5	0.455	No significant difference
Lung	Erythrophagocytosis	1/6	2/5	0.545	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	4/6	3/5	1.000	No significant difference
Lung	Edema, perivascular	0/6	0/5	1.000	No significant difference
Lung	Ateletasis, alveolar α	2/6	5/5	0.061	No significant difference
Lung	Histiocytosis, alveolar	1/6	2/5	0.545	No significant difference
Lung	Infiltrate, granulocytic	0/6	1/5	0.454	No significant difference
Lung	Edema, subpleural	0/6	1/5	0.454	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	0/5	1.000	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	1/5	0.454	No significant difference

Fisher's Exact Test p-value < .05 was considered statistically significant

* Number of animals with the finding out of the total number in the group.

ACUTE STUDY HISTOLOGIC FINDINGS IN (0.6mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO (AIR VEHICLE) CONTROL RATS					
TISSUE	**LESION or HISTOLOGIC CHANGE**	**Control***	**0.6 mg/L***	**Fisher's Exact Test P-value**	**Conclusion**
Lung	Congestion, alveolar septal	1/6	5/5	0.015	0.6mg/L > Control
Lung	Congestion, venous	2/6	4/5	0.242	No significant difference
Lung	Erythrocyte extravasation, alveolar	4/6	5/5	0.455	No significant difference
Lung	Erythrophagocytosis	1/6	2/5	0.545	No significant difference
Lung	Hemorrhage, perivascular or peribronchiolar	4/6	5/5	0.454	No significant difference
Lung	Edema, perivascular	0/6	1/5	0.454	No significant difference
Lung	Ateletasis, alveolar α	2/6	4/5	0.242	No significant difference
Lung	Histiocytosis, alveolar	1/6	1/5	1.000	No significant difference
Lung	Infiltrate, granulocytic	0/6	4/5	0.015	0.6mg/L > Control
Lung	Edema, subpleural	0/6	0/5	1.000	No significant difference
Lung	Fibrosis, alveolar, focal	0/6	0/5	1.000	No significant difference
Lung	Crystals, eosinophilic, alveolar	0/6	0/5	1.000	No significant difference
Fisher's Exact Test p-value < .05 was considered statistically significant					
* Number of animals with the finding out of the total number in the group.					

ACUTE STUDY SEVERITY SCORES for MALE RATS EXPOSED to RED SMOKE at: 2 mg/L, 1.7 mg/L, 0.6 mg/L and AIR CONTROL

Lung	Congestion, alveolar septal						
		0	1	2	3	4	Total
	Control	5	1	.	.	.	6
	2	1	2	2	.	.	5
	1.7	1	.	1	3	.	5
	0.6	.	2	2	1	.	5
Lung	Congestion, venous						
		0	1	2	3	4	Total
	Control	4	2	.	.	.	6
	2	4	1	.	.	.	5
	1.7	1	2	1	1	.	5
	0.6	1	2	1	1	.	5
Lung	Erythrocyte extravasation, alveolar						
		0	1	2	3	4	Total
	Control	2	4	.	.	.	6
	2	1	4	.	.	.	5
	1.7	.	1	4	.	.	5
	0.6	.	1	3	1	.	5

Lung	Erythrophagocytosis						
		0	1	2	3	4	Total
	Control	5	1	.	.	.	6
	2	5	.	.	.	.	5
	1.7	3	2	.	.	.	5
	0.6	3	2	.	.	.	5
Lung	Hemorrhage, perivascular or peribronchiolar						
		0	1	2	3	4	Total
	Control	2	4	.	.	.	6
	2	3	2	.	.	.	5
	1.7	2	1	2	.	.	5
	0.6	.	1	4	.	.	5
Lung	Edema, perivascular						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	3	2	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	4	.	1	.	.	5
Lung	Ateletasis, alveolar						
		0	1	2	3	4	Total
	Control	4	1	1	.	.	6
	2	1	3	1	.	.	5
	1.7	.	3	1	1	.	5
	0.6	1	2	2	.	.	5
Lung	Histiocytosis, alveolar						
		0	1	2	3	4	Total
	Control	5	1	.	.	.	6
	2	1	4	.	.	.	5
	1.7	3	2	.	.	.	5
	0.6	4	1	.	.	.	5
Lung	Infiltrate, granulocytic						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	3	2	.	.	.	5
	1.7	4	1	.	.	.	5
	0.6	1	4	.	.	.	5
Lung	Edema, subpleural						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	2	2	.	1	.	5
	1.7	4	1	.	.	.	5
	0.6	5	.	.	.	.	5

Lung	Fibrosis, alveolar, focal						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	4	1	.	.	.	5
	1.7	5	.	.	.	.	5
	0.6	5	.	.	.	.	5
Lung	Crystals, eosinophilic, alveolar						
		0	1	2	3	4	Total
	Control	6	.	.	.	.	6
	2	5	.	.	.	.	5
	1.7	4	1	.	.	.	5
	0.6	5	.	.	.	.	5

* Scores: 1= minimal (<5% of the tissue is affected); 2 = mild (6-15%); 3 =moderate (16-30%); 4 = marked (>30%).

APPENDIX C –INCIDENCE SUMMARIES OF SUBACUTE RED SMOKE STUDY

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (1.5 mg/L) RED SMOKE-EXPOSED FEMALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

RED SMOKE EXPOSURE LEVEL-->	Control	1.5 mg/L	P-Value	Conclusion
Stomach, glandular				
Dilation, gastric pits	0/6	0/6	1.000	No Significant Difference
Infiltrate, lymphoplasmacytic, fat	0/6	1/6	1.000	No Significant Difference
Salivary gland, submand, sublingual, parotid				
Lymph node, hyperplasia, plasmacytic, with germinal centers.	3/5	0/5	0.017	Controls more often than RED SMOKE-exposed females
Infiltrate, lymphoplasmacytic, submandibular saliv gl, periductal	0/6	0/5	1.000	No Significant Difference
Mammary tissue				
Mammary epith cell prolif, with atypia	2/2	1/2	1.000	No Significant Difference
Eye with Harderian gland				
Secretion, pigmented, inspissated	1/6	0/6	1.000	No Significant Difference
Infiltrate, lymphoplasmacytic, focal	1/6	1/6	1.000	No Significant Difference
Palpebral abscess (stye)	0/6	0/6	1.000	No Significant Difference

Thymus				
Hemorrhage	0/6	0/6	1.000	No Significant Difference
Hyperplasia, epithelial, focal	0/6	0/6	1.000	No Significant Difference
Ectopic parathyroid tissue	1/6	0/6	1.000	No Significant Difference
LUNG				
Congestion, alveolar septal	0/6	1/6	1.000	No Significant Difference
Congestion, venous	1/6	4/6	0.242	No Significant Difference
Erythrocyte extravasation, alveolar	1/6	2/6	1.000	No Significant Difference
Erythrophagocytosis	0/6	0/6	1.000	No Significant Difference
Hemorrhage, perivascular or peribronchiolar	3/6	0/6	0.182	No Significant Difference
Edema, perivascular	0/6	0/6	1.000	No Significant Difference
Ateletasis, alveolar **α**	2/6	4/6	0.567	No Significant Difference
Histiocytosis, alveolar	0/6	2/6	0.455	No Significant Difference
Infiltrate, granulocytic	1/6	1/6	1.000	No Significant Difference
Edema, subpleural	0/6	0/6	1.000	No Significant Difference
Fibrosis, alveolar, focal	0/6	0/6	1.000	No Significant Difference
Crystals, eosinophilic, alveolar	0/6	0/6	1.000	No Significant Difference

Trachea				
Infiltrate, lymphocytic, subepithelial	0/6	0/6	1.000	No Significant Difference
Increased mucosal eosinophilic droplets:Y/N	1/6	4/6	0.242	No Significant Difference
Thyroid gland				
Hyperplasia, C cell	0/4	0/4	1.000	No Significant Difference
Cyst, thyroid, squamous	2/4	0/4	0.429	No Significant Difference
Ectopic thymus	1/4	1/6	1.000	No Significant Difference
Skeletal muscle				
Infiltrate, lymphohistiocytic, focal, skeletal muscle	0/6	1/6	1.000	No Significant Difference
Lymph node, tracheal				
Draining hemorrhage	1/5	1/5	1.000	No Significant Difference
Pigment, cytoplasmic, macrophages	1/5	0/5	1.000	No Significant Difference
Infiltrate, eosinophilic	1/5	0/5	1.000	No Significant Difference
Heart with great vessels				
Lymphatics, ectatic, heart base	0/6	0/6	1.000	No Significant Difference
Infiltrate, mastocytic and lymphocytic, epicardial fat	0/6	0/6	1.000	No Significant Difference

Adrenal gland				
Ectopic medullary cells	0/6	0/6	1.000	No Significant Difference
Vacuoles, cortical	0/6	1/6	1.000	No Significant Difference
Kidney				
Increased proteinaceous fluid, proximal tubules	1/6	1/6	1.000	No Significant Difference
Basophilic tubules	0/6	1/6	1.000	No Significant Difference
Renal tubule-Hyperplasia, oncocytic	0/6	0/6	1.000	No Significant Difference
infiltrate, lymphoplasmacytic	0/6	3/6	0.182	No Significant Difference
Cystic tubules, focal	0/6	2/6	0.455	No Significant Difference
Liver				
Hepatocellular loss, focal, with leukocytes	0/5	0/6	1.000	No Significant Difference
Infiltrate, histiocytic, focal	3/5	1/6	0.242	No Significant Difference
Infiltrate, lymphocytic, portal	1/5	0/6	1.000	No Significant Difference
Fibrosis, portal, focal	0/5	1/6	1.000	No Significant Difference
Uterus				
Hyperplasia, endometrial	2/6	0/6	0.455	No Significant Difference
NASAL TURBINATE, LEVEL 1				
Level 1- Hyperplasia, transitional epithelium	0/4	5/5	0.008	1.5 > controls
Level 1 - Hyperplasia, respiratory epithelium	2/4	3/5	1.000	No Significant Difference
Level 1- Infiltrate, granulocytic	0/4	1/5	1.000	No Significant Difference
Level 1- Infiltrate, lymphocytic	0/4	0/5	1.000	No Significant Difference
Level 1 -Nasoturbinate, mucosal degeneration	0/4	3/5	0.167	No Significant Difference
Level 1 Goblet cell hyperplasia, nasal septum	4/4	4/5	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 2				
Level 2- Goblet cell hyperplasia, nasal septum	1/4	0/6	0.400	No Significant Difference
Level 2 - Hyperplasia, respiratory epithelium	0/4	1/6	1.000	No Significant Difference
Level 2- Infiltrate, granulocytic	0/4	2/6	0.467	No Significant Difference
Level 2-Infiltrate, lymphocytic	1/4	0/6	0.400	No Significant Difference
NASAL TURBINATE, LEVEL 3				
Level 3 - Hyperplasia, respiratory epithelium	2/6	2/5	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 3				
Level 3 - Hyperplasia, respiratory epithelium	2/6	1/5	1.000	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (0.5 mg/L) RED SMOKE-EXPOSED FEMALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

NASAL TURBINATE, LEVEL 1				
Level 1- Hyperplasia, transitional epithelium	0/4	3/3	0.029	0.5 mg/kg > Control
Level 1 - Hyperplasia, respiratory epithelium	2/4	1/3	1.000	No Significant Difference
Level 1- Infiltrate, granulocytic	0/4	1/3	0.429	No Significant Difference
Level 1- Infiltrate, lymphocytic	0/4	1/3	0.429	No Significant Difference
Level 1 -Nasoturbinate, mucosal degeneration	0/4	1/3	0.429	No Significant Difference
Level 1 Goblet cell hyperplasia, nasal septum	4/4	3/3	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 2				
Level 2- Goblet cell hyperplasia, nasal septum	1/4	0/6	0.400	No Significant Difference
Level 2 - Hyperplasia, respiratory epithelium	0/4	4/6	0.076	No Significant Difference
Level 2- Infiltrate, granulocytic	0/4	0/6	1.000	No Significant Difference
Level 2-Infiltrate, lymphocytic	1/4	0/6	0.400	No Significant Difference
NASAL TURBINATE, LEVEL 3				
Level 3 - Hyperplasia, respiratory epithelium	2/6	1/5	1.000	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (0.1 mg/L) RED SMOKE-EXPOSED FEMALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

NASAL TURBINATE, LEVEL 1				
Level 1- Hyperplasia, transitional epithelium	0/4	4/4	0.029	0.1 mg/kg > Control
Level 1 - Hyperplasia, respiratory epithelium	2/4	2/4	1.000	No Significant Difference
Level 1- Infiltrate, granulocytic	0/4	4/4	0.029	0.1 mg/kg > Control
Level 1- Infiltrate, lymphocytic	0/4	4/4	0.029	0.1 mg/kg > Control
Level 1 -Nasoturbinate, mucosal degeneration	0/4	1/4	1.000	No Significant Difference
Level 1 Goblet cell hyperplasia, nasal septum	4/4	4/4	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 2				
Level 2- Goblet cell hyperplasia, nasal septum	1/4	2/5	1.000	No Significant Difference
Level 2 - Hyperplasia, respiratory epithelium	0/4	1/5	1.000	No Significant Difference
Level 2- Infiltrate, granulocytic	0/4	4/5	0.048	0.1 mg/kg > Control
Level 2-Infiltrate, lymphocytic	1/4	4/5	0.206	No Significant Difference
NASAL TURBINATE, LEVEL 3				
Level 3 - Hyperplasia, respiratory epithelium	2/6	2/6	1.000	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (1.5 mg/L) RED SMOKE-EXPOSED, THEN RECOVERED FEMALE RATS COMPARED TO AGE-MATCHED AIR-EXPOSED CONTROLS

RED SMOKE EXPOSURE LEVEL-->	Recovered Controls	Treated with 1.5mg/L, then Recovered	P-Value	Conclusion
Stomach, glandular				
Dilation, gastric pits	3/6	2/5	1.000	No Significant Difference
Infiltrate, lymphoplasmacytic, fat	0/6	0/5	1.000	No Significant Difference
Salivary gland, submand, sublingual, parotid				
Lymph node, hyperplasia, plasmacytic, with germinal centers.	2/4	1/5	0.524	No Significant Difference
Infiltrate, lymphoplasmacytic, submandibular saliv gl, periductal	0/5	0/6	1.000	No Significant Difference
Mammary tissue				
Mammary epith cell prolif, with atypia	0/3	1/3	1.000	No Significant Difference
Eye with Harderian gland				
Secretion, pigmented, inspissated	1/5	1/5	1.000	No Significant Difference
Infiltrate, lymphoplasmacytic, focal	1/5	1/5	1.000	No Significant Difference
Palpebral abscess (stye)	0/5	0/5	1.000	No Significant Difference
Thymus				
Hemorrhage	2/5	3/6	1.000	No Significant Difference
Hyperplasia, epithelial, focal	1/5	0/6	1.000	No Significant Difference
Ectopic parathyroid tissue	0/5	0/6	1.000	No Significant Difference
LUNG				
Congestion, alveolar septal	3/5	2/6	0.567	No Significant Difference
Congestion, venous	1/5	2/6	1.000	No Significant Difference
Erythrocyte extravasation, alveolar	2/5	4/6	0.567	No Significant Difference
Erythrophagocytosis	0/5	1/6	1.000	No Significant Difference
Hemorrhage, perivascular or peribronchiolar	1/5	2/6	1.000	No Significant Difference
Edema, perivascular	0/5	0/6	1.000	No Significant Difference
Ateletasis, alveolar	3/5	4/6	1.000	No Significant Difference
Histiocytosis, alveolar	0/5	1/6	1.000	No Significant Difference
Infiltrate, granulocytic	0/5	2/6	0.455	No Significant Difference
Edema, subpleural	0/5	0/6	1.000	No Significant Difference
Fibrosis, alveolar, focal	0/5	0/6	1.000	No Significant Difference
Crystals, eosinophilic, alveolar	0/5	0/6	1.000	No Significant Difference

Trachea				
Infiltrate, lymphocytic, subepithelial	1/5	0/6	1.000	No Significant Difference
Increased mucosal eosinophilic droplets:Y/N	3/5	2/6	0.567	No Significant Difference
Thyroid gland				
Hyperplasia, C cell	2/5	0/4	0.444	No Significant Difference
Cyst, thyroid, squamous	0/5	0/4	1.000	No Significant Difference
Ectopic thymus	0/5	0/6	1.000	No Significant Difference
Skeletal muscle				
Infiltrate, lymphohistiocytic, focal, skeletal muscle	0/5	0/6	1.000	No Significant Difference
Lymph node, tracheal				
Draining hemorrhage	1/4	1/4	1.000	No Significant Difference
Pigment, cytoplasmic, macrophages	2/4	2/4	1.000	No Significant Difference
Infiltrate, eosinophilic	0/4	0/4	1.000	No Significant Difference
Heart with great vessels				
Lymphatics, ectatic, heart base	1/5	0/6	1.000	No Significant Difference
Infiltrate, mastocytic and lymphocytic, epicardial fat	0/5	1/6	1.000	No Significant Difference
Adrenal gland				
Ectopic medullary cells	0/6	1/6	1.000	No Significant Difference
Vacuoles, cortical	1/6	1/6	1.000	No Significant Difference
Kidney				
Increased proteinaceous fluid, proximal tubules	5/6	5/6	1.000	No Significant Difference
Basophilic tubules	0/6	1/6	1.000	No Significant Difference
Renal tubule-Hyperplasia, oncocytic	0/6	1/6	1.000	No Significant Difference
infiltrate, lymphoplasmacytic	0/6	0/6	1.000	No Significant Difference
Cystic tubules, focal	0/6	0/6	1.000	No Significant Difference
Liver				
Hepatocellular loss, focal, with leukocytes	1/6	0/6	1.000	No Significant Difference
Infiltrate, histiocytic, focal	3/6	4/6	1.000	No Significant Difference
Infiltrate, lymphocytic, portal	1/6	0/6	1.000	No Significant Difference
Fibrosis, portal, focal	0/6	0/6	1.000	No Significant Difference
Uterus				
Hyperplasia, endometrial	0/6	0/6	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 1				
Level 1- Hyperplasia, transitional epithelium	1/6	1/5	1.000	No Significant Difference
Level 1 - Hyperplasia, respiratory epithelium	2/6	3/5	0.567	No Significant Difference
Level 1- Infiltrate, granulocytic	3/6	3/5	1.000	No Significant Difference
Level 1- Infiltrate, lymphocytic	0/6	1/5	1.000	No Significant Difference
Level 1 -Nasoturbinate, mucosal degeneration	1/6	0/5	1.000	No Significant Difference
Level 1 - Goblet cell hyperplasia, nasal septum	5/6	4/5	1.000	No Significant Difference

NASAL TURBINATE, LEVEL 2				
Level 2- Goblet cell hyperplasia, nasal septum	1/6	2/5	0.545	No Significant Difference
Level 2 - Hyperplasia, respiratory epithelium	3/6	1/5	0.545	No Significant Difference
Level 2- Infiltrate, granulocytic	1/6	1/5	1.000	No Significant Difference
Level 2-Infiltrate, lymphocytic	2/6	2/5	1.000	No Significant Difference
NASAL TURBINATE, LEVEL 3				
Level 3 - Hyperplasia, respiratory epithelium	1/5	2/3	0.464	No Significant Difference

SUBACUTE STUDY SEVERITY SCORES FOR FEMALE RATS EXPOSED TO RED SMOKE AT: 1.5mg/L, 0.5mg/L, 0.1mg/L or 1.5mg/L WITH 30 DAY RECOVERY PERIOD

Stomach, glandular		0	1	2	3	4	Total
Dilation, gastric pits	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	3	3	0	0	0	6
	R-1.5	3	2	0	0	0	5

Stomach, glandular		0	1	2	3	4	Total
Infiltrate, lymphoplasmacytic, fat	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	0	0	0	5
Salivary gland, submand, sublingual, parotid		0	1	2	3	4	Total
Lymph node, hyperplasia, plasmacytic, with germinal centers.	CTRL	2	1	2	0	0	5
	1.5	5	0	0	0	0	5
	0.5						0
	0.1						0
	R-CTRL	2	1	1	0	0	4
	R-1.5	4	0	0	1	0	5

Salivary gland, submand, sublingual, parotid		0	1	2	3	4	Total
Infiltrate, lymphoplasmacytic, submandibular saliv gland, periductal	CTRL	6	0	0	0	0	6
	1.5	5	0	0	0	0	5
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6
Mammary tissue		0	1	2	3	4	Total
Epithelial cell proliferation	CTRL	0	1	1	0	0	2
	1.5	1	1	0	0	0	2
	0.5						0
	0.1						0
	R-CTRL	3	0	0	0	0	3
	R-1.5	2	1	0	0	0	3
Eye with Harderian gland		0	1	2	3	4	Total
Secretion, pigmented, inspissated	CTRL	5	1	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	1	0	0	0	5
	R-1.5	4	1	0	0	0	5
Eye with Harderian gland		0	1	2	3	4	Total
Infiltrate, lymphoplasmacytic, focal	CTRL	5	1	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	0	1	0	0	5
	R-1.5	4	1	0	0	0	5

Eye with Harderian gland		0	1	2	3	4	Total
Palpebral abscess (hordeoleum)	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	0	0	0	0	5
Thymus		0	1	2	3	4	Total
Hemorrhage	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	3	2	0	0	0	5
	R-1.5	3	3	0	0	0	6
Thymus		0	1	2	3	4	Total
Hyperplasia, epithelial, focal	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	1	0	0	0	5
	R-1.5	6	0	0	0	0	6
Thymus		0	1	2	3	4	Total
Ectopic parathyroid tissue	CTRL	5	1	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6
LUNG		0	1	2	3	4	Total
Congestion, alveolar septal	CTRL	6	0	0	0	0	6
	1.5	5	0	1	0	0	6
	0.5						0
	0.1						0
	R-CTRL	2	2	1	0	0	5
	R-1.5	4	1	1	0	0	6

LUNG		0	1	2	3	4	Total
Congestion, venous	CTRL	5	0	1	0	0	6
	1.5	2	4	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	1	0	0	0	5
	R-1.5	4	1	1	0	0	6

LUNG		0	1	2	3	4	Total
Erythrocyte extravasation, alveolar	CTRL	5	1	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	3	2	0	0	0	5
	R-1.5	2	3	1	0	0	6

LUNG		0	1	2	3	4	Total
Erythrophagocytosis	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	1	0	0	0	6

LUNG		0	1	2	3	4	Total
Hemorrhage, perivascular or peribronchiolar	CTRL	3	3	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	1	0	0	0	5
	R-1.5	4	2	0	0	0	6

LUNG		0	1	2	3	4	Total
Edema, perivascular	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Ateletasis, alveolar α	CTRL	4	2	0	0	0	6
	1.5	2	3	1	0	0	6
	0.5						0
	0.1						0
	R-CTRL	2	3	0	0	0	5
	R-1.5	2	2	1	0	1	6

LUNG		0	1	2	3	4	Total
Histiocytosis, alveolar	CTRL	6	0	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	1	0	0	0	6

LUNG		0	1	2	3	4	Total
Infiltrate, granulocytic	CTRL	5	0	1	0	0	6
	1.5	5	0	1	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	4	2	0	0	0	6

LUNG		0	1	2	3	4	Total
Edema, subpleural	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Fibrosis, alveolar, focal	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Crystals, eosinophilic, alveolar	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

Trachea		0	1	2	3	4	Total
Infiltrate, lymphocytic, subepithelial	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	1	0	0	0	5
	R-1.5	6	0	0	0	0	6

Trachea		0	1	2	3	4	Total
Increased mucosal eosinophilic droplets:Y/N	CTRL	5	1	0	0	0	6
	1.5	2	4	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	2	3	0	0	0	5
	R-1.5	4	2	0	0	0	6
Thyroid gland		0	1	2	3	4	Total
Hyperplasia, C cell	CTRL	4	0	0	0	0	4
	1.5	4	0	0	0	0	4
	0.5						0
	0.1						0
	R-CTRL	3	2	0	0	0	5
	R-1.5	4	0	0	0	0	4
Thyroid gland		0	1	2	3	4	Total
Cyst, thyroid, squamous	CTRL	2	2	0	0	0	4
	1.5	4	0	0	0	0	4
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	4	0	0	0	0	4
Thyroid gland		0	1	2	3	4	Total
Ectopic thymus	CTRL	3	1	0	0	0	4
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6
Skeletal muscle		0	1	2	3	4	Total
Infiltrate, lymphohistiocytic, focal, skeletal muscle	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6
Lymph node, tracheal		0	1	2	3	4	Total
Draining hemorrhage	CTRL	4	1	0	0	0	5
	1.5	4	1	0	0	0	5
	0.5						0
	0.1						0
	R-CTRL	3	1	0	0	0	4
	R-1.5	3	1	0	0	0	4

Lymph node, tracheal		0	1	2	3	4	Total
Pigment, cytoplasmic, macrophages	CTRL	4	1	0	0	0	5
	1.5	5	0	0	0	0	5
	0.5						0
	0.1						0
	R-CTRL	2	2	0	0	0	4
	R-1.5	2	2	0	0	0	4

Lymph node, tracheal		0	1	2	3	4	Total
Infiltrate, eosinophilic	CTRL	4	1	0	0	0	5
	1.5	5	0	0	0	0	5
	0.5						0
	0.1						0
	R-CTRL	4	0	0	0	0	4
	R-1.5	4	0	0	0	0	4

Heart with great vessels		0	1	2	3	4	Total
Lymphatics, ectatic, heart base	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	4	0	1	0	0	5
	R-1.5	6	0	0	0	0	6

Heart with great vessels		0	1	2	3	4	Total
Infiltrate, mastocytic and lymphocytic, epicardial fat	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	1	0	0	0	6

Adrenal gland		0	1	2	3	4	Total
Ectopic medullary cells	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

Adrenal gland		0	1	2	3	4	Total
Vacuoles, cortical	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	1	0	0	0	6
	R-1.5	5	1	0	0	0	6

Kidney		0	1	2	3	4	Total
Increased proteinaceous fluid, proximal tubules	CTRL	5	1	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	1	4	1	0	0	6
	R-1.5	1	3	2	0	0	6

Kidney		0	1	2	3	4	Total
Basophilic tubules	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

Kidney		0	1	2	3	4	Total
Renal tubule-Hyperplasia, oncocytic	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

Kidney		0	1	2	3	4	Total
infiltrate, lymphoplasmacytic	CTRL	6	0	0	0	0	6
	1.5	3	3	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

Kidney		0	1	2	3	4	Total
Cystic tubules, focal	CTRL	6	0	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

Liver		0	1	2	3	4	Total
Hepatocellular loss, focal, with leukocytes	CTRL	5	0	0	0	0	5
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	5	1	0	0	0	6
	R-1.5	6	0	0	0	0	6

Liver		0	1	2	3	4	Total
Infiltrate, histiocytic, focal	CTRL	2	3	0	0	0	5
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	3	3	0	0	0	6
	R-1.5	2	4	0	0	0	6

Liver		0	1	2	3	4	Total
Fibrosis, portal, focal	CTRL	5	0	0	0	0	5
	1.5	5	1	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

Uterus		0	1	2	3	4	Total
Hyperplasia, endometrial	CTRL	4	1	1	0	0	6
	1.5	6	0	0	0	0	6
	0.5						0
	0.1						0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Hyperplasia, transitional epithelium	CTRL	4	0	0	0	0	4
	1.5	0	0	4	1	0	5
	0.5	0	1	0	2	0	3
	0.1	0	1	2	1	0	4
	R-CTRL	5	0	0	1	0	6
	R-1.5	4	1	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 - Hyperplasia, respiratory epithelium	CTRL	2	2	0	0	0	4
	1.5	2	2	1	0	0	5
	0.5	2	0	1	0	0	3
	0.1	2	0	1	1	0	4
	R-CTRL	4	2	0	0	0	6
	R-1.5	2	2	1	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Infiltrate, granulocytic	CTRL	4	0	0	0	0	4
	1.5	4	1	0	0	0	5
	0.5	2	1	0	0	0	3
	0.1	0	3	1	0	0	4
	R-CTRL	3	3	0	0	0	6
	R-1.5	2	3	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Infiltrate, lymphocytic	CTRL	4	0	0	0	0	4
	1.5	5	0	0	0	0	5
	0.5	2	1	0	0	0	3
	0.1	0	4	0	0	0	4
	R-CTRL	6	0	0	0	0	6
	R-1.5	4	1	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 -Nasoturbinate, mucosal degeneration	CTRL	4	0	0	0	0	4
	1.5	2	2	1	0	0	5
	0.5	2	1	0	0	0	3
	0.1	3	0	0	1	0	4
	R-CTRL	5	1	0	0	0	6
	R-1.5	5	0	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 Goblet cell hyperplasia, nasal septum	CTRL	0	1	2	1	0	4
	1.5	1	1	3	0	0	5
	0.5	0	0	2	1	0	3
	0.1	0	0	1	3	0	4
	R-CTRL	1	1	3	1	0	6
	R-1.5	1	2	2	0	0	5

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2- Goblet cell hyperplasia, nasal septum	CTRL	3	1	0	0	0	4
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	3	1	1	0	0	5
	R-CTRL	5	0	1	0	0	6
	R-1.5	3	1	1	0	0	5

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2 - Hyperplasia, respiratory epithelium	CTRL	4	0	0	0	0	4
	1.5	5	1	0	0	0	6
	0.5	2	3	1	0	0	6
	0.1	4	0	1	0	0	5
	R-CTRL	3	3	0	0	0	6
	R-1.5	4	1	0	0	0	5

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2- Infiltrate, granulocytic	CTRL	4	0	0	0	0	4
	1.5	4	2	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	4	0	0	0	5
	R-CTRL	5	1	0	0	0	6
	R-1.5	4	1	0	0	0	5

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2-Infiltrate, lymphocytic	CTRL	3	1	0	0	0	4
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	4	0	0	0	5
	R-CTRL	4	2	0	0	0	6
	R-1.5	3	2	0	0	0	5
NASAL TURBINATE, LEVEL 3		0	1	2	3	4	Total
Level 3 - Hyperplasia, respiratory epithelium	CTRL	4	2	0	0	0	6
	1.5	3	2	0	0	0	5
	0.5	4	1	0	0	0	5
	0.1	4	2	0	0	0	6
	R-CTRL	4	1	0	0	0	5
	R-1.5	1	2	0	0	0	3

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (1.5 mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

Males

RED SMOKE EXPOSURE LEVEL-->	Control	1.5 mg/L	P-Value	Conclusion
STOMACH, GLANDULAR				
Dilation, gastric pits	3/6	0/6	0.182	No Significant Difference
SALIVARY GLANDS (submandibular, sublingual, parotid)				
Infiltrate, lymphoplasmacytic, submnd saliv gl	0/5	1/6	1.000	No Significant Difference
EYE W/HARDERIAN GLAND				
Infiltrate, lymphocytic, subepithelial, palpebra	0/6	0/6	1.000	No Significant Difference
Secretion, pigmented, inspissated	1/6	0/6	1.000	No Significant Difference
Palpebral abscess (sty)	0/6	0/6	1.000	No Significant Difference
THYMUS				
Hemorrhage	0/6	0/6	1.000	No Significant Difference

LUNG				
Congestion, alveolar septal	1/6	3/6	0.545	No Significant Difference
Congestion, venous	2/6	1/6	1.000	No Significant Difference
Erythrocyte extravasation, alveolar	4/6	1/6	0.242	No Significant Difference
Erythrophagocytosis	1/6	2/6	1.000	No Significant Difference
Hemorrhage, perivascular or peribronchiolar	4/6	2/6	0.567	No Significant Difference
Edema, perivascular	0/6	2/6	0.455	No Significant Difference
Ateletasis, alveolar **α**	2/6	5/6	0.242	No Significant Difference
Histiocytosis, alveolar	1/6	2/6	1.000	No Significant Difference
Infiltrate, granulocytic	0/6	1/6	1.000	No Significant Difference
Edema, subpleural	0/6	0/6	1.000	No Significant Difference
Fibrosis, alveolar, focal	0/6	1/6	1.000	No Significant Difference
Hypertrophy, smooth muscle, vascular	0/6	1/6	1.000	No Significant Difference
Crystals, eosinophilic, alveolar	0/6	0/6	1.000	No Significant Difference

TRACHEA				
Increased mucosal eosinophilic droplets:Y/N	3/5	6/6	0.182	No Significant Difference
THYROID GLAND				
Ectopic thymus	0/6	0/6	1.000	No Significant Difference
Ultimobranchial cysts	0/6	0/6	1.000	No Significant Difference
LYMPH NODE, Tracheal				
Draining hemorrhage	2/3	0/5	0.107	No Significant Difference
ADRENAL GLAND				
Vacuoles, cortical	2/6	3/6	1.000	No Significant Difference
KIDNEY				
Basophilic tubules	4/6	2/6	0.567	No Significant Difference
infiltrate, lymphoplasmacytic	1/6	3/6	0.545	No Significant Difference
Cystic tubules, focal	0/6	1/6	1.000	No Significant Difference
Congestion	0/6	0/6	1.000	No Significant Difference
Infarct	0/6	0/6	1.000	No Significant Difference

LIVER				
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	0/6	0/6	1.000	No Significant Difference
Angiectasis, cavernous	0/6	0/6	1.000	No Significant Difference
Congestion	0/6	0/6	1.000	No Significant Difference
Infiltrate, histiocytic, focal	1/6	3/6	0.545	No Significant Difference
Infiltrate, granulocytic, focal	1/6	0/6	1.000	No Significant Difference
Infiltrate, lymphocytic, portal	1/6	2/6	1.000	No Significant Difference
Fibrosis, portal, focal	0/6	1/6	1.000	No Significant Difference
TESTIS				
Diameter reduced by > 30%	0/6	0/6	1.000	No Significant Difference
Seminiferous tubules degenerate (or Atrophic)	0/6	0/6	1.000	No Significant Difference
SEMINAL VESICLE				
Hyperplasia, epithelial (Unilateral or Bilateral)	0/6	2/6	0.455	No Significant Difference
PROSTATE, dorsal lobe				
infiltrate, lymphoplasmacytic	1/6	0/6	1.000	No Significant Difference

NASAL TURBINATES, Level 1				
Level 1- Hyperplasia, transitional epithelium	0/6	6/6	0.020	1.5 mg/kg > Control
Level 1 - Hyperplasia, respiratory epithelium	2/6	5/6	0.242	No Significant Difference
Level 1- Infiltrate, granulocytic	1/6	4/6	0.242	No Significant Difference
Level 1- Infiltrate, lymphocytic	1/6	3/6	0.545	No Significant Difference
Level 1- Nasal turbinate, mucosa, degeneration	0/6	2/6	0.455	No Significant Difference
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	0/1	0/0	-	No Significant Difference
Level 1 - Goblet cell hyperplasia, nasal septum	4/6	6/6	0.455	No Significant Difference
NASAL TURBINATE, Level 2				
Level 2 - Goblet cell hyperplasia, nasal septum	1/6	3/6	0.545	No Significant Difference
Level 2-Hyperplasia, respiratory epithelium	4/6	4/6	1.000	No Significant Difference
Level 2- Infiltrate, granulocytic	0/6	5/6	0.015	1.5 mg/kg > Control
Level 2- Nasal turbinate, mucosa, degeneration	0/6	3/6	0.182	No Significant Difference
Level 2 - Infiltrate, lymphocytic	2/6	0/6	0.455	No Significant Difference
NASAL TURBINATE, Level 3				
Level 3-Hyperplasia, respiratory epithelium	0/3	2/2	0.100	No Significant Difference
T3 non-NALT Infiltrate, lymphocytic, subepithelial	0/3	0/2	1.000	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (0.5 mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

Males

RED SMOKE EXPOSURE LEVEL-->	Control	0.5 mg/L	P-Value	Conclusion
LUNG				
Congestion, alveolar septal	1/6	5/6	0.080	No Significant Difference
Congestion, venous	2/6	2/6	1.000	No Significant Difference
Erythrocyte extravasation, alveolar	4/6	5/6	1.000	No Significant Difference
Erythrophagocytosis	1/6	0/6	1.000	No Significant Difference
Hemorrhage, perivascular or peribronchiolar	4/6	5/6	1.000	No Significant Difference
Edema, perivascular	0/6	0/6	1.000	No Significant Difference
Ateletasis, alveolar **α**	2/6	3/6	1.000	No Significant Difference
Histiocytosis, alveolar	1/6	2/6	1.000	No Significant Difference
Infiltrate, granulocytic	0/6	0/6	1.000	No Significant Difference
Edema, subpleural	0/6	0/6	1.000	No Significant Difference
Fibrosis, alveolar, focal	0/6	0/6	1.000	No Significant Difference
Hypertrophy, smooth muscle, vascular	0/6	1/6	1.000	No Significant Difference
Crystals, eosinophilic, alveolar	0/6	0/6	1.000	No Significant Difference
TRACHEA				
Increased mucosal eosinophilic droplets:Y/N	3/5	1/6	0.242	No Significant Difference
THYROID GLAND				
Ectopic thymus	0/6	1/6	1.000	No Significant Difference
Ultimobranchial cysts	0/6	1/6	1.000	No Significant Difference
LYMPH NODE, Tracheal				
Draining hemorrhage	2/3	2/4	1.000	No Significant Difference
ADRENAL GLAND				
Vacuoles, cortical	2/6	1/6	1.000	No Significant Difference
KIDNEY				
Basophilic tubules	4/6	0/6	0.061	No Significant Difference
infiltrate, lymphoplasmacytic	1/6	0/6	1.000	No Significant Difference
Cystic tubules, focal	0/6	0/6	1.000	No Significant Difference
Congestion	0/6	0/6	1.000	No Significant Difference
Infarct	0/6	0/6	1.000	No Significant Difference

LIVER				
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	0/6	0/6	1.000	No Significant Difference
Angiectasis, cavernous	0/6	0/6	1.000	No Significant Difference
Congestion	0/6	2/6	0.455	No Significant Difference
Infiltrate, histiocytic, focal	1/6	0/6	1.000	No Significant Difference
Infiltrate, granulocytic, focal	1/6	0/6	1.000	No Significant Difference
Infiltrate, lymphocytic, portal	1/6	1/6	1.000	No Significant Difference
Fibrosis, portal, focal	0/6	0/6	1.000	No Significant Difference
NASAL TURBINATES, Level 1				
Level 1- Hyperplasia, transitional epithelium	0/6	4/6	0.061	No Significant Difference
Level 1 - Hyperplasia, respiratory epithelium	2/6	2/6	1.000	No Significant Difference
Level 1- Infiltrate, granulocytic	1/6	3/6	0.545	No Significant Difference
Level 1- Infiltrate, lymphocytic	1/6	0/6	1.000	No Significant Difference
Level 1- Nasal turbinate, mucosa, degeneration	0/6	0/6	1.000	No Significant Difference
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	0/1	0/0	-	No Significant Difference
Level 1 - Goblet cell hyperplasia, nasal septum	4/6	6/6	0.455	No Significant Difference

NASAL TURBINATE, Level 2				
Level 2 - Goblet cell hyperplasia, nasal septum	1/6	4/5	0.080	No Significant Difference
Level 2-Hyperplasia, respiratory epithelium	4/6	2/5	0.567	No Significant Difference
Level 2- Infiltrate, granulocytic	0/6	0/5	1.000	No Significant Difference
Level 2- Nasal turbinate, mucosa, degeneration	0/6	1/5	0.455	No Significant Difference
Level 2 - Infiltrate, lymphocytic	2/6	0/5	0.455	No Significant Difference
NASAL TURBINATE, Level 3				
Level 3-Hyperplasia, respiratory epithelium	0/3	3/6	0.464	No Significant Difference
T3 non-NALT Infiltrate, lymphocytic, subepithelial	0/3	2/6	0.500	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (0.1 mg/L) RED SMOKE-EXPOSED MALE RATS COMPARED TO AIR (VEHICLE) CONTROLS

Males

RED SMOKE EXPOSURE LEVEL-->	Control	0.1 mg/L	P-Value	Conclusion
NASAL TURBINATES, Level 1				
Level 1- Hyperplasia, transitional epithelium	0/6	1/1	0.143	No Significant Difference
Level 1 - Hyperplasia, respiratory epithelium	2/6	1/1	0.429	No Significant Difference
Level 1- Infiltrate, granulocytic	1/6	1/1	0.286	No Significant Difference
Level 1- Infiltrate, lymphocytic	1/6	1/1	0.286	No Significant Difference
Level 1- Nasal turbinate, mucosa, degeneration	0/6	1/1	0.143	No Significant Difference
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	0/1	0/1	1.000	No Significant Difference
Level 1 - Goblet cell hyperplasia, nasal septum	4/6	1/1	1.000	No Significant Difference
NASAL TURBINATE, Level 2				
Level 2 - Goblet cell hyperplasia, nasal septum	1/6	3/6	0.545	No Significant Difference
Level 2-Hyperplasia, respiratory epithelium	4/6	3/6	1.000	No Significant Difference
Level 2- Infiltrate, granulocytic	0/6	3/6	0.182	No Significant Difference
Level 2- Nasal turbinate, mucosa, degeneration	0/6	0/6	1.000	No Significant Difference
Level 2 - Infiltrate, lymphocytic	2/6	1/6	1.000	No Significant Difference
NASAL TURBINATE, Level 3				
Level 3-Hyperplasia, respiratory epithelium	0/3	4/4	0.029	0.1mg/kg > Control
T3 non-NALT Infiltrate, lymphocytic, subepithelial	0/3	0/4	1.000	No Significant Difference

SUBACUTE STUDY HISTOLOGIC FINDINGS IN (1.5 mg/L) RED SMOKE-EXPOSED, THEN RECOVERED MALE RATS COMPARED TO AGE-MATCHED AIR-EXPOSED CONTROLS

Males

RED SMOKE EXPOSURE LEVEL-->	Recovered Controls	Treated with 1.5mg/L, then Recovered	P-Value	Conclusion
STOMACH, GLANDULAR				
Dilation, gastric pits	3/6	3/6	1.000	No Significant Difference
SALIVARY GLANDS (submandibular, sublingual, parotid)				
Infiltrate, lymphoplasmacytic, submnd saliv gl	0/6	0/5	1.000	No Significant Difference
EYE W/HARDERIAN GLAND				
Infiltrate, lymphocytic, subepithelial, palpebra	1/6	0/6	1.000	No Significant Difference
Secretion, pigmented, inspissated	4/6	0/6	0.061	No Significant Difference
Palpebral abscess (sty)	0/6	1/6	1.000	No Significant Difference
THYMUS				
Hemorrhage	3/6	0/6	0.182	No Significant Difference

LUNG				
Congestion, alveolar septal	6/6	5/6	1.000	No Significant Difference
Congestion, venous	4/6	5/6	1.000	No Significant Difference
Erythrocyte extravasation, alveolar	3/6	4/6	1.000	No Significant Difference
Erythrophagocytosis	0/6	0/6	1.000	No Significant Difference
Hemorrhage, perivascular or peribronchiolar	4/6	0/6	0.061	No Significant Difference
Edema, perivascular	0/6	1/6	1.000	No Significant Difference
Ateletasis, alveolar α	2/6	4/6	0.567	No Significant Difference
Histiocytosis, alveolar	0/6	1/6	1.000	No Significant Difference
Infiltrate, granulocytic	0/6	0/6	1.000	No Significant Difference
Edema, subpleural	0/6	0/6	1.000	No Significant Difference
Fibrosis, alveolar, focal	0/6	0/6	1.000	No Significant Difference
Hypertrophy, smooth muscle, vascular	0/6	0/6	1.000	No Significant Difference
Crystals, eosinophilic, alveolar	0/4	0/0	-	No Significant Difference
TRACHEA				
Increased mucosal eosinophilic droplets:Y/N	0/5	4/6	0.061	No Significant Difference
THYROID GLAND				
Ectopic thymus	1/5	0/5	1.000	No Significant Difference
Ultimobranchial cysts	1/5	0/5	1.000	No Significant Difference
LYMPH NODE, Tracheal				
Draining hemorrhage	0/5	2/4	0.167	No Significant Difference
ADRENAL GLAND				
Vacuoles, cortical	2/6	3/6	1.000	No Significant Difference

KIDNEY				
Basophilic tubules	2/6	0/6	0.455	No Significant Difference
infiltrate, lymphoplasmacytic	2/6	2/6	1.000	No Significant Difference
Cystic tubules, focal	1/6	1/6	1.000	No Significant Difference
Congestion	1/6	0/6	1.000	No Significant Difference
Infarct	0/6	0/6	1.000	No Significant Difference
LIVER				
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	1/6	1/6	1.000	No Significant Difference
Angiectasis, cavernous	0/6	1/6	1.000	No Significant Difference
Congestion	1/6	0/6	1.000	No Significant Difference
Infiltrate, histiocytic, focal	1/6	3/6	0.545	No Significant Difference
Infiltrate, granulocytic, focal	0/6	1/6	1.000	No Significant Difference
Infiltrate, lymphocytic, portal	3/6	2/6	1.000	No Significant Difference
Fibrosis, portal, focal	0/6	0/6	1.000	No Significant Difference

TESTIS				
Diameter reduced by > 30%	0/6	1/6	1.000	No Significant Difference
Seminiferous tubules degenerate (or Atrophic)	0/6	1/6	1.000	No Significant Difference
SEMINAL VESICLE				
Hyperplasia, epithelial (Unilateral or Bilateral)	0/6	3/6	0.182	No Significant Difference
PROSTATE, dorsal lobe				
infiltrate, lymphoplasmacytic	0/5	0/2	1.000	No Significant Difference
NASAL TURBINATES, Level 1				
Level 1- Hyperplasia, transitional epithelium	0/5	0/5	1.000	No Significant Difference
Level 1 - Hyperplasia, respiratory epithelium	2/5	1/5	1.000	No Significant Difference
Level 1- Infiltrate, granulocytic	1/5	0/5	1.000	No Significant Difference
Level 1- Infiltrate, lymphocytic	0/5	2/5	0.444	No Significant Difference
Level 1- Nasal turbinate, mucosa, degeneration	0/5	0/5	1.000	No Significant Difference
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	0/0	0/0	-	No Significant Difference
Level 1 - Goblet cell hyperplasia, nasal septum	5/5	5/5	1.000	No Significant Difference
NASAL TURBINATE, Level 2				
Level 2 - Goblet cell hyperplasia, nasal septum	2/5	3/6	1.000	No Significant Difference
Level 2-Hyperplasia, respiratory epithelium	0/5	4/6	0.061	No Significant Difference
Level 2- Infiltrate, granulocytic	0/5	0/6	1.000	No Significant Difference
Level 2- Nasal turbinate, mucosa, degeneration	0/5	0/6	1.000	No Significant Difference
Level 2 - Infiltrate, lymphocytic	1/5	2/6	1.000	No Significant Difference
NASAL TURBINATE, Level 3				
Level 3-Hyperplasia, respiratory epithelium	2/5	0/0	-	No Significant Difference
T3 non-NALT Infiltrate, lymphocytic, subepithelial	0/6	0/0	-	No Significant Difference

SUBACUTE STUDY SEVERITY SCORES FOR MALE RATS EXPOSED TO RED SMOKE AT: 1.5mg/L, 0.5mg/L, 0.1mg/L or 1.5mg/L WITH 30 DAY RECOVERY PERIOD

Stomach, glandular		0	1	2	3	4	Total
Dilation, gastric pits	CTRL	3	3	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	3	3	0	0	0	6
	R-1.5	3	3	0	0	0	6
Salivary gland, submand,		0	1	2	3	4	Total
Infiltrate, lymphoplasmacytic, submandibular saliv gl, periductal	CTRL	5	0	0	0	0	5
	1.5	5	1	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	0	0	0	5

Eye with Harderian gland		0	1	2	3	4	Total
Infiltrate, lymphocytic, subepithelial, palpebra	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	5	1	0	0	0	6
	R-1.5	6	0	0	0	0	6

Eye with Harderian gland		0	1	2	3	4	Total
Secretion, pigmented, inspissated	CTRL	5	1	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	2	4	0	0	0	6
	R-1.5	6	0	0	0	0	6

Eye with Harderian gland		0	1	2	3	4	Total
Palpebral abscess (sty)	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	0	1	0	6

Thymus		0	1	2	3	4	Total
Hemorrhage	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	3	2	1	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Congestion, alveolar septal	CTRL	5	1	0	0	0	6
	1.5	3	1	1	1	0	6
	0.5	1	2	3	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	0	1	4	1	0	6
	R-1.5	1	1	4	0	0	6

LUNG		0	1	2	3	4	Total
Congestion, venous	CTRL	4	2	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	4	2	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	2	1	2	1	0	6
	R-1.5	1	1	2	2	0	6

LUNG		0	1	2	3	4	Total
Erythrocyte extravasation, alveolar	CTRL	2	4	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	1	3	2	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	3	2	0	1	0	6
	R-1.5	2	3	1	0	0	6

LUNG		0	1	2	3	4	Total
Erythrophagocytosis	CTRL	5	1	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Hemorrhage, perivascular or peribronchiolar	CTRL	2	4	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	1	4	1	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	2	4	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Edema, perivascular	CTRL	6	0	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

LUNG		0	1	2	3	4	Total
Ateletasis, alveolar	CTRL	4	1	1	0	0	6
	1.5	1	2	3	0	0	6
	0.5	3	3	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	1	0	0	1	6
	R-1.5	2	2	2	0	0	6

LUNG		0	1	2	3	4	Total
Histiocytosis, alveolar	CTRL	5	1	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	4	2	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

LUNG		0	1	2	3	4	Total
Infiltrate, granulocytic	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Edema, subpleural	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Fibrosis, alveolar, focal	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Hypertrophy, smooth muscle, vascular	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	5	1	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

LUNG		0	1	2	3	4	Total
Crystals, eosinophilic, alveolar	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	0	0	0	0	4
	R-1.5	0	0	0	0	0	0

Trachea		0	1	2	3	4	Total
Increased mucosal eosinophilic droplets:Y/N	CTRL	2	3	0	0	0	5
	1.5	0	6	0	0	0	6
	0.5	5	1	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	5	0	0	0	0	5
	R-1.5	2	4	0	0	0	6

Thyroid gland		0	1	2	3	4	Total
Ectopic thymus	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	5	1	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	1	0	0	0	5
	R-1.5	5	0	0	0	0	5

Thyroid gland		0	1	2	3	4	Total
Ultimobranchial cysts	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	5	0	1	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	1	0	0	0	5
	R-1.5	5	0	0	0	0	5

Lymph node, tracheal		0	1	2	3	4	Total
Draining hemorrhage	CTRL	1	2	0	0	0	3
	1.5	5	0	0	0	0	5
	0.5	2	2	0	0	0	4
	0.1	0	0	0	0	0	0
	R-CTRL	5	0	0	0	0	5
	R-1.5	2	1	1	0	0	4

Adrenal gland		0	1	2	3	4	Total
Vacuoles, cortical	CTRL	4	2	0	0	0	6
	1.5	3	3	0	0	0	6
	0.5	5	1	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	2	0	0	0	6
	R-1.5	3	3	0	0	0	6

Kidney		0	1	2	3	4	Total
Basophilic tubules	CTRL	2	4	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	2	0	0	0	6
	R-1.5	6	0	0	0	0	6

Kidney		0	1	2	3	4	Total
infiltrate, lymphoplasmacytic	CTRL	5	1	0	0	0	6
	1.5	3	3	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	4	2	0	0	0	6
	R-1.5	4	2	0	0	0	6

Kidney		0	1	2	3	4	Total
Cystic tubules, focal	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	5	1	0	0	0	6
	R-1.5	5	1	0	0	0	6

Kidney		0	1	2	3	4	Total
Congestion	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	5	1	0	0	0	6
	R-1.5	6	0	0	0	0	6

Kidney		0	1	2	3	4	Total
Infarct	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

Liver		0	1	2	3	4	Total
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	0	0	0	0	1
	R-CTRL	5	1	0	0	0	6
	R-1.5	5	0	0	1	0	6

Liver		0	1	2	3	4	Total
Angiectasis, cavernous	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	0	0	0	0	1
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	1	0	0	6

Liver		0	1	2	3	4	Total
Congestion	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	4	2	0	0	0	6
	0.1	1	0	0	0	0	1
	R-CTRL	5	1	0	0	0	6
	R-1.5	6	0	0	0	0	6

Liver		0	1	2	3	4	Total
Infiltrate, histiocytic, focal	CTRL	5	1	0	0	0	6
	1.5	3	3	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	0	0	0	0	1
	R-CTRL	5	1	0	0	0	6
	R-1.5	3	3	0	0	0	6

Liver		0	1	2	3	4	Total
Infiltrate, granulocytic, focal	CTRL	5	1	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	0	0	0	0	1
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	1	0	0	0	6

Liver		0	1	2	3	4	Total
Infiltrate, lymphocytic, portal	CTRL	5	1	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	5	1	0	0	0	6
	0.1	1	1	0	0	0	2
	R-CTRL	3	3	0	0	0	6
	R-1.5	4	2	0	0	0	6

Liver		0	1	2	3	4	Total
Fibrosis, portal, focal	CTRL	6	0	0	0	0	6
	1.5	5	1	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	1	0	0	0	1	2
	R-CTRL	6	0	0	0	0	6
	R-1.5	6	0	0	0	0	6

Testis		0	1	2	3	4	Total
Diameter reduced by > 30%	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	0	0	1	6

Testis		0	1	2	3	4	Total
Seminiferous tubules degenerate (or Atrophic)	CTRL	6	0	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	5	0	0	0	1	6

Seminal Vesicle		0	1	2	3	4	Total
Hyperplasia, epithelial (Unilateral or Bilateral)	CTRL	6	0	0	0	0	6
	1.5	4	2	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	6	0	0	0	0	6
	R-1.5	3	2	1	0	0	6

Prostate, dorsal lobe		0	1	2	3	4	Total
infiltrate, lymphoplasmacytic	CTRL	5	0	1	0	0	6
	1.5	6	0	0	0	0	6
	0.5	0	0	0	0	0	0
	0.1	0	0	0	0	0	0
	R-CTRL	5	0	0	0	0	5
	R-1.5	2	0	0	0	0	2

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Hyperplasia, transitional epithelium	CTRL	6	0	0	0	0	6
	1.5	0	0	1	4	1	6
	0.5	2	0	1	2	1	6
	0.1	0	1	0	0	0	1
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	0	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 - Hyperplasia, respiratory epithelium	CTRL	4	2	0	0	0	6
	1.5	1	3	2	0	0	6
	0.5	4	1	1	0	0	6
	0.1	0	1	0	0	0	1
	R-CTRL	3	2	0	0	0	5
	R-1.5	4	1	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Infiltrate, granulocytic	CTRL	5	1	0	0	0	6
	1.5	2	4	0	0	0	6
	0.5	3	3	0	0	0	6
	0.1	0	1	0	0	0	1
	R-CTRL	4	1	0	0	0	5
	R-1.5	5	0	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1- Infiltrate, lymphocytic	CTRL	5	1	0	0	0	6
	1.5	3	3	0	0	0	6
	0.5	6	0	0	0	0	6
	0.1	0	1	0	0	0	1
	R-CTRL	5	0	0	0	0	5
	R-1.5	3	2	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 -Nasoturbinate, mucosal degeneration	CTRL	6	0	0	0	0	6
	1.5	4	0	0	2	0	6
	0.5	6	0	0	0	0	6
	0.1	0	1	0	0	0	1
	R-CTRL	5	0	0	0	0	5
	R-1.5	5	0	0	0	0	5

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	CTRL	1	0	0	0	0	1
	1.5	0	0	0	0	0	0
	0.5	0	0	0	0	0	0
	0.1	1	0	0	0	0	1
	R-CTRL	0	0	0	0	0	0
	R-1.5	0	0	0	0	0	0

NASAL TURBINATE, LEVEL 1		0	1	2	3	4	Total
Level 1 Goblet cell hyperplasia, nasal septum	CTRL	2	1	3	0	0	6
	1.5	0	0	5	1	0	6
	0.5	0	0	4	2	0	6
	0.1	0	1	0	0	0	1
	R-CTRL	0	0	3	1	1	5
	R-1.5	0	2	2	1	0	5

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2- Goblet cell hyperplasia, nasal septum	CTRL	5	0	1	0	0	6
	1.5	3	2	1	0	0	6
	0.5	1	0	2	2	0	5
	0.1	3	0	3	0	0	6
	R-CTRL	3	2	0	0	0	5
	R-1.5	3	0	3	0	0	6

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2 - Hyperplasia, respiratory epithelium	CTRL	2	4	0	0	0	6
	1.5	2	0	4	0	0	6
	0.5	3	2	0	0	0	5
	0.1	3	2	1	0	0	6
	R-CTRL	5	0	0	0	0	5
	R-1.5	2	2	2	0	0	6

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2- Infiltrate, granulocytic	CTRL	6	0	0	0	0	6
	1.5	1	5	0	0	0	6
	0.5	5	0	0	0	0	5
	0.1	3	3	0	0	0	6
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2- Nasal turbinate, mucosa, degeneration	CTRL	6	0	0	0	0	6
	1.5	3	1	1	1	0	6
	0.5	4	1	0	0	0	5
	0.1	6	0	0	0	0	6
	R-CTRL	5	0	0	0	0	5
	R-1.5	6	0	0	0	0	6

NASAL TURBINATE, LEVEL 2		0	1	2	3	4	Total
Level 2-Infiltrate, lymphocytic	CTRL	4	2	0	0	0	6
	1.5	6	0	0	0	0	6
	0.5	5	0	0	0	0	5
	0.1	5	1	0	0	0	6
	R-CTRL	4	1	0	0	0	5
	R-1.5	4	1	1	0	0	6

NASAL TURBINATE, LEVEL 3		0	1	2	3	4	Total
Level 3 - Hyperplasia, respiratory epithelium	CTRL	3	0	0	0	0	3
	1.5	0	2	0	0	0	2
	0.5	3	3	0	0	0	6
	0.1	0	4	0	0	0	4
	R-CTRL	3	2	0	0	0	5
	R-1.5	0	0	0	0	0	0

NASAL TURBINATE, LEVEL 3		0	1	2	3	4	Total
T3 non-NALT Infiltrate, lymphocytic, subepithelial	CTRL	3	0	0	0	0	3
	1.5	2	0	0	0	0	2
	0.5	4	2	0	0	0	6
	0.1	4	0	0	0	0	4
	R-CTRL	6	0	0	0	0	6
	R-1.5	0	0	0	0	0	0

APPENDIX D – INDIVIDUAL ANIMAL SCORES – ACUTE STUDY

RED SMOKE ACUTE EXPOSURE	550	552	553	560	566	579	525	526	527	528	529	732	733	734	735	736	780	781	782	783	784
Euthanasia (# days post-exposure)	1 day						2 wks					1 day			2 wks		1 day			2 wks	
Units of exposure mg/L-->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	2.0*	2.0*	2.0*	2.0*	2.0*	1.7	1.7	1.7	1.7	1.7	0.6	0.6	0.6	0.6	0.6
LUNG	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male	Male
Alveolar septal dilation(artifact)*	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
Congestion, alveolar septal	0	0	0	1	0	0	2	1	2	1	0	0	2	3	3	3	1	1	2	2	3
Congestion, venous	1	0	0	1	0	0	0	0	1	0	0	0	2	3	1	1	0	1	1	2	3
Erythrocyte extravasation, alveolar	0	1	1	0	1	1	1	1	1	0	1	1	2	2	2	2	2	2	1	3	2
Erythrophagocytosis	0	0	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	1
Hemorrhage, perivascular or peribronchiolar	0	1	1	1	0	1	1	1	0	0	0	0	2	2	0	1	2	1	2	2	2
Edema, perivascular	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	2
Ateletasis, alveolar **α**	0	0	0	1	0	2	2	1	1	1	0	2	1	1	3	1	1	2	0	1	2
Histiocytosis, alveolar	0	0	1	0	0	0	1	1	1	1	0	1	0	1	0	0	1	0	0	0	0
Infiltrate, granulocytic	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	1	1	0	1	1
Edema, subpleural	0	0	0	0	0	0	0	1	3	1	0	0	1	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
* Water-inflated lungs																					
α Atelectasis is often observed but is generally an artifact of necropsy (insuffucient formalin perfusion). "Diffuse lack of inflation, no evidence of inflammatory process, " suggests processing artifact.																					
1= minimal (<5%); 2 = mild (6-15%); 3 =moderate (16-30%); 4 = marked (>30% of the tissue is affected).																					

RED SMOKE ACUTE EXPOSURE	586	591	601	602	605	612	530	531	532	533	534	737	738	739	740	741	785	786	787	788	789
Euthanasia (# days post-exposure)	1 day						2 wks					1 day			2 wks		1 day			2 wks	
Units of exposure mg/L-->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	2.0*	2.0*	2.0*	2.0*	2.0*	1.7	1.7	1.7	1.7	1.7	0.6	0.6	0.6	0.6	0.6
Fe = FEMALE LUNG	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe	Fe
Alveolar septal dilation(artifact)*	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
Congestion, alveolar septal	0	0	0	0	0	0	1	0	0	0	1	1	1	0	3	2	0	0	0	3	3
Congestion, venous	0	0	0	0	2	0	0	0	0	0	0	1	0	1	2	1	0	1	1	3	3
Erythrocyte extravasation, alveolar	0	0	1	0	0	0	0	0	1	0	1	0	0	0	2	0	2	0	1	3	0
Erythrophagocytosis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Hemorrhage, perivascular or peribronchiolar	0	1	0	0	1	1	0	0	0	0	1	0	0	1	1	0	1	1	1	2	0
Edema, perivascular	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	1	0
Ateletasis, alveolar **α**	0	0	1	0	1	0	1	0	1	0	2	3	1	0	0	0	0	0	0	0	0
Histiocytosis, alveolar	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Infiltrate, granulocytic	0	0	0	0	2	1	0	1	0	0	0	0	1	0	0	0	1	1	1	1	0
Edema, subpleural	0	0	0	0	0	0	1	0	2	0	1	0	0	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
* Water-inflated lungs																					
α Atelectasis is often observed but is generally an artifact of necropsy (insuffucient formalin perfusion). "Diffuse lack of inflation, no evidence of inflammatory process, " suggests processing artifact.																					
1= minimal (<5%); 2 = mild (6-15%); 3 =moderate (16-30%); 4 = marked (>30% of the tissue is affected).																					

APPENDIX E – INDIVIDUAL ANIMAL SCORES SUBACUTE STUDY

All main study animals are 10 wks old. * R-ctrl = recovery control animals, 14 wks old. NE = Not evaluable.

Y = Yes, there is loss of bone in a section that sometimes contains bone. N= NO, there is no loss of bone; that is, it is present.

Scoring criteria: ''0' = virtually no lesion = <1% of the tissue affected; '1' = minimal (generally, affecting 1-5% of the tissue) e.g., kidney-basophilic tubules '1' = 3-5 tubules observed. '2' = mild (6-15% of tissue affected), '3' = moderate (16-30% of the tissue affected. '4' = marked (affects > 30% of the sampled tissue).

35-15-01-01 RED SMOKE SUBACUTE STUDY

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	556	564	565	567	574	577
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	1.5	**1.5**	**1.5**	**1.5**	**1.5**	**1.5**
Brain, olfactory lobe	P	P	P	P	P	P	P	P	P	P	P	P
Brain, level 2	P	P	P	P	P	P	P	P	P	P	P	P
Brain, levels 3, 4 or 5	P	P	P	P	P	P	P	P	P	P	P	P
Brain, level 6 or 7	P	P	P	P	P	P	P	P	P	P	P	P
PITUITARY	P	P	P	NP	NP	NP	NP	NP	P	NP	NP	NP
STOMACH, SQUAMOUS	P	P	P	P	NP	NP	P	P	P	P	P	P
STOMACH, GLANDULAR	P	P	P	P	P	P	P	P	P	P	P	P
Dilation, gastric pits	1	1	0	1	0	0	0	0	0	0	0	0
SALIVARY GLANDS (submandibular, sublingual, parotid)	NP	P	P	P	P	P	P	P	P	P	P	P
Infiltrate, lymphoplasmacytic, submnd saliv gl	.	0	0	0	0	0	0	0	1	0	0	0
LARGE INTESTINE	.	.	.	.	.	.	.	.	.	P	P	P
EYE W/HARDERIAN GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Infiltrate, lymphocytic, subepithelial, palpebra	0	0	0	0	0	0	0	0	0	0	0	0
Secretion, pigmented, inspissated	0	0	0	0	1	0	0	0	0	0	0	0
Palpebral abscess (Sty or Hordeolum)	0	0	0	0	0	0	0	0	0	0	0	0
THYMUS	P	P	P	P	P	P	P	P	P	P	P	P
Hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0
LUNG	P	P	P	P	P	P	P	P	P	P	P	P
Congestion, alveolar septal	0	0	0	1	0	0	0	0	0	3	1	2
Congestion, venous	1	0	0	1	0	0	0	0	0	1	0	0
Erythrocyte extravasation, alveolar	0	1	1	0	1	1	0	0	0	0	1	0
Erythrophagocytosis	0	0	1	0	0	0	0	0	0	1	1	0
Hemorrhage, perivascular or peribronchiolar	0	1	1	1	0	1	0	0	0	1	1	0
Edema, perivascular	0	0	0	0	0	0	1	0	0	0	0	1
Ateletasis, alveolar **α**	0	0	0	1	0	2	2	2	1	0	1	2
Histiocytosis, alveolar	0	0	1	0	0	0	0	0	0	1	1	0
Infiltrate, granulocytic	0	0	0	0	0	0	0	0	0	0	1	0
Edema, subpleural	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	1	0
Hypertrophy, smooth muscle, vascular	0	0	0	0	0	0	1	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	0

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	556	564	565	567	574	577
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	1.5	1.5	1.5	1.5	1.5	1.5
TRACHEA	P	P	NP	P	P	P	P	P	P	P	P	P
Increased mucosal eosinophilic droplets:Y/N	1	0	.	0	1	1	1	1	1	1	1	1
THYROID GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Ectopic thymus	0	0	0	0	0	0	0	0	0	0	0	0
Ultimobranchial cysts	0	0	0	0	0	0	0	0	0	0	0	0
ESOPHAGUS	P	P	P	P	P	P	P	P	P	P	P	P
SKELETAL MUSCLE	P	P	P	P	P	P	P	P	P	P	P	P
LYMPH NODE, Tracheal	NP	P	NP	NP	P	P	P	P	NP	P	P	P
Draining hemorrhage	.	1	.	.	0	1	0	0	.	0	0	0
HEART with great vessels	P	P	P	P	P	NP	P	P	P	P	P	P
ADRENAL GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Vacuoles, cortical	0	1	0	0	1	0	1	0	1	1	0	0
KIDNEY	P	P	P	P	P	P	P	P	P	P	P	P
Basophilic tubules	1	0	0	1	1	1	0	0	1	1	0	0
infiltrate, lymphoplasmacytic	0	0	0	1	0	0	0	0	1	1	1	0
Cystic tubules, focal	0	0	0	0	0	0	0	0	0	1	0	0
Congestion	0	0	0	0	0	0	0	0	0	0	0	0
Infarct	0	0	0	0	0	0	0	0	0	0	0	0
SPLEEN	P	P	P	P	P	P	P	P	P	P	P	P
LIVER	P	P	P	P	P	P	P	P	P	P	P	P
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	0	0	0	0	0	0	0	0	0	0	0	0
Angiectasis, cavernous	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	0	0	0	0	0	0	0	0	0	0	0	0
Infiltrate, histiocytic, focal	0	0	0	1	0	0	1	1	0	0	1	0
Infiltrate, granulocytic, focal	0	0	0	1	0	0	0	0	0	0	0	0
Infiltrate, lymphocytic, portal	0	0	0	0	1	0	1	1	0	0	0	0
Fibrosis, portal, focal	0	0	0	0	0	0	0	1	0	0	0	0
TESTIS	P	P	P	P	P	P	P	P	P	P	P	P
Diameter reduced by > 30%	0	0	0	0	0	0	0	0	0	0	0	0
Seminiferous tubules degenerate (or Atrophic)	0	0	0	0	0	0	0	0	0	0	0	0
SEMINAL VESICLE	P	P	P	P	P	P	P	P	P	P	P	P
Hyperplasia, epithelial (Unilateral or Bilateral)	0	0	0	0	0	0	0	1	0	1	0	0
COAGULATING GLAND	NP	P	P	P	P	P	P	P	P	P	P	P
PROSTATE, dorsal lobe	P	P	P	P	P	P	P	P	P	P	P	P
infiltrate, lymphoplasmacytic	2	0	0	0	0	0	0	0	0	0	0	0

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	556	564	565	567	574	577
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	1.5	**1.5**	**1.5**	**1.5**	**1.5**	**1.5**
NASAL TURBINATES, Level 1	P	P	P	P	P	P	P	P	P	P	P	P
Level 1- Hyperplasia, transitional epithelium	0	0	0	0	0	0	3	2	3	3	3	4
Level 1 - Hyperplasia, respiratory epithelium	0	1	0	0	0	1	1	1	0	2	2	1
Level 1- Infiltrate, granulocytic	0	1	0	0	0	0	1	1	1	0	0	1
Level 1- Infiltrate, lymphocytic	0	0	0	0	1	0	1	1	1	0	0	0
Level 1- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	3	0	3	0	0	0
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	.	0	.	.	.	.	.	.	.	.	.	.
Level 1 - Goblet cell hyperplasia, nasal septum	0	2	2	0	1	2	2	2	2	2	2	3
NASAL TURBINATE, Level 2	P	P	P	P	P	P	P	P	P	P	P	P
Level 2 - Goblet cell hyperplasia, nasal septum	0	0	0	0	0	2	0	0	0	2	1	1
Level 2-Hyperplasia, respiratory epithelium	0	1	1	0	1	1	0	0	2	2	2	2
Level 2- Infiltrate, granulocytic	0	0	0	0	0	0	1	1	1	1	1	0
Level 2- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	2	0	3	0	0	1
Level 2 - Infiltrate, lymphocytic	0	0	0	1	1	0	0	0	0	0	0	0
NASAL TURBINATE, Level 3	NP	P	NP	P	P	NP	NP	P	NP	NP	NP	P
Level 3-Hyperplasia, respiratory epithelium	.	0	.	0	0	.		1	.	.	.	1
T3 non-NALT Infiltrate, lymphocytic, subepithelial	.	0	.	0	0	.	.	0	.	.	.	0

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	554	555	561	569	575	580
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
LUNG	P	P	P	P	P	P	P	P	P	P	P	P
Congestion, alveolar septal	0	0	0	1	0	0	2	1	1	2	2	0
Congestion, venous	1	0	0	1	0	0	1	0	0	1	0	0
Erythrocyte extravasation, alveolar	0	1	1	0	1	1	2	1	1	0	2	1
Erythrophagocytosis	0	0	1	0	0	0	0	0	0	0	0	0
Hemorrhage, perivascular or peribronchiolar	0	1	1	1	0	1	1	0	2	1	1	1
Edema, perivascular	0	0	0	0	0	0	0	0	0	0	0	0
Ateletasis, alveolar **α**	0	0	0	1	0	2	0	1	1	0	1	0
Histiocytosis, alveolar	0	0	1	0	0	0	1	1	0	0	0	0
Infiltrate, granulocytic	0	0	0	0	0	0	0	0	0	0	0	0
Edema, subpleural	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	0	0
Hypertrophy, smooth muscle, vascular	0	0	0	0	0	0	1	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	0

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	554	555	561	569	575	580
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
TRACHEA	P	P	NP	P	P	P	P	P	P	P	P	P
Increased mucosal eosinophilic droplets:Y/N	1	0	.	0	1	1	0	0	1	0	0	0
THYROID GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Ectopic thymus	0	0	0	0	0	0	0	0	0	0	0	1
Ultimobranchial cysts	0	0	0	0	0	0	0	0	0	0	0	2
ESOPHAGUS	P	P	P	P	P	P	P	P	P	P	P	P
SKELETAL MUSCLE	P	P	P	P	P	P	P	P	P	P	P	P
LYMPH NODE, Tracheal	NP	P	NP	NP	P	P	NP	P	P	P	P	NP
Draining hemorrhage	.	1	.	.	0	1	.	0	0	1	1	.
HEART with great vessels	P	P	P	P	P	NP						
ADRENAL GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Vacuoles, cortical	0	1	0	0	1	0	0	0	0	0	1	0
KIDNEY	P	P	P	P	P	P	P	P	P	P	P	P
Basophilic tubules	1	0	0	1	1	1	0	0	0	0	0	0
infiltrate, lymphoplasmacytic	0	0	0	1	0	0	0	0	0	0	0	0
Cystic tubules, focal	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	0	0	0	0	0	0	0	0	0	0	0	0
Infarct	0	0	0	0	0	0	0	0	0	0	0	0
SPLEEN	P	P	P	P	P	P	P	P	P	P	P	P
LIVER	P	P	P	P	P	P	P	P	P	P	P	P
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	0	0	0	0	0	0	0	0	0	0	0	0
Angiectasis, cavernous	0	0	0	0	0	0	0	0	0	0	0	0
Congestion	0	0	0	0	0	0	0	1	0	1	0	0
Infiltrate, histiocytic, focal	0	0	0	1	0	0	0	0	0	0	0	0
Infiltrate, granulocytic, focal	0	0	0	1	0	0	0	0	0	0	0	0
Infiltrate, lymphocytic, portal	0	0	0	0	1	0	0	0	0	0	0	1
Fibrosis, portal, focal	0	0	0	0	0	0	0	0	0	0	0	0

NASAL TURBINATES, Level 1	P	P	P	P	P	P	P	P	P	P	P	P
Level 1- Hyperplasia, transitional epithelium	0	0	0	0	0	0	0	2	0	4	3	3
Level 1 - Hyperplasia, respiratory epithelium	0	1	0	0	0	1	0	0	0	2	0	1
Level 1- Infiltrate, granulocytic	0	1	0	0	0	0	0	0	0	1	1	1
Level 1- Infiltrate, lymphocytic	0	0	0	0	1	0	0	0	0	0	0	0
Level 1- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	0	0	0	0	0	0
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	.	0	.	.	.	.	.	.	.	.	.	.
Level 1 - Goblet cell hyperplasia, nasal septum	0	2	2	0	1	2	3	3	2	2	2	2
NASAL TURBINATE, Level 2	P	P	P	P	P	P	NP	P	P	P	P	P
Level 2 - Goblet cell hyperplasia, nasal septum	0	0	0	0	0	2	.	0	3	3	2	2
Level 2-Hyperplasia, respiratory epithelium	0	1	1	0	1	1	.	0	1	0	0	1
Level 2- Infiltrate, granulocytic	0	0	0	0	0	0	.	0	0	0	0	0
Level 2- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	.	0	0	0	0	1
Level 2 - Infiltrate, lymphocytic	0	0	0	1	1	0	.	0	0	0	0	0
NASAL TURBINATE, Level 3	NP	P	NP	P	P	NP	P	P	P	P	P	P
Level 3-Hyperplasia, respiratory epithelium	.	0	.	0	0	.	1	0	0	0	1	1
T3 non-NALT Infiltrate, lymphocytic, subepithelial	.	0	.	0	0	.	1	0	0	0	0	1

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	551	557	571	572	573	582
MALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**
LIVER	P	P	P	P	P	P	P				P	
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	0	0	0	0	0	0	0					
Angiectasis, cavernous	0	0	0	0	0	0	0					
Congestion	0	0	0	0	0	0	0					
Infiltrate, histiocytic, focal	0	0	0	1	0	0	0					
Infiltrate, granulocytic, focal	0	0	0	1	0	0	0					
Infiltrate, lymphocytic, portal	0	0	0	0	1	0	0				1	
Fibrosis, portal, focal	0	0	0	0	0	0	0				4	
NASAL TURBINATES, Level 1	P	P	P	P	P	P	NP	NP	NP	NP	P	NP
Level 1- Hyperplasia, transitional epithelium	0	0	0	0	0	0	.	.	.	.	1	.
Level 1 - Hyperplasia, respiratory epithelium	0	1	0	0	0	1	.	.	.		1	.
Level 1- Infiltrate, granulocytic	0	1	0	0	0	0	.	.	.	.	1	.
Level 1- Infiltrate, lymphocytic	0	0	0	0	1	0	.	.	.	.	1	.
Level 1- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	.	.	.	.	1	.
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	.	0	.	.	.	.	.	.	.		0	.
Level 1 - Goblet cell hyperplasia, nasal septum	0	2	2	0	1	2	.	.	.		1	.
NASAL TURBINATE, Level 2	P	P	P	P	P	P	P	P	P	P	P	P
Level 2 - Goblet cell hyperplasia, nasal septum	0	0	0	0	0	2	2	0	2	0	2	0
Level 2-Hyperplasia, respiratory epithelium	0	1	1	0	1	1	1	1	2	0	0	0
Level 2- Infiltrate, granulocytic	0	0	0	0	0	0	0	1	1	0	1	0
Level 2- Nasal turbinate, mucosa, degeneration	0	0	0	0	0	0	0	0	0	0	0	0
Level 2 - Infiltrate, lymphocytic	0	0	0	1	1	0	0	0	0	0	1	0

NASAL TURBINATE, Level 3	NP	P	NP	P	P	NP	P	NP	P	P	P	NP
Level 3-Hyperplasia, respiratory epithelium	.	0	.	0	0	.	1	.	1	1	1	
T3 non-NALT Infiltrate, lymphocytic, subepithelial	.	0	.	0	0	.	0	.	0	0	0	.

Animal ID numbers all are prefixed with '15-	548	558	559	562	568	570	549	563	576	578	581	583
MALES Dosage (mg/kg) -->	**R-Ctrl**	**R-Ctrl**	**R-Ctrl**	**R-Ctrl**	**R-Ctrl**	**R-Ctrl**	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv
Brain, olfactory lobe	P	P	P	P	P	P	P	P	P	P	P	P
Brain, level 2	P	P	P	P	P	NP	P	P	P	P	P	P
Brain, levels 3, 4 or 5	P	P	P	P	P	P	P	P	P	P	P	P
Brain, level 6 or 7	P	P	P	P	P	P	P	P	P	P	P	P
PITUITARY	P	P	P	P	P	NP	P	P	P	P	P	P
STOMACH, SQUAMOUS	P	P	P	P	NP	P	P	P	P	P	P	P
STOMACH, GLANDULAR	P	P	P	P	P	P	P	P	P	P	P	P
Dilation, gastric pits	0	1	0	0	1	1	1	0	1	0	1	0
SALIVARY GLANDS (submandibular, sublingual, parotid)	P	P	P	P	P	P	P	NP	P	P	P	P
Infiltrate, lymphoplasmacytic, submnd saliv gl	0	0	0	0	0	0	0	.	0	0	0	0
LARGE INTESTINE	.	.	.	.	.	P	P	P	.	P	.	.
EYE W/HARDERIAN GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Infiltrate, lymphocytic, subepithelial, palpebra	0	1	0	0	0	0	0	0	0	0	0	0
Secretion, pigmented, inspissated	1	1	1	1	0	0	0	0	0	0	0	0
Palpebral abscess (Sty or Hordeolum)	0	0	0	0	0	0	0	0	0	0	3	0
THYMUS	P	P	P	P	P	P	P	P	P	P	P	P
Hemorrhage	1	0	2	1	0	0	0	0	0	0	0	0
LUNG	P	P	P	P	P	P	P	P	P	P	P	P
Congestion, alveolar septal	2	2	3	1	2	2	0	1	2	2	2	2
Congestion, venous	2	0	3	1	2	0	0	3	2	1	2	3
Erythrocyte extravasation, alveolar	0	1	0	1	3	0	1	1	0	0	1	2
Erythrophagocytosis	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage, perivascular or peribronchiolar	0	1	1	1	1	0	0	0	0	0	0	0
Edema, perivascular	0	0	0	0	0	0	0	0	0	0	1	0
Ateletasis, alveolar **α**	0	4	0	0	0	1	1	0	2	0	2	1
Histiocytosis, alveolar	0	0	0	0	0	0	0	0	1	0	0	0
Infiltrate, granulocytic	0	0	0	0	0	0	0	0	0	0	0	0
Edema, subpleural	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	0	0
Hypertrophy, smooth muscle, vascular	0	0	0	0	0	0	0	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	0

TRACHEA	NP	P	P	P	P	P	P	P	P	P	P	P
Increased mucosal eosinophilic droplets:Y/N	.	0	0	0	0	0	1	1	0	1	1	0
THYROID GLAND	P	P	P	P	P	NP	P	P	P	P	P	NP
Ectopic thymus	0	0	0	1	0	.	0	0	0	0	0	.
Ultimobranchial cysts	0	0	0	0	1	.	0	0	0	0	0	.
ESOPHAGUS	P	P	P	P	P	P	P	P	P	P	P	P
SKELETAL MUSCLE	P	P	P	P	P	P	P	P	P	P	P	P
LYMPH NODE, Tracheal	P	NP	P	NP	P	P	NP	P	P	NP	P	P
Draining hemorrhage	0	.	0	0	0	0	.	0	1	.	0	2
HEART with great vessels	NP	P	P	P	P	P	P	P	P	P	P	P
ADRENAL GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Vacuoles, cortical	1	1	0	0	0	0	0	0	1	0	1	1
KIDNEY	P	P	P	P	P	P	P	P	P	P	P	P
Basophilic tubules	0	1	0	1	0	0	0	0	0	0	0	0
infiltrate, lymphoplasmacytic	0	0	0	1	1	0	1	0	0	0	1	0
Cystic tubules, focal	0	0	0	1	0	0	0	1	0	0	0	0
Congestion	0	0	0	1	0	0	0	0	0	0	0	0
Infarct	0	0	0	0	0	0	0	0	0	0	0	0
SPLEEN	P	P	P	P	P	P	P	P	P	P	P	P
LIVER	P	P	P	P	P	P	P	P	P	P	P	P
Hepatocellular loss, multifocal, w/hemorrhage and leukocytes	1	0	0	0	0	0	0	0	0	0	0	3
Angiectasis, cavernous	0	0	0	0	0	0	0	0	0	0	2	0
Congestion	0	0	0	0	1	0	0	0	0	0	0	0
Infiltrate, histiocytic, focal	0	0	0	0	1	0	0	0	1	0	1	1
Infiltrate, granulocytic, focal	0	0	0	0	0	0	0	0	0	0	0	1
Infiltrate, lymphocytic, portal	1	0	0	1	1	0	0	0	0	0	1	1
Fibrosis, portal, focal	0	0	0	0	0	0	0	0	0	0	0	0
TESTIS	P	P	P	P	P	P	P	P	P	P	P	P
Diameter reduced by > 30%	0	0	0	0	0	0	0	0	0	4	0	0
Seminiferous tubules degenerate (or Atrophic)	0	0	0	0	0	0	0	0	0	4	0	0
SEMINAL VESICLE	P	P	P	P	P	P	P	P	P	P	P	P
Hyperplasia, epithelial (Unilateral or Bilateral)	0	0	0	0	0	0	0	1	2	0	0	1
COAGULATING GLAND	P	P	P	P	P	P	P	P	P	0	P	NP
PROSTATE, dorsal lobe	NP	P	P	P	P	P	P	NP	NP	NP	NP	P
infiltrate, lymphoplasmacytic	.	0	0	0	0	0	0	.	.	.	.	0

NASAL TURBINATES, Level 1	P	P	P	P	NE	P	P	P	P	P	P	NE
Level 1- Hyperplasia, transitional epithelium	0	0	0	0	.	0	0	0	0	0	0	.
Level 1 - Hyperplasia, respiratory epithelium	0	0	1	1	.	0	0	0	0	0	1	.
Level 1- Infiltrate, granulocytic	0	0	0	0	.	1	0	0	0	0	0	.
Level 1- Infiltrate, lymphocytic	0	0	0	0	.	0	0	0	1	1	0	.
Level 1- Nasal turbinate, mucosa, degeneration	0	0	0	0	.	0	0	0	0	0	0	.
Level 1-Nasal turbinate, bone loss -level of resp epith in dorsal meatus	.	.	.	.	.	.	.	.	.	.	.	.
Level 1 - Goblet cell hyperplasia, nasal septum	2	2	3	4	.	2	2	1	2	1	3	.
NASAL TURBINATE, Level 2	P	P	P	P	.NP	P	P	P	P	P	P	P
Level 2 - Goblet cell hyperplasia, nasal septum	0	0	0	1	.	1	0	2	0	0	2	2
Level 2-Hyperplasia, respiratory epithelium	0	0	0	0	.	0	2	0	0	1	2	1
Level 2- Infiltrate, granulocytic	0	0	0	0	.	0	0	0	0	0	0	0
Level 2- Nasal turbinate, mucosa, degeneration	0	0	0	0	.	0	0	0	0	0	0	0
Level 2 - Infiltrate, lymphocytic	0	0	0	0	.	1	0	0	2	1	0	0
NASAL TURBINATE, Level 3	P	P	P	P	P	P	NP	NP	NP	NP	NP	NE
Level 3-Hyperplasia, respiratory epithelium	1	0	0	NE	0	1	.	.	.	.	.	.
T3 non-NALT Infiltrate, lymphocytic, subepithelial	0	0	0	0	0	0	.	.	.	.	.	.

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	586	591	601	602	605	612	584	597	606	609	614	615
FEMALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	1.5	**1.5**	**1.5**	**1.5**	**1.5**	**1.5**
Brain, olfactory lobe	NP	P	P	P	P	P	P	P	P	P	P	P
Brain, level 2	P	P	P	P	P	P	P	P	P	P	P	P
Brain, levels 3, 4 or 5	P	P	P	P	P	P	P	P	P	P	P	P
Brain, level 6 or 7	P	P	P	P	P	P	P	P	P	P	P	P
Pituitary	NP	P	NP	P	P	NP	NP	P	P	P	NP	P
STOMACH, Squamous	NP	P	P	NP	P	P	NP	P	P	P	P	P
STOMACH, glandular	P	P	P	P	P	P	P	P	P	P	P	P
Dilation, gastric pits	0	0	0	0	0	0	0	0	0	0	0	0
Infiltrate, lymphoplasmacytic, fat	0	0	0	0	0	0	1	0	0	0	0	0
SALIVARY GLAND, submand, sublingual, parotid	P	P	P	P	P	P	P	P	P	NP	P	P
Lymph node, hyperplasia, plasmacytic, with germinal centers.	0	2	1	2	NP	0	0	0	0	.	0	0
Infiltrate, lymphoplasmacytic, submandibular saliv gl, periductal	0	0	0	0	0	0	0	0	0	.	0	0
Mammary tissue	NP	P	NP	P	NP	NP	NP	P	NP	NP	NP	P
Mammary epith cell prolif, with atypia	.	1	.	2	.	.	.	0	.	.	.	1

Large intestine	NP	NP	NP	NP	NP	NP	P	NP	P	NP	P	P
EYE WITH HARDERIAN GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Secretion, pigmented, inspissated	0	0	0	0	1	0	0	0	0	0	0	0
Infiltrate, lymphoplasmacytic, focal	0	0	0	1	0	0	0	0	0	1	0	0
Palpebral abscess (sty or Hordeolum)	0	0	0	0	0	0	0	0	0	0	0	0
THYMUS	P	P	P	P	P	P	P	P	P	P	P	P
Lymph node with draining hemorrhage	.	.	.	.	.	.	.	.	.	.	.	.
Hemorrhage	0	0	0	0	0	0	0	0	0	0	0	0
Hyperplasia, epithelial, focal	0	0	0	0	0	0	0	0	0	0	0	0
Ectopic parathyroid tissue	0	1	0	0	0	0	0	0	0	0	0	0
LUNG	P	P	P	P	P	P	P	P	P	P	P	P
Congestion, alveolar septal	0	0	0	0	0	0	0	0	0	0	2	0
Congestion, venous	0	0	0	0	2	0	1	1	0	1	1	0
Erythrocyte extravasation, alveolar	0	0	1	0	0	0	0	0	1	0	1	0
Erythrophagocytosis	0	0	0	0	0	0	0	0	0	0	0	0
Hemorrhage, perivascular or peribronchiolar	0	1	0	0	1	1	0	0	0	0	0	0
Edema, perivascular	0	0	0	0	0	0	0	0	0	0	0	0
Ateletasis, alveolar **α**	0	0	1	0	1	0	1	1	2	1	0	0
Histiocytosis, alveolar	0	0	0	0	0	0	0	0	0	1	1	0
Infiltrate, granulocytic	0	0	0	0	2	0	0	0	2	0	0	0
Edema, subpleural	0	0	0	0	0	0	0	0	0	0	0	0
Fibrosis, alveolar, focal	0	0	0	0	0	0	0	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0	0	0	0	0	0	0	0	0	0	0
TRACHEA	P	P	P	P	P	P	P	P	P	P	P	P
Infiltrate, lymphocytic, subepithelial	0	0	0	0	0	0	0	0	0	0	0	0
Increased mucosal eosinophilic droplets	0	0	0	1	0	0	1	1	1	0	0	1
THYROID GLAND	NP	NP	P	P	P	P	P	P	P	P	NP	NP
Hyperplasia, C cell	.	.	0	0	0	0	0	0	0	0	.	.
Cyst, thyroid, squamous	.	.	1	1	0	0	0	0	0	0	.	.
Ectopic thymus	.	.	0	0	1	0	0	1	0	0	0	0
ESOPHAGUS	P	P	P	P	P	P	P	P	P	P	P	P
SKELETAL MUSCLE	P	P	P	P	P	P	P	P	P	P	P	P
Infiltrate, lymphohistiocytic, focal, skeletal muscle	0	0	0	0	0	0	0	0	0	1	0	0
Lymph node, tracheal	NP	P	P	P	P	P	P	NP	P	P	P	P
Draining hemorrhage	.	0	0	0	0	1	0	.	0	0	1	0
Pigment, cytoplasmic, macrophages	.	0	0	0	0	1	0	.	0	0	0	0
Infiltrate, eosinophilic	.	0	0	0	0	1	0	.	0	0	0	0
HEART WITH GREAT VESSELS	P	P	P	P	P	P	P	P	P	P	P	P
Lymphatics, ectatic, heart base	0	0	0	0	0	0	0	0	0	0	0	0
Infiltrate, mastocytic and lymphocytic, epicardial fat	0	0	0	0	0	0	0	0	0	0	0	0
ADRENAL GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Ectopic medullary cells	0	0	0	0	0	0	0	0	0	0	0	0
Vacuoles, cortical	0	0	0	0	0	0	1	0	0	0	0	0

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	586	591	601	602	605	612	584	597	606	609	614	615
FEMALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	1.5	1.5	1.5	1.5	1.5	1.5
KIDNEY	P	P	P	P	P	P	P	P	P	P	P	P
Increased proteinaceous fluid, proximal tubules	0	0	1	0	0	0	0	0	1	0	0	0
Basophilic tubules	0	0	0	0	0	0	0	0	0	1	0	0
Renal tubule-Hyperplasia, oncocytic	0	0	0	0	0	0	0	0	0	0	0	0
infiltrate, lymphoplasmacytic	0	0	0	0	0	0	1	1	1	0	0	0
Cystic tubules, focal	0	0	0	0	0	0	0	1	1	0	0	0
SPLEEN	P	P	P	NP	P	P	P	P	P	P	P	P
LIVER	P	P	P	NP	P	P	P	P	P	P	P	P
Hepatocellular loss, focal, with leukocytes	0	0	0	.	0	0	0	0	0	0	0	0
Infiltrate, histiocytic, focal	1	1	0	.	1	0	1	0	0	0	0	0
Infiltrate, lymphocytic, portal	0	1	0	.	0	0	0	0	0	0	0	0
Fibrosis, portal, focal	0	0	0	.	0	0	0	0	0	0	0	1
UTERUS	P	P	P	P	P	P	P	P	P	P	P	P
Hyperplasia, endometrial	0	0	0	2	0	1	0	0	0	0	0	0
OVARY	P	P	P	P	P	P	P	P	P	P	P	P
Reproductive cycle: Proestrus				X			X			X		
Estrus						X		X				
Metestrus	X	X	X		X				X			X
Diestrus								X			X	
NASAL TURBINATE, LEVEL 1	NP	P	P	P	P	NP	NP	P	P	P	P	P
Level 1- Hyperplasia, transitional epithelium	.	0	0	0	0	.	.	2	2	2	3	2
Level 1 - Hyperplasia, respiratory epithelium	.	1	1	0	0	.	.	0	2	1	0	1
Level 1- Infiltrate, granulocytic	.	0	0	0	0	.	.	0	1	0	0	0
Level 1- Infiltrate, lymphocytic	.	0	0	0	0	.	.	0	0	0	0	0
Level 1 -Nasoturbinate, mucosal degeneration	.	0	0	0	0	.	.	0	2	0	1	1
Level 1 - Nasoturbinate bone loss at lvl of resp epith, dorsal meatus	.	N	Y	.	.	.	.	.	.	.	.	.
Level 1 Goblet cell hyperplasia, nasal septum	.	2	1	2	3	.	.	2	2	2	0	1
NASAL TURBINATE, LEVEL 2	NP	P	P	P	P	NP	P	P	P	P	P	P
Level 2- Goblet cell hyperplasia, nasal septum	.	0	0	0	1	.	0	0	0	0	0	0
Level 2 - Hyperplasia, respiratory epithelium	.	0	0	0	0	.	0	0	0	0	0	1
Level 2- Infiltrate, granulocytic	.	0	0	0	0	.	0	1	1	0	0	0
Level 2-Infiltrate, lymphocytic	.	0	0	1	0	.	0	0	0	0	0	0
NASAL TURBINATE, LEVEL 3	P	P	P	P	P	P	P	P	P	P	P	NP
Level 3 - Hyperplasia, respiratory epithelium	0	0	1	1	0	0	0	1	1	0	0	.

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	586	591	601	602	605	612	588	590	594	600	603	610
FEMALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
NASAL TURBINATE, LEVEL 1	NP	P	P	P	P	NP	P	NP	P	NP	P	NP
Level 1- Hyperplasia, transitional epithelium	.	0	0	0	0	.	3	.	1	.	3	.
Level 1 - Hyperplasia, respiratory epithelium	.	1	1	0	0	.	0	.	2	.	0	.
Level 1- Infiltrate, granulocytic	.	0	0	0	0	.	0	.	0	.	1	.
Level 1- Infiltrate, lymphocytic	.	0	0	0	0	.	1	.	0	.	0	.
Level 1 -Nasoturbinate, mucosal degeneration	.	0	0	0	0	.	1	.	0	.	0	.
Level 1 - Nasoturbinate bone loss at lvl of resp epith, dorsal meatus	.	N	Y	.	.	.	.	.	.	.	.	.
Level 1 Goblet cell hyperplasia, nasal septum	.	2	1	2	3	.	2	.	3	.	2	.
NASAL TURBINATE, LEVEL 2	NP	P	P	P	P	NP	P	P	P	P	P	P
Level 2- Goblet cell hyperplasia, nasal septum	.	0	0	0	1	.	0	0	0	0	0	0
Level 2 - Hyperplasia, respiratory epithelium	.	0	0	0	0	.	0	1	1	0	2	1
Level 2- Infiltrate, granulocytic	.	0	0	0	0	.	0	0	0	0	0	0
Level 2-Infiltrate, lymphocytic	.	0	0	1	0	.	0	0	0	0	0	0
NASAL TURBINATE, LEVEL 3	P	P	P	P	P	P	P	P	P	P	NP	P
Level 3 - Hyperplasia, respiratory epithelium	0	0	1	1	0	0	0	0	0	1	.	0

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	586	591	601	602	605	612	595	596	607	616	618	619
FEMALES Dosage (mg/kg) -->	CTRL	CTRL	CTRL	CTRL	CTRL	CTRL	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**	**0.1**
NASAL TURBINATE, LEVEL 1	NP	P	P	P	P	NP	P	NP	P	P	P	NP
Level 1- Hyperplasia, transitional epithelium	.	0	0	0	0	.	2	.	2	1	3	.
Level 1 - Hyperplasia, respiratory epithelium	.	1	1	0	0	.	0	.	3	2	0	.
Level 1- Infiltrate, granulocytic	.	0	0	0	0	.	1	.	1	1	2	.
Level 1- Infiltrate, lymphocytic	.	0	0	0	0	.	1	.	1	1	1	.
Level 1 -Nasoturbinate, mucosal degeneration	.	0	0	0	0	.	0	.	0	0	3	.
Level 1 - Nasoturbinate bone loss at lvl of resp epith, dorsal meatus	.	N	Y	.	.	.	.	.	.	.	Y	.
Level 1 Goblet cell hyperplasia, nasal septum	.	2	1	2	3	.	3	.	3	3	2	.
NASAL TURBINATE, LEVEL 2	NP	P	P	P	P	NP	P	P	NP	P	P	P
Level 2- Goblet cell hyperplasia, nasal septum	.	0	0	0	1	.	0	0	.	0	1	2
Level 2 - Hyperplasia, respiratory epithelium	.	0	0	0	0	.	0	0	.	0	0	2
Level 2- Infiltrate, granulocytic	.	0	0	0	0	.	1	1	.	0	1	1
Level 2-Infiltrate, lymphocytic	.	0	0	1	0	.	1	1	.	0	1	1
NASAL TURBINATE, LEVEL 3	P	P	P	P	P	P	P	P	P	P	P	P
Level 3 - Hyperplasia, respiratory epithelium	0	0	1	1	0	0	1	0	0	0	1	0

35-15-01-01 RED SMOKE SUBACUTE STUDY												
Animal ID numbers all are prefixed with '15-	585	589/ 592	592	599	604	611	587	593	598	608	613	617
FEMALES Dosage (mg/kg) -->	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv
Brain, olfactory lobe	P	P	.	P	P	P	P	P	P	P	P	P
Brain, level 2	P	P	.	P	P	P	P	P	P	P	NP	P
Brain, levels 3, 4 or 5	P	P	.	P	P	P	P	P	P	P	P	P
Brain, level 6 or 7	P	P	.	P	P	P	P	P	P	P	P	P
Pituitary	P	NP	P	P	P	P	P	P	P	P	P	P
STOMACH, Squamous	P	P	P	NP	P	P	P	NP	P	P	P	P
STOMACH, glandular	P	P	P	P	P	P	P	NP	P	P	P	P
Dilation, gastric pits	1	0	0	0	1	1	0	.	0	1	1	0
Infiltrate, lymphoplasmacytic, fat	0	0	0	0	0	0	0	.	0	0	0	0
SALIVARY GLAND, submand, sublingual, parotid	P	P	.	P	P	P	P	P	P	P	P	P
Lymph node, hyperplasia, plasmacytic, with germinal centers.	NP	0	.	1	0	2	0	0	3	NP	0	0
Infiltrate, lymphoplasmacytic, submandibular saliv gl, periductal	0	0	.	0	0	0	0	0	0	0	0	0
Mammary tissue	P	NP	.	P	NP	P	NP	P	NP	P	P	NP
Mammary epith cell prolif, with atypia	0	.	.	0	.	0	.	0	.	1	0	.
Large intestine	P	P	.	NP	NP	NP	.	.	P	NP	.	NP
EYE WITH HARDERIAN GLAND	P	P	.	P	P	P	P	P	P	P	P	NP
Secretion, pigmented, inspissated	0	0	.	0	1	0	0	0	0	0	1	.
Infiltrate, lymphoplasmacytic, focal	0	0	.	0	2	0	1	0	0	0	0	.
Palpebral abscess (sty or Hordeolum)	0	0	.	0	0	0	0	0	0	0	0	.
THYMUS	P	P	.	P	P	P	P	P	P	P	P	P
Lymph node with draining hemorrhage	.	.	.	1	.	.	.	.	.	.	.	.
Hemorrhage	0	1	.	0	1	0	0	1	1	0	1	0
Hyperplasia, epithelial, focal	1	0	.	0	0	0	0	0	0	0	0	0
Ectopic parathyroid tissue	0	0	.	0	0	0	0	0	0	0	0	0
LUNG	P	P	.	P	P	P	P	P	P	P	P	P
Congestion, alveolar septal	0	0		2	1	1	2	1	0	0	0	0
Congestion, venous	1	0	.	0	0	0	2	0	1	0	0	0
Erythrocyte extravasation, alveolar	1	0	.	0	0	1	0	1	0	1	2	1
Erythrophagocytosis	0	0		0	0	0	1	0	0	0	0	0
Hemorrhage, perivascular or peribronchiolar	0	0		1	0	0	1	0	0	1	0	0
Edema, perivascular	0	0		0	0	0	0	0	0	0	0	0
Ateletasis, alveolar **α**	1	0		0	1	1	1	0	0	4	2	1
Histiocytosis, alveolar	0	0	.	0	0	0	1	0	0	0	0	0
Infiltrate, granulocytic	0	0	.	0	0	0	1	1	0	0	0	0
Edema, subpleural	0	0		0	0	0	0	0	0	0	0	0

Animal ID numbers all are prefixed with '15-	585	589/592	592	599	604	611	587	593	598	608	613	617
FEMALES Dosage (mg/kg) -->	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv
Fibrosis, alveolar, focal	0	0	.	0	0	0	0	0	0	0	0	0
Crystals, eosinophilic, alveolar	0	0		0	0	0	0	0	0	0	0	0
TRACHEA	P	P	.	P	P	P	P	P	P	P	P	P
Infiltrate, lymphocytic, subepithelial	0	1		0	0	0	0	0	0	0	0	0
Increased mucosal eosinophilic droplets	1	0	.	1	1	0	0	1	0	0	0	1
THYROID GLAND	P	P	.	P	P	P	P	P	P	NP	NP	P
Hyperplasia, C cell	0	0	.	1	1	0	0	0	0	.	.	0
Cyst, thyroid, squamous	0	0	.	0	0	0	0	0	0	.	.	0
Ectopic thymus	0	0	.	0	0	0	0	0	0	.	.	0
ESOPHAGUS	P	P	.	P	P	P	P	P	P	P	P	P
SKELETAL MUSCLE	P	P	.	P	P	P	P	P	P	P	P	P
Infiltrate, lymphohistiocytic, focal, skeletal muscle	0	0	.	0	0	0	0	0	0	0	0	0
Lymph node, tracheal	NP	P	.	P	P	P	P	P	P	NP	NP	P
Draining hemorrhage	.	0	.	0	1	0	0	0	0	.	.	1
Pigment, cytoplasmic, macrophages	.	0	.	1	1	0	1	0	0	.	.	1
Infiltrate, eosinophilic	.	0	.	0	0	0	0	0	0	.	.	0
HEART WITH GREAT VESSELS	P	P	.	P	P	P	P	P	P	P	P	P
Lymphatics, ectatic, heart base	0	0	.	2	0	0	0	0	0	0	0	0
Infiltrate, mastocytic and lymphocytic, epicardial fat	0	0	.	0	0	0	0	1	0	0	0	0
ADRENAL GLAND	P	P	P	P	P	P	P	P	P	P	P	P
Ectopic medullary cells	0	0	0	0	0	0	1	0	0	0	0	0
Vacuoles, cortical	0	1	0	0	0	0	0	0	1	0	0	0
KIDNEY	P	P	P	P	P	P	P	P	P	P	P	P
Increased proteinaceous fluid, proximal tubules	1	1	1	1	2	0	0	1	1	2	1	2
Basophilic tubules	0	0	0	0	0	0	1	0	0	0	0	0
Renal tubule-Hyperplasia, oncocytic	0	0	0	0	0	0	1	0	0	0	0	0
infiltrate, lymphoplasmacytic	0	0	0	0	0	0	0	0	0	0	0	0
Cystic tubules, focal	0	0	0	0	0	0	0	0	0	0	0	0
SPLEEN	P	P	P	P	P	P	P	P	P	P	P	P
LIVER	P	P	P	p	P	P	P	P	P	P	P	P
Hepatocellular loss, focal, with leukocytes	0	0	1	0	0	0	0	0	0	0	0	0
Infiltrate, histiocytic, focal	0	1	0	1	1	0	1	1	1	0	1	0
Infiltrate, lymphocytic, portal	0	1	0	0	0	0	0	0	0	0	0	0
Fibrosis, portal, focal	0	0	0	0	0	0	0	0	0	0	0	0
UTERUS	P	P	P	p	P	P	P	P	P	P	P	P
Hyperplasia, endometrial	0	0	0	0	0	0	0	0	0	0	0	0
OVARY	P	P	P	P	P	P	P	P	P	P	P	P
Reproductive cycle: Proestrus					X			X		X	X	
Estrus						X						X
Metestrus		X		X								
Diestrus	X	.	X				X		X			

Animal ID numbers all are prefixed with '15-	585	589/ 592	592	599	604	611	587	593	598	608	613	617
FEMALES Dosage (mg/kg) -->	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	R-Ctrl	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv	1.5 Rcv
NASAL TURBINATE, LEVEL 1	P	P	P	P	P	P	P	P	P	P	P	NP
Level 1- Hyperplasia, transitional epithelium	3	0	0	0	0	0	0	1	0	0	0	.
Level 1 - Hyperplasia, respiratory epithelium	1	1	0	0	0	0	1	0	2	1	0	.
Level 1- Infiltrate, granulocytic	1	1	1	0	0	0	1	1	0	1	0	.
Level 1- Infiltrate, lymphocytic	0	0	0	0	0	0	0	0	0	1	0	.
Level 1 -Nasoturbinate, mucosal degeneration	1	0	0	0	0	0	0	0	0	0	0	.
Level 1 - Nasoturbinate bone loss at lvl of resp epith, dorsal meatus	.	.	.	.	.	.	Y	Y	.	.	.	.
Level 1 Goblet cell hyperplasia, nasal septum	3	2	2	0	1	2	1	1	2	2	0	
NASAL TURBINATE, LEVEL 2	P	P	P	P	P	P	P	P	P	P	P	.
Level 2- Goblet cell hyperplasia, nasal septum	0	0	2	0	0	0	1	2	0	0	0	.
Level 2 - Hyperplasia, respiratory epithelium	0	1	1	0	1	0	1	0	0	0	0	
Level 2- Infiltrate, granulocytic	1	0	0	0	0	0	0	1	0	0	0	.
Level 2-Infiltrate, lymphocytic	1	1	0	0	0	0	1	0	0	1	0	.
NASAL TURBINATE, LEVEL 3	NP	P	P	P	P	P	NP	NP	P	P	P	NP
Level 3 - Hyperplasia, respiratory epithelium	.	0	0	0	0	1	.	.	1	1	0	.

All main study animals are 10 wks old. * R-ctrl are recovery control animals, 14 wks old. NE = Not evaluable. Y = Yes, there is loss of bone in a section that sometimes contains bone. N= NO, the section is present without loss of bone.

APPENDIX F STORAGE OF STUDY MATERIALS AND RECORDS RETENTION

The study records and pathology final report will be archived and maintained at or under the direction of U.S. Army Public Health Center's (APHC) Toxicology Portfolio (TOX), according to TOX SOPs and EPA requirements. The Pathology specimens will also be archived and maintained at or under the direction of APHC Toxicology Portfolio, according to TOX SOP and EPA requirements.

ADDENDUM TO

PATHOLOGY REPORT

For

Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke

Protocol No.: 35-15-01-01

Study Director:
Lee Crouse

Prepared by:

MAJ Keith Koistinen, DVM, Diplomate, ACVP

KOISTINEN.KEITH.AARON.1246838085

Digitally signed by KOISTINEN.KEITH.AARON.1246838085
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=KOISTINEN.KEITH.AARON.1246838085
Date: 2017.04.12 09:23:17 -04'00'

Keith Koistinen, DVM, Diplomate ACVP
Major, Veterinary Corps
Toxicology Directorate
U.S. Army Public Health Center

Date

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

This pathology investigation was conducted in a manner consistent with the principles of the United States Environmental Protection Agency (USEPA) Good Laboratory Practice regulations of the Toxic Substances Control Act (TSCA), as detailed in 40 CFR Part 792, plus amendments.

Keith Koistinen, DVM, Diplomate ACVP
Major, Veterinary Corps
Toxicology Directorate
U.S. Army Public Health Center

Date

QUALITY ASSURANCE STATEMENT

For The Addendum to the Pathology Report for Protocol No. 35-15-01-01 entitled *"Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke"*, the following critical phases were audited by the APHC Quality Systems and Regulatory Compliance Office (QSARC), Laboratory and Toxicology Accreditation and Compliance Office (LTACO):

Critical Phase Inspected/Audited	Date Inspected /Audited	Date Reported to Management/SD
Pathology Contributing Scientist Inspection - Summary Data and Summary Table Review	01/13/2017	04/11/2017
Pathology Contributing Scientist Inspection- Final Pathology Report GLP Standard Regulation Review	01/13/2017	04/11/2017

Note 1 All findings were made known to the Study Director and the Program Manager at the time of the audit/inspection. If there were no findings during the inspection, the inspection was reported to Management and the Study Director on the date shown in the table.

Note 2 In addition to the study specific critical phase inspections listed here, general facility and process based inspections not specifically related to this study are done monthly or annually in accordance with QSARC, LTACO Standing Operating Procedures.

Note 3 This report has been audited by the Quality Assurance Unit (QSARC, LTACO) and is considered to be an accurate account of the data generated and of the procedures followed

Michael P. Kefauver — 04/11/2017

Michael P. Kefauver
Quality Assurance Specialist, QSARC

Date

BACKGROUND:

In the original pathology report, sections of Level 1 nasal turbinate from 13 animals were reported to be "NP (not-present)" on microscopic examination. Among the 13 rats reported as NP, several (5 of 6) animals were assigned to the low-dose group, 0.1 mg/L. Therefore, the study director, requested reevaluation of the Level 1 section of nasal turbinates from the subacute rats. Only the main study subacute animals were evaluated and the "recovery" animals were not evaluated.

METHODS

The slides that were reported to be NP were screened for adequacy of the section present. Duplicate microscope slides were prepared for slides that were determined to be poor quality due to the presence of non-intact turbinates or inadequate tissue sections present.

In a similar method as the original pathology report, statistical analysis was performed on the histologic scores of the sections examined using a Fisher's Exact Test, comparing the number of animals of a given exposure group with a non-zero score for a given lesion to the number of control animals with a non-zero score. Given the small sample size, the initial statistical question asked was simply 'is the lesion present?' with a comparison of exposed versus control groups.

RESULTS

In the original pathology report, Level 1 nasal turbinates in 13 rats were reported to be not present (NP). The author of this addendum report interpreted level 1 tissue sections to be adequate quality from 45 of 48 rats after processing additional tissue section. Inadequate sample quality from a limited number (three) of rats was due to either loss of tissue during processing or inappropriate level sectioned.

The distribution of observed lesions within nasal cavity at level 1 included the ventral and lateral surfaces of the nasoturbinates, dorsolateral surfaces of the maxilloturbinates and the adjacent lateral wall of the lateral meatus, as depicted in the Figure 9 diagram in the original pathology report.

Incidences of histologic lesions observed in each individual group are available as Table 1 and 2 below. Individual rat scores are in Appendix B. Within the high dose group, six of six high-exposure male rats exhibited epithelial hyperplasia in level 1 with varying amounts of neutrophilic infiltrates and mucosal degeneration in four of six male rats. Lesions were also present in the 0.1 and 0.5 mg/L exposure males but were at decreased frequencies and did not reach statistical significance. Five of six 1.5 mg/L-exposed females had minimal to mild transitional epithelial hyperplasia at level 1 ($p=0.0152$), which was consistently associated with mucosal degeneration ($p=0.0152$). Transitional epithelial hyperplasia was also observed in 0.1 mg/L-exposure female rats ($p=0.0152$). Squamous epithelial metaplasia and goblet cell hyperplasia was observed in a few animals in this report, but was inconsistently observed and was not statistically significant when compared to the incidence in the controls.

Table 1 Incidence of Level 1 nasal turbinate lesions by group and sex

Sex	F				M			
mg/L Red Smoke	Control	0.1	0.5	1.5	Control	0.1	0.5	1.5
NASAL TURBINATES, Level 1 (Present)	5/6	6/6	6/6	6/6	6/6	4/6	6/6	6/6
Tissue Absent or not adequate for evaluation	1/6					2/6		
Essentially normal tissue	4/5	1/6	4/6	1/6	3/6	2/4	2/6	0/6
Hyperplasia, epithelium, respiratory or transitional		**5/6***	2/6	**5/6***	1/6	1/4	4/6	**6/6***
Infiltrate, granulocytic		2/6	1/6	2/6	3/6	1/4	4/6	6/6
Infiltrate, lymphocytic								
Nasal turbinate, mucosa, degeneration		1/6	2/6	**5/6***				4/6
Nasal turbinate, mucosa, metaplasia, squamous				1/6			1/6	1/6
Nasal turbinate, bone loss								
Goblet cell hyperplasia, nasal septum	1/5	4/6	1/6	3/6	2/6		3/6	5/6

* Statistically significant ($p<0.05$) compared to the control group.
Blank cell indicates that the lesion/finding was absent from all animals that were examined.

Table 2. Incidence of Level 1 nasal turbinate lesions by group, with combined males and females

	Males and Females Combined			
mg/L Red Smoke	Control	0.1	0.5	1.5
NASAL TURBINATES, Level 1 (Present)	11/12	10/12	12/12	12/12
Tissue Absent or not adequate for evaluation	1/12	2/12		
Essentially normal tissue	7/11	3/10	6/12	**1/12***
Hyperplasia, epithelium, respiratory or transitional	1/11	**6/10***	6/12	**11/12***
Infiltrate, granulocytic	3/11	3/10	5/12	8/12
Infiltrate, lymphocytic				
Nasal turbinate, mucosa, degeneration		1/10	2/12	**9/12***
Nasal turbinate, mucosa, metaplasia, squamous			1/12	2/12
Nasal turbinate, bone loss				
Goblet cell hyperplasia, nasal septum	3/11	4/10	4/12	8/12

Bold and asterisk indicates lesion incidence that is statistically significant when compared to the control group. Blank cell indicates that the lesion/finding was absent from all animals that were examined.

DISCUSSION

As similarly concluded in the original pathology report, nasal turbinate injury in the anterior aspects of the rat nasal passages is attributed to pyrotechnically disseminated M18 red smoke exposure.

Transitional epithelium covers the ventral tip of nasoturbinates and the dorsal tip of the maxilloturbinates at Level 1 and 2, and is the location where inhaled substances would first make contact with the animal. Transitional epithelial hyperplasia of these areas was present in at least some animals every exposure level of both genders of rats. Concomitant transitional mucosal degeneration

was also observed. Based on the nature and distribution of the nasal turbinate lesions pyrotechnically disseminated M18 red smoke most likely represents a physical irritant, but the possibility that it represents a primary toxicant, or one that is metabolized to an active form by enzymes cannot be ruled out.

Lymphocytes within nasal turbinate lesion that were occasionally noted in high-exposure males in the original report were not observed in the histopathologic analysis performed for this addendum report, and the lymphocytes observed were interpreted to be normal resident lymphocytes, which may explain the lymphocytic infiltrates observed in the original report.

The distribution of the lesions as illustrated in Figure 9 of the original report was on the ventral and lateral surfaces of the nasoturbinates, dorsolateral surfaces of the maxilloturbinates and the adjacent lateral wall of the lateral meatus. These locations are where inhaled substances would first make contact with the animal. Injury to these initial tissues with which it came into contact, supports the irritant nature of pyrotechnically disseminated M18 red smoke. Epithelial hyperplasia of these areas was present in every exposure level of both genders of rats.

As the original pathology report also commented, the observed lesions are likely reversible as the lesions are primarily at the superficial aspects of the epithelium; superficial injury to respiratory epithelium is reported to be frequently reversible (Harkema et al 2006). The reversible nature of the lesions is supported by the presence of only infrequent respiratory epithelial hyperplasia without other nasal turbinate lesions in the high-dose recovery animals.

In this study inhalational exposure to pyrotechnically disseminated M18 red smoke was associated only with injury to those initial tissues (nasal turbinates and epithelia) with which it came into contact, which supports the irritant nature of pyrotechnically disseminated M18 red smoke.

DEFINITIONS

Nasal Turbinate, Level 1: As defined by OECD TG #125, the most rostral section of the nasal turbinates sampled, this is a section through the nasal turbinates that is at the level of the posterior part of the upper incisors.

REFERENCE

Harkema, J.R., S.A. Carey, and J.G. Wagner, *The nose revisited: a brief review of the comparative structure, function, and toxicologic pathology of the nasal epithelium*. Toxicol Pathol, 2006. 34(3): p. 252-69.

Renne, R., et al., Guidance Document on Histopathology for Inhalation Toxicity Studies, Supporting TG 412 (Subacute Inhalation Toxicity: 28-Day Study) and TG 413 (Subchronic inhalation Toxicity: 90-Day Study), in Series on Testing and Assessment, Secretariat, Editor. 2010, Organisation for Economic Co-operation and Development: Paris, France

APPENDIX A - PHOTOMICROGRAPHS

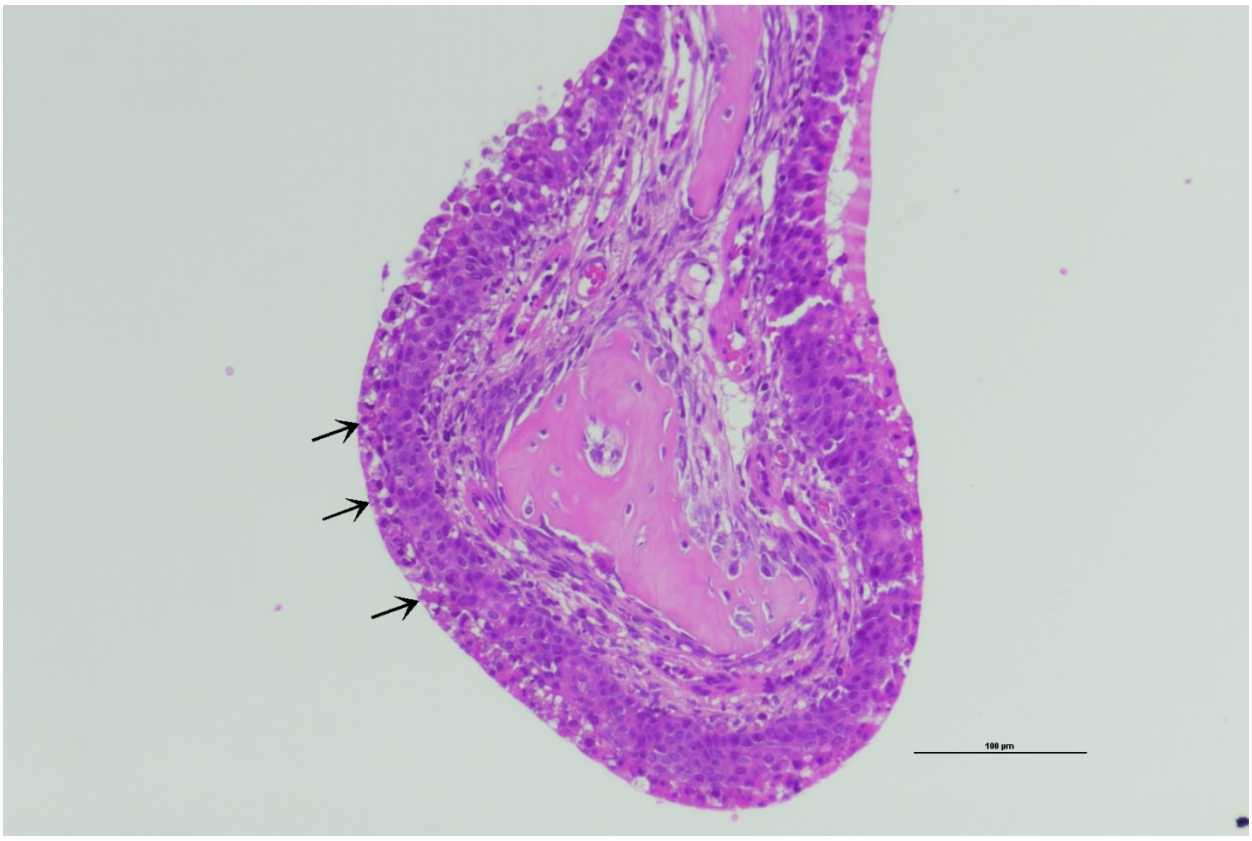

Figure 1. Rat 15-556 Male 1.5 mg/L, portion of nasal turbinate at level 1. There is degeneration of the mucosal epithelium with separation of the epithelial cells with occasional sloughing of epithelial cells. 20X H&E

APPENDIX B
HISTOPATHOLOGY FINDINGS, by ANIMAL

Animal ID numbers all are prefixed with '15-	550	552	553	560	566	579	551	557	571	572	573	582	554	555	561	569	575	580	556	564	565	567	574	577
Dosage (mg/L) -->	control	control	control	control	control	control	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L
Sex	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M	M
NASAL TURBINATES, Level 1 (Present)	1	1	1	1	1	1	1		1		1	1	1	1	1	1	1	1	1	1	1	1	1	1
Tissue Absent or not adequate for evaluation								1*		1*														
Essentially normal tissue	1		1	1			1					1	1					1						
Level 1- Hyperplasia, epithelium, respiratory or transitional						1					1			1	1	1	1		3	1	1	1	1	1
Level 1- Infiltrate, granulocytic		1			1	1			1					1	1	1	1		1	1	1	1	1	1
Level 1- Infiltrate, lymphocytic																								
Level 1- Nasal turbinate, mucosa, degeneration																			3	1	2			1
Level 1- Nasal turbinate, mucosa, metaplasia, squamous																1			1					
Level 1 - Nasal turbinate, bone loss -level of resp epith in dorsal meatus																								
Level 1 - Goblet cell hyperplasia, nasal septum		1				1								1	2	1			3	1	1		1	2

Animal ID numbers all are prefixed with '15-	586	591	601	602	605	612	595	596	607	616	618	619	588	590	594	600	603	610	584	597	606	609	614	615
Dosage (mg/L) -->	control	control	control	control	control	control	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.1 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	0.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L	1.5 mg/L
Sex	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F	F
NASAL TURBINATES, Level 1 (Present)	1	1	1	1	1		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Tissue Absent or not adequate for evaluation						1^																		
Essentially normal tissue	1	1	1	1				1						1	1	1		1	1					
Level 1- Hyperplasia, epithelium, respiratory or transitional							1		1	1	1	1	1				1			1	1	2	1	1
Level 1- Infiltrate, granulocytic										1	1						1				1	1		
Level 1- Infiltrate, lymphocytic																								
Level 1- Nasal turbinate, mucosa, degeneration										2			2				1			1	1	1	2	1
Level 1- Nasal turbinate, mucosa, metaplasia, squamous																								1
Level 1 - Nasal turbinate, bone loss -level of resp epith in dorsal meatus																								
Level 1 - Goblet cell hyperplasia, nasal septum					1		2		1	1	1		1							1	1	1		

All main study animals 10 wks old

Blank cell indicates absence of finding, '1' = present, or minimal (generally, affecting 1-5% of the tissue) e.g., kidney-basophilic tubules '1' = 3-5 tubules observed. '2' = mild (6-15% of tissue affected), '3' = moderate (16-30% of the tissue affected. '4' = marked (affects > 30% of the sampled tissue).
* Inappropriate location and not able to be evaluated, section taken more caudal than location specified for Level 1.
^ - Tissue absent, tissue degraded beyond usefullness during processing .

APPENDIX B
STATISTICAL ANALYSES

NASAL TURBINATES, Level 1, Lesion Statistical Results, Treatment groups compared to Controls

Females

Dosage (mg/L) -->	control	0.1 mg/L	P-Value	Conclusion
Essentially normal tissue	4/5	1/6	0.0801	No significant difference
Hyperplasia, epithelium, respiratory or transitional	0/5	5/6	0.0152	0.1 > Control
Infiltrate, granulocytic	0/5	2/6	0.454	No significant difference
Infiltrate, lymphocytic	0/5	0/6	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/5	1/6	1	No significant difference
Nasal turbinate, mucosa, metaplasia, squamous	0/5	0/6	All showed no damage	
Nasal turbinate, bone loss	0/5	0/6	All showed no damage	
Goblet cell hyperplasia, nasal septum	1/5	4/6	0.2424	No significant difference

Dosage (mg/L) -->	control	0.5 mg/L	P-Value	Conclusion
Essentially normal tissue	4/5	4/6	1	No significant difference
Hyperplasia, epithelium, respiratory or transitional	0/5	2/6	0.4545	No significant difference
Infiltrate, granulocytic	0/5	1/6	1	No significant difference
Infiltrate, lymphocytic	0/5	0/6	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/5	2/6	0.4545	No significant difference
Nasal turbinate, mucosa, metaplasia, squamous	0/5	0/6	All showed no damage	
Nasal turbinate, bone loss	0/5	0/6	All showed no damage	
Goblet cell hyperplasia, nasal septum	1/5	1/6	1	No significant difference

Dosage (mg/L) -->	control	1.5 mg/L	P-Value	Conclusion
Essentially normal tissue	4/5	1/6	0.0801	No significant difference
Hyperplasia, epithelium, respiratory or transitional	0/5	5/6	0.0152	1.5 > Control
Infiltrate, granulocytic	0/5	2/6	0.4545	No significant difference
Infiltrate, lymphocytic	0/5	0/6	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/5	5/6	0.0152	1.5 > Control
Nasal turbinate, mucosa, metaplasia, squamous	0/5	1/6	1	No significant difference
Nasal turbinate, bone loss	0/5	0/6	All showed no damage	
Goblet cell hyperplasia, nasal septum	1/5	3/6	0.5454	No significant difference

NASAL TURBINATES, Level 1, Lesion Statistical Results, Treatment groups compared to Controls

Males

Dosage (mg/L) -->	control	0.1 mg/L	P-Value	Conclusion
Essentially normal tissue	3/6	2/4	1	No significant difference
Hyperplasia, epithelium, respiratory or transitional	1/6	1/4	1	No significant difference
Infiltrate, granulocytic	3/6	1/4	0.5714	No significant difference
Infiltrate, lymphocytic	0/6	0/4	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/6	0/4	All showed no damage	
Nasal turbinate, mucosa, metaplasia, squamous	0/6	0/4	All showed no damage	
Nasal turbinate, bone loss	0/6	0/4	All showed no damage	
Goblet cell hyperplasia, nasal septum	2/6	0/4	0.4667	No significant difference

Dosage (mg/L) -->	control	0.5 mg/L	P-Value	Conclusion
Essentially normal tissue	3/6	2/6	1	No significant difference
Hyperplasia, epithelium, respiratory or transitional	1/6	4/6	0.2424	No significant difference
Infiltrate, granulocytic	3/6	4/6	0	No significant difference
Infiltrate, lymphocytic	0/6	0/6	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/6	0/6	All showed no damage	
Nasal turbinate, mucosa, metaplasia, squamous	0/6	1/6	1	No significant difference
Nasal turbinate, bone loss	0/6	0/6	All showed no damage	
Goblet cell hyperplasia, nasal septum	2/6	3/6	1	No significant difference

Dosage (mg/L) -->	control	1.5 mg/L	P-Value	Conclusion
Essentially normal tissue	3/6	0/6	0.1818	No significant difference
Hyperplasia, epithelium, respiratory or transitional	1/6	6/6	0.0152	1.5 > Control
Infiltrate, granulocytic	3/6	6/6	0.1818	No significant difference
Infiltrate, lymphocytic	0/6	0/6	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/6	4/6	0.0606	No significant difference
Nasal turbinate, mucosa, metaplasia, squamous	0/6	1/6	1	No significant difference
Nasal turbinate, bone loss	0/6	0/6	All showed no damage	
Goblet cell hyperplasia, nasal septum	2/6	5/6	0.2424	No significant difference

NASAL TURBINATES, Level 1, Lesion Statistical Results, Treatment groups compared to Controls

Males and Females Combined

Dosage (mg/L) -->	control	0.1 mg/L	P-Value	Conclusion
Essentially normal tissue	7/11	3/10	0.1984	No significant difference
Hyperplasia, epithelium, respiratory or transitional	1/11	6/10	0.0237	0.1 > Control
Infiltrate, granulocytic	3/11	3/10	1	No significant difference
Infiltrate, lymphocytic	0/11	0/10	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/11	1/10	0.4762	No significant difference
Nasal turbinate, mucosa, metaplasia, squamous	0/11	0/10	All showed no damage	
Nasal turbinate, bone loss	0/11	0/10	All showed no damage	
Goblet cell hyperplasia, nasal septum	3/11	4/10	0.6594	No significant difference

Dosage (mg/L) -->	control	0.5 mg/L	P-Value	Conclusion
Essentially normal tissue	7/11	6/12	0.6802	No significant difference
Hyperplasia, epithelium, respiratory or transitional	1/11	6/12	0.0686	No significant difference
Infiltrate, granulocytic	3/11	5/12	0.6668	No significant difference
Infiltrate, lymphocytic	0/11	0/12	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/11	2/12	0.4783	No significant difference
Nasal turbinate, mucosa, metaplasia, squamous	0/11	1/12	1	No significant difference
Nasal turbinate, bone loss	0/11	0/12	All showed no damage	
Goblet cell hyperplasia, nasal septum	3/11	4/12	1	No significant difference

Dosage (mg/L) -->	control	1.5 mg/L	P-Value	Conclusion
Essentially normal tissue	7/11	1/12	0.0094	Control > 1.5
Hyperplasia, epithelium, respiratory or transitional	1/11	11/12	0.0001	1.5 > Control
Infiltrate, granulocytic	3/11	8/12	0.0995	No significant difference
Infiltrate, lymphocytic	0/11	0/12	All showed no damage	
Nasal turbinate, mucosa, degeneration	0/11	9/12	0.0003	1.5 > Control
Nasal turbinate, mucosa, metaplasia, squamous	0/11	2/12	0.4783	No significant difference
Nasal turbinate, bone loss	0/11	0/12	All showed no damage	
Goblet cell hyperplasia, nasal septum	3/11	8/12	0.0995	No significant difference

APPENDIX C

STORAGE OF STUDY MATERIALS AND RECORDS RETENTION

The study records and pathology final report will be archived and maintained at or under the direction of U.S. Army Public Health Center's (APHC) Toxicology Portfolio (TOX), according to TOX SOPs and EPA requirements. The Pathology specimens will also be archived and maintained at or under the direction of APHC Toxicology Portfolio, according to TOX SOP and EPA requirements.

Appendix R

Acute and Subacute Analytical Results

US Army Aberdeen Test Center
Warfighter Directorate
Applied Science Test Division
Field Sampling and Analysis Branch
400 Colleran Road, Building 363, Aberdeen Proving Ground, MD 21005-5059

Conducted For:

Mr. Lee Crouse

Toxicity Evaluation Division (TEV) Toxicology Directorate
Army Public Health Center (APHC), MCHB-PH-TEV
5158 Blackhawk Road
Aberdeen Proving Ground, MD 21010-5403

FSAB Test Report # : 2017-FSAB-001

Report Title : Red Smoke Inhalation Toxicity Study Air Sampling Results

Report Prepared By:

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APPLIED SCIENCE TEST DIVISION
FIELD SAMPLING AND ANALYSIS BRANCH
REPORT NUMBER 2017-FSAB-001

TEDT-AT-WFA

Title of Report: Red Smoke Inhalation Toxicity Study Air Sampling Results

Project Number: D0802 (FSAB Customer Test)

Conducted for: Mr. Lee Crouse, Biologist, U.S. Army Public Health Center, Directorate of Toxicology.

1.1 INTRODUCTION

The U.S. Army uses colored smokes in a variety of ways, including identification of potential targets and friendly troops, simulation of battlefield events, and as a means of communication. Previously used smoke formulations were developed strictly based on their ability to produce the desired color for a specified period of time. Recent changes made to the smoke formulations and dissemination systems have focused on soldier and environmental safety.

The U.S. Army Public Health Center Toxicology Directorate performed an acute and a 2-week repeated-dose inhalation toxicity test with a new pyrotechnic red smoke formulation. The U.S. Army Aberdeen Test Center (ATC) Field Sampling and Analysis Branch (FSAB) provided analytical chemistry support for this effort by sampling the atmosphere inside an exposure chamber for selected trials during the study. The scope of the analytical support was to sample the air in order to characterize and quantify the gaseous by-products emitted by the pyrotechnic when it is burned. Multiple methods were used to sample the air inside the exposure chamber. Continuous real-time gas measurements were made by Fourier Transform Infrared (FTIR) spectroscopy. Sorbent tube media were used to collect aldehyde (carbonyl) analytes in the air, these sampled were extracted and analyzed by High Performance Liquid Chromatography (HPLC) following EPA Method TO-11. Finally, whole air (canister) samples were collected and submitted for laboratory analysis for volatile organic compounds (VOCs) by Gas Chromatography / Mass Spectrometry (GC/MS) following EPA Method TO-15.

A total of twenty four (24) compounds were identified as combustion by-products of the new pyrotechnic red smoke formulation. The primary/major constituents emitted by the red smoke grenades included: carbon dioxide (CO2), carbon monoxide (CO), acetaldehyde, acrolein, formaldehyde, and several simple hydrocarbons.

2.1 OBJECTIVE

The purpose of this test was to identify and quantify the gaseous chemical species produced from the combustion of the pyrotechnic mixture in the reformulated red smoke grenade.

2.2 CRITERIA

There is no specific exposure criteria established for this test. The data obtained will be for informational purposes and used by USAPHC Directorate of Toxicology (DTOX) personnel in their toxicological assessment of the red smoke grenades.

2.3 TEST PROCEDURE

a. Testing was conducted in Lab 10, Building 2101, located in the Edgewood Area of Aberdeen Proving Ground. The test fixture used for these exposure experiments consisted of two stainless steel chambers, the exposure chamber and an ignition chamber, connected via a 2" PVC transfer pipe. Elevated air temperatures produced from the burning grenade prevented the inhalation exposures from being performed in a single chamber.

b. A single grenade was used for each day that exposure trials were conducted. In order to facilitate the generation of test atmospheres, the grenade was placed upside down and secured to a ring stand attached to the floor of the ignition chamber. Each grenade was ignited with its own fuse by pulling the fuse pin that was attached to string run through a port in the initiation chamber. The positive pressure created by the burning smoke grenade in the ignition chamber forced the test material through the transfer pipe and into the exposure chamber as illustrated in the schematic in Figure 2.3.1.

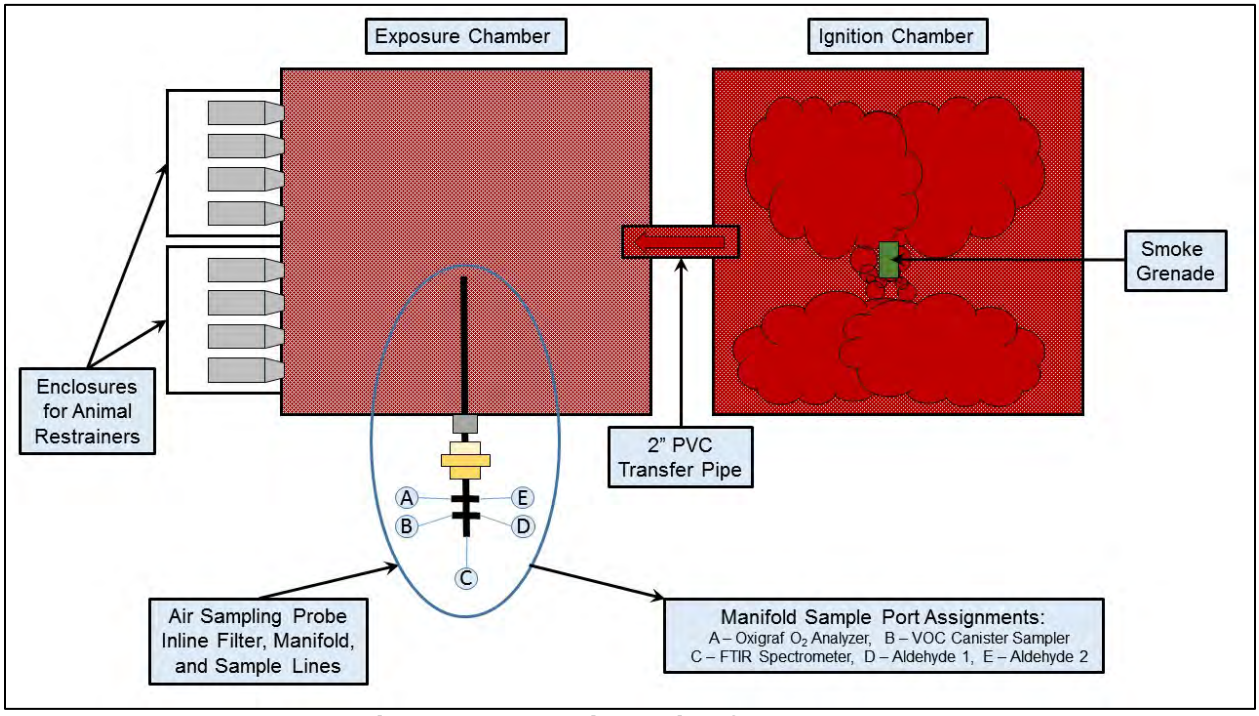

Figure 2.3.1 – Schematic of Test Setup

c. The burn time for each grenade was approximately one minute and was determined by pressure fluctuations in the Magnehelic gauges attached to the chambers. When the grenade completed its burn, preliminary gravimetric samples were taken to determine the particulate concentration in the exposure chamber. Once the particulate concentration in the exposure chamber was within the acceptable range for each animal exposure level, the rats (each contained within an animal restrainer) were placed in the faceplate (within the Plexiglas enclosures) for the 30-minute exposure period. To minimize loss of the test atmosphere from the exposure chamber, the animals were inserted one at a time over the span of approximately 1-2 minutes. Once all of the rats were positioned within the enclosure, a cover was placed over the rear to prevent leakage of the test atmosphere into the laboratory. Immediately thereafter, sampling of the air within the exposure chamber commenced. Detailed photos of the ignition and exposure chambers are provided in Figure 2.3.2.

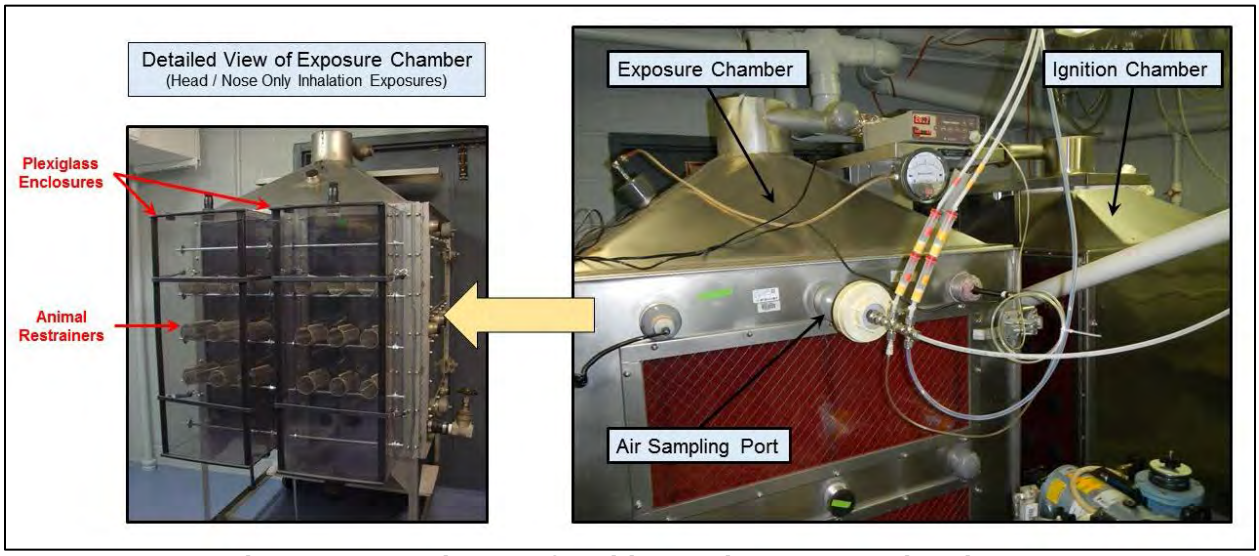

Figure 2.3.2 – Photos of Ignition and Exposure Chambers

d. The air sampling system devised for these experiments is also detailed in Figures 2.3.2 and 2.3.3. It consisted of a single 3/8" O.D. stainless steel sample probe equipped with a 90-mm PTFE inline filter (to prevent particulate contamination), followed by a multi-port sample manifold. The probe was inserted through a sample port near the top center of the exposure chamber and extended approximately 18" inside. The sample manifold was constructed of stainless steel Swagelok fittings. The individual sample lines were connected to the manifold so that a common representative air sample was drawn by all of the equipment. A summary detailing the specifics of each of the sampling/analysis methods is provided in Section 2.3.1.

e. At the conclusion of each of the 30-minute exposures, all sampling equipment was stopped and the animals were removed from the enclosures on the exposure chamber. When the area was clear of PHC personnel and test animals, all sample media were recovered by FSAB personnel.

f. At the conclusion of the single acute exposure trial, the chambers were evacuated and testing was completed for the day. The sample probe and 90-mm filter were removed and cleaned before being returned and reinstalled for the subsequent repeated dose exposure trials.

g. For the repeated (sub-acute) dose exposures, a single grenade also produced adequate test atmosphere concentration levels for all 3 test groups each day (design concentration levels of 0.1, 0.5, and 1.5 mg/L). Sampling was conducted for each of the three decreasing concentration levels investigated. At the start of sampling each of these days, background air samples from inside of the exposure chamber were collected to account for any elevated analyte concentrations that may potentially bias the test results. The procedures outlined above in steps b, and c. were followed to initiate the exposure trials each day. Following each trial, all data was saved and samples recovered. Before the next exposure began, data acquisition systems were reset and new media installed. Test atmospheres for the high and intermediate concentration levels were allowed to naturally settle in the exposure chamber until the appropriate concentration was obtained. For the low concentration exposures, an exhaust pump fitted with a HEPA filter was connected to the initiation chamber and the exhaust line valve was opened. The red smoke particulate was drawn out of the exposure chamber into the initiation chamber until the exposure chamber reached the appropriate concentration for the low level exposures.

2.3.1 METHODS OF SAMPLING / ANALYSIS

a. Continuous Real-time Gas Measurements (FTIR and Oxigraf O_2 analyzer)

(1) Continuous real-time gas/vapor concentration measurements were made using a Midac Model I4001 Fourier Transform Infrared (FTIR) spectrometer equipped with a gas sampling cell. The FTIR multi-component gas analyzer is an instrument capable of measuring virtually any compound that absorbs energy in the mid-infrared region of the electromagnetic spectrum. Testing with the FTIR was conducted in general accordance with FSAB-IOP-008 (Reference A). Figure 2.3.3 shows the setup of the spectrometer near the exposure chamber. Table 2.3.1 contains specific information regarding the spectrometer used for this test. The instrument case and light tubes were purged with ultra-high purity (UHP) nitrogen to remove any potentially interfering species (i.e. CO_2 and water vapor) not attributed to the sample gas.

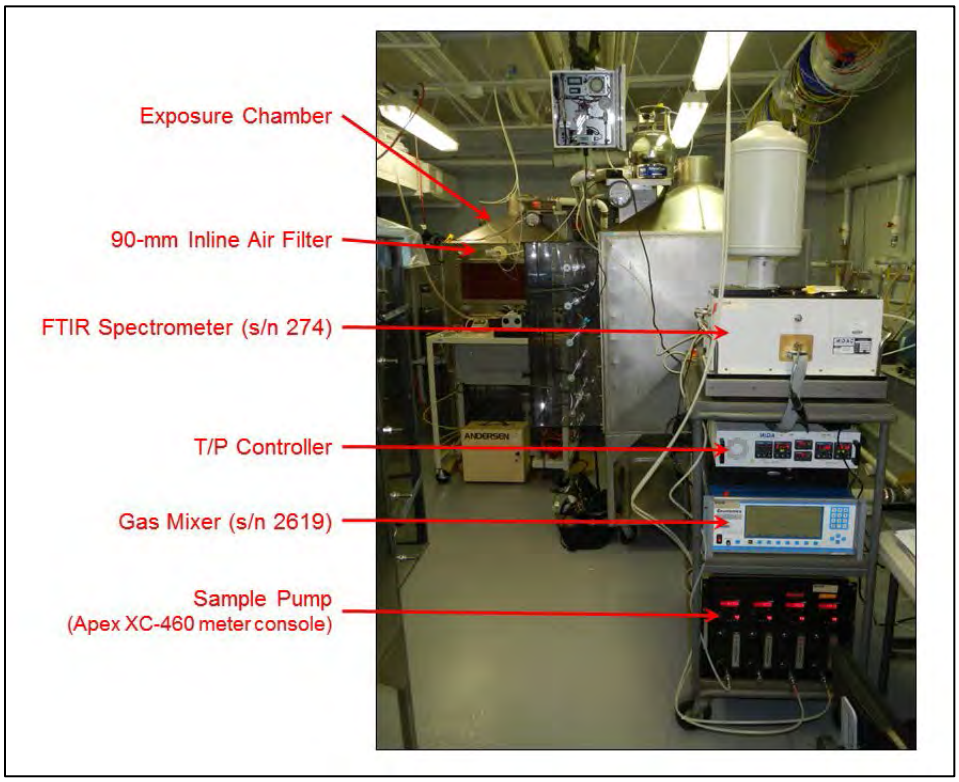

Figure 2.3.3 - FTIR Spectrometer System

Table 2.3.1: FTIR Configuration – Instrument (serial number) 274

Instrument Optics	ZnSe	Detector Type	MCT
Instrument Resolution	0.5 cm^{-1}	Apodization Function	Triangular
Spectra Range	650-4500 cm^{-1}	Zero Filling Factor	1x
Absorption Pathlength	7.13 meters	Scan Speed	117 kHz
Cell Temperature	121 ^oC	Detector Gain – Hardware	Jumper F
Cell Pressure	~ 1 atm	Detector Gain - Software	1x

(2) The spectrometer was controlled by a laptop computer with *AutoQuant*™ software. Spectral data from the FTIR was collected at the rate of 1 scan approximately every 0.6 seconds; however, 16 scans were co-averaged for each sample in order to increase the signal to noise ratio resulting in lower analyte detection limits. A background spectrum, collected while UHP nitrogen was flowing through the instrument gas cell, was collected prior to each test. In addition to the absorbance spectra, interferograms of all test and background spectra were saved to the computer hard-drive and back-up storage media.

(3) A series of calibration spectra were collected on the FTIR spectrometer for use in the quantitative analysis of CO_2, CO, CH_4, C_2H_2, C_2H_4, NO, NO_2, and SO_2. Commercially prepared certified gas standards were used to generate the calibration spectra. The gas standards were diluted with UHP nitrogen using an Environics computerized gas mixing/dilution system to obtain reference spectra over a range of concentrations. All calibration spectra and background spectra were collected with longer integration times than used during testing in order to increase the signal-to-noise ratio and improve quantitative results. A standard analytical method was then developed with these spectra using *AutoQuant*™ software to be used for data collection during these tests. *AutoQuant*™ uses a classic least squares algorithm to compute analyte concentrations. The recorded concentrations were then exported to a spreadsheet program for preliminary analysis.

(4) Instrument calibration checks were performed each day of testing. The performance/stability of the FTIR spectrometer was checked by performing a series of calibration checks for selected analytes prior to testing. The calibration checks were performed by introducing the certified gas standard directly into the FTIR sample cell. The calibration gas was diluted to the appropriate concentration with UHP nitrogen using an Environics, Model 2040, computerized gas mixer. The instrument conditions, integration time, and analysis of the calibration checks were identical to those used during the actual test events. The results of the checks and other quality control information can be found in Appendix A.

(5) Spectral analysis was performed to identify the analytes present in the sample stream as this was non-typical experiment that was fairly complex. The FTIR does not physically separate the analytes for analysis (such as gas chromatography), the absorbance bands produced by each compound are additive and can quickly convolute the spectrum. Spectral analysis starts with the identification of absorbance features for known or obvious materials (such as CO_2 and water vapor) and subtracting them from the sample spectra. The process continues with the identification of the remaining spectral features, by either analyst experience or by searching commercially available reference libraries, and subtraction from the sample. This recursive process is repeated until all major absorbance features have been accounted for in the spectra.

(6) Post-processing of the test data with a modified *AutoQuant Pro*™ analytical method, containing reference spectra of analytes and possible interferences, was used to produce the final quantitative analysis results for this project. The method included the following reported analytes: carbon dioxide (CO_2), carbon monoxide (CO), methane (CH_4), acetylene (C_2H_2), ethylene (C_2H_4), nitric oxide (NO), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2). The reference spectra for these compounds were generated on the instrument used to collect the test data. The results for analytes are presented in Section 3.1. The results are reported as the average of the observed concentrations inside the chamber during the 30-minute exposure

period. Additional reference spectra obtained from the QASoft™ library (Infrared Analysis, Inc.) were also included. These compounds included: acetaldehyde, acrolein, butanone, formaldehyde, formic acid, isopropanol, propene, and m/p-xylenes. These additional spectra were added to reduce any potential interferences that might affect the concentration values of the reported analytes. The results for these compounds are not reported from the FTIR as they are considered qualitative estimates and are accounted for by other methodologies used for these experiments.

(7) Model O2 Fast Oxygen Analyzer, manufactured by Oxigraf, Inc. was used to continuously measure the oxygen (O_2) concentration within the exposure chamber. This analyzer uses laser absorption spectroscopy to measure the concentration of oxygen in the air sample. No data was recorded from the analyzer but the concentration reading on the analyzer display was used as a confirmatory check that the equipment used by PHC was operating properly. The Oxigraf analyzer was operated according to the manufacturer's instructions and FSAB-IOP-023 (Reference B).

b. Aldehyde (Carbonyls) Sorbent Tube Sampling

H30 high capacity sorbent tube cartridges (Supelco/Sigma Aldrich, part # 535323) designed for sampling carbonyls (e.g. aldehydes such formaldehyde, etc.) in air were used for this investigation. The aldehyde analytes in the air sample are trapped on a high-purity silica gel adsorbent coated with 2,4-dinitrophenylhydrazine, where they are converted to the hydrazone derivatives. Samples were drawn from the sample manifold on the exposure chamber at a rate of ~0.30 to 1.0 L/min via an air sampling pump (Apex Instruments XC-460 Meter Console – operated according to FSAB-IOP-006, Reference C). For selected exposure trials, samples were collected using two sorbent tubes connected in a "piggy-back" configuration to verify that no analyte breakthrough occurred. Additionally, duplicate samples were collected periodically so that the precision of the sampling method could be assessed. Figure 2.3.4 contains photos detailing the aldehyde sampling trains. The labelled H30 tubes were capped immediately after sampling, placed in foil envelopes and stored in a cooler with ice until returned to ATC. All samples were then properly handled and stored (Reference D) until submitted to the ATC Chemical Sampling and Analysis Brach (CSAB) for extraction with acetonitrile and analysis by High Performance Liquid Chromatography (HPLC) in general accordance with EPA Method TO-11. Tabulated results for the 15 measured analytes are summarized in section 3.1. Copies of the laboratory reports (References E through H) for this analysis are provided in Appendix B.

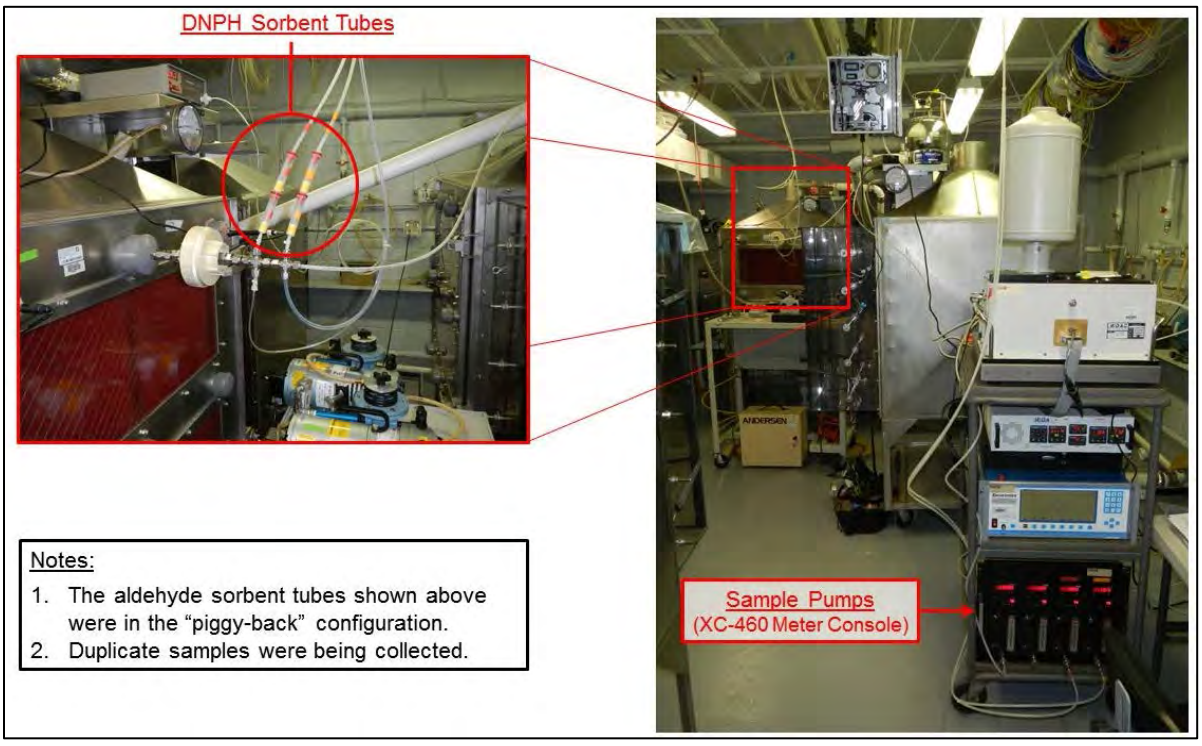

Figure 2.3.4 - Aldehyde Sampler(s) Details

c. Volatile Organic Compounds (VOCs) Sampling

VOCs were sampled using a XonTech®, Inc. Model 911 ambient air canister sampler. The 90-mm PTFE inline filter on the sample probe was used to prevent particulate contamination of the sampler and canisters. The air was sampled from the manifold at a rate of approximately 1 L/minute. The XonTech® sampler delivered a portion of the sample to a certified VOC free silicon-lined (SilcoCan®) canister at a rate 400 mL/min. Sampling was started at the beginning of each of the selected 30-minute exposure trials. The VOC sampler flow rate was checked using a calibrated primary flow meter (BIOS, DC-Lite) before and after each sampling run in general accordance with Reference D. Figure 2.3.5 contains a photo detailing the VOC sampling train. After each individual sample was collected, the VOC canister valve was closed and the canister was capped. The VOC canisters were submitted to U.S. Army Public Health Command (USAPHC) (Provisional) Directorate of Laboratory Sciences for analysis. Eurofins Lancaster Laboratories, under contract with USAPHC, performed a Gas Chromatography/Mass Spectrometry analysis of the samples in accordance with EPA Method TO-15. The Lancaster Labs TO-15 method analyzes each sample for a total of 81 different VOC analytes. The tabulated results summarized in Section 3.1 contain only the abbreviated composite list of the 32 compounds that were detected in the canister samples. Copies of the full laboratory reports (References I through K), containing the results for all 81 compounds, are included in Appendix C.

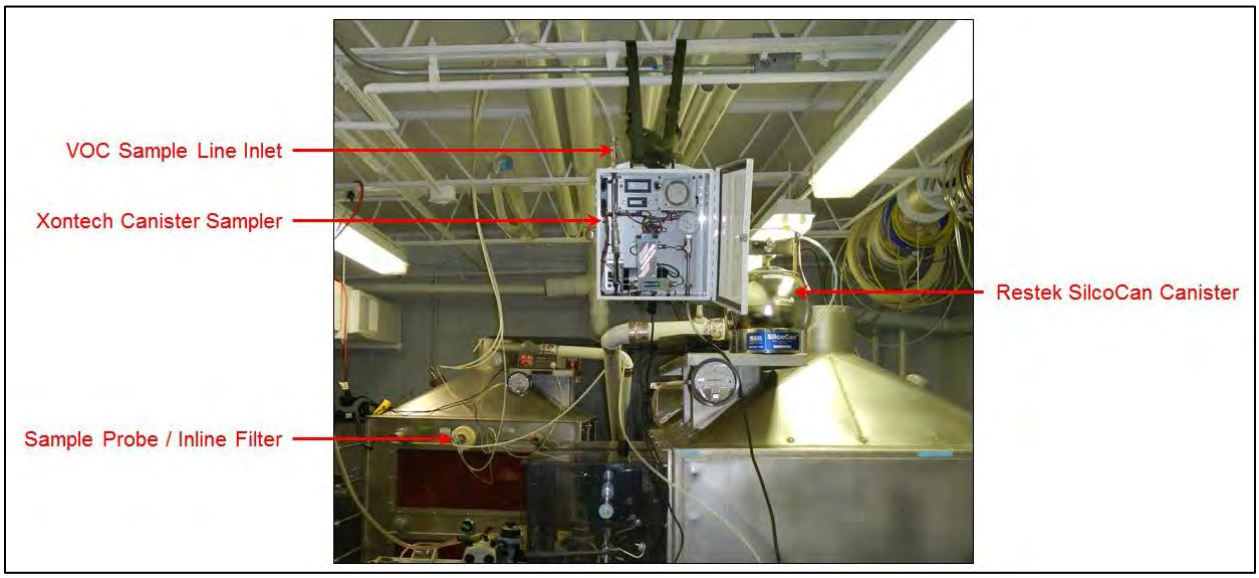

Figure 2.3.5 - VOC Canister Sampler

2.4 TEST ITEM DESCRIPTION

The test item being investigated for this inhalation toxicity test is a reformulated M18 red smoke grenade (Figure 2.4.1). This type of pyrotechnic functions by forming a dye cloud; the dye is first vaporized by the burning energetic, followed by rapid condensation into fine aerosol particles in the air. To avoid combustion of the organic dye, a relatively cool burning fuel / oxidizer combination is used. In addition, a flame retardant is added as a coolant. The formulation of the smoke grenade filler is provided in Table 2.4.1. The grenade contains four pressed pellets of the smoke mixture (weighing a total of 11.5 ounces) and was ignited with a standard delay fuse (Reference L).

Figure 2.4.1 – Photo Illustration of a M18 Smoke Grenade

Table 2.4.1 - Pyrotechnic Red Smoke Formulation

Component	Approximate Composition (Parts By Weight)	Function
Dye, Solvent Red 169	36.5	Color Production
Sugar	25.5	Fuel
Potassium Chlorate	20.5	Oxidizer
Magnesium Carbonate	16.5	Coolant

3.1 TEST FINDINGS

All values in bold type represent the actual measured concentrations. Results preceded by a less-than sign indicate that the analyte was not detected above the value provided, which represents the instrument/method reporting limit.

The reported FTIR results are the average of the measured concentrations for the entire sampling period during each exposure.

a. Tables 3.1.1 through 3.1.3 contain the tabulated analytical results for acute dose exposure trial conducted on 29 April 2015.

Table 3.1.1 - Acute Dose Exposure FTIR Results

Analyte	Average Measured Concentration	
	Chamber Background (ppm)	Acute Exposure (ppm)
Carbon Dioxide	**615**	**1986**
Carbon Monoxide	< 5	**149**
Methane	**2.1**	**12**
Acetylene	< 1	**1.1**
Ethylene	< 1	**2.6**
Nitric Oxide	< 3	**5.6**
Nitrogen Dioxide	< 1	< 1
Sulfur Dioxide	< 3	< 3

Table 3.1.2 - Acute Dose Exposure TO-11 Analysis Results

Analyte	Measured Concentration		
	Chamber Background (ppm)	Acute Exposure	
		Acute Exp_1 (ppm)	Acute Exp_2 (ppm)
Formaldehyde	NA	**26.08**	**26.15**
Acetaldehyde	NA	**14.64**	**12.04**
Acetone	NA	**0.28**	**0.77**
Acrolein	NA	**0.58**	< 0.58
Propionaldehyde	NA	**0.73**	**0.15**
Crotonaldehyde	NA	**0.65**	**0.57**
Butyraldehyde	NA	< 0.48	< 0.45
Benzaldehyde	NA	< 0.32	< 0.31
Isovaleraldehyde	NA	< 0.40	< 0.38
Valeraldehyde	NA	< 0.40	< 0.38
o,m,p-Tolualdehyde	NA	< 0.29	< 0.27
Hexaldehyde	NA	< 0.34	< 0.32
2,5-DMB	NA	< 0.26	< 0.24

NOTES:
NA = Not Applicable, a Chamber Background TO-11 sample was not collected.

Table 3.1.3- Acute Exposure VOC Results

Detected Analytes	Measured Concentration	
	Chamber Background ($\mu g/m^3$)	Acute Exposure ($\mu g/m^3$)
1,2,4-Trimethylbenzene	NA	< 25
1,2-Dichloroethane	NA	< 20
1,3,5-Trimethylbenzene	NA	< 25
2-Butanone {MEK}	NA	**2100**
4-Ethyltoluene	NA	< 25
Acetone	NA	**9400**
Acetonitrile	NA	**1400**
Acrolein	NA	**6700**
Acrylonitrile	NA	**49**
Benzene	NA	**590**
Butadiene	NA	**510**
Carbon disulfide	NA	< 31
Chlorodifluoromethane	NA	< 18
Chloroethane	NA	**6.3**
Chloroform	NA	**56**
Chloromethane	NA	**330**
Dichlorodifluoromethane	NA	< 18
Ethyl acetate	NA	< 22
Ethylbenzene	NA	**250**
Hexane	NA	**24**
Isopropyl alcohol	NA	**42**
m,p-Xylene	NA	**900**
Methyl methacrylate	NA	< 41
Methylene chloride	NA	**45**
n-Heptane	NA	< 20
Octane	NA	**11**
o-Xylene	NA	**180**
Propylene	NA	**7600**
Styrene	NA	**40**
Toluene	NA	**270**
Trichlorofluoromethane	NA	< 28
Vinyl chloride	NA	**19**

NOTES:
NA = Not Applicable, a Chamber Background VOC canister sample was not collected.

b. Tables 3.1.4 through 3.1.6 contain the tabulated analytical results for repeated dose exposure #2 trials conducted on 3 June 2015.

Table 3.1.4 - Repeated Dose Exposure #2 FTIR Results

Analyte	Average Measured Concentration			
	Chamber Background (ppm)	High Level Exposure (ppm)	Mid-Level Exposure (ppm)	Low-Level Exposure (ppm)
Carbon Dioxide	**519**	**1940**	**3312**	**3514**
Carbon Monoxide	< 5	**133**	**108**	**74.5**
Methane	**1.8**	**9.1**	**7.6**	**5.8**
Acetylene	< 1	< 1	< 1	< 1
Ethylene	< 1	**2.1**	**2.0**	**1.6**
Nitric Oxide	< 3	**4.1**	**3.5**	**3.2**
Nitrogen Dioxide	< 1	< 1	< 1	< 1
Sulfur Dioxide	< 3	< 3	< 3	< 3

Table 3.1.5 - Repeated Dose Exposure #2 TO-11 Analysis Results

Analyte	Measured Concentration				
	Chamber Background (ppm)	High Level Exposure		Mid-Level Exposure (ppm)	Low-Level Exposure (ppm)
		High_1 (ppm)	High_2 (ppm)		
Formaldehyde	< 0.44	**23.8**	**21.2**	**17.6**	**12.7**
Acetaldehyde	< 0.30	**14.3**	**12.2**	**11.7**	**10.7**
Acetone	< 0.23	**0.13**	< 0.38	**0.18**	**1.37**
Acrolein	< 0.24	**1.79**	**1.76**	**1.57**	**1.14**
Propionaldehyde	< 0.23	**0.54**	**0.45**	**0.54**	**0.56**
Crotonaldehyde	< 0.19	**0.59**	**0.52**	**0.66**	**0.76**
Butyraldehyde	< 0.18	< 0.34	< 0.30	< 0.30	**0.16**
Benzaldehyde	< 0.13	< 0.23	< 0.21	< 0.20	**0.05**
Isovaleraldehyde	< 0.15	< 0.28	< 0.25	< 0.25	< 0.25
Valeraldehyde	< 0.15	< 0.28	< 0.25	< 0.25	< 0.25
o,m,p-Tolualdehyde	< 0.11	< 0.20	< 0.18	< 0.18	< 0.18
Hexaldehyde	< 0.13	< 0.24	< 0.22	< 0.22	< 0.22
2,5-DMB	< 0.10	< 0.18	< 0.16	< 0.16	< 0.16

Table 3.1.6 - Repeated Dose Exposure #2 VOC Results

Detected Analytes	Measured Concentration			
	Chamber Background (µg/m³)	High Level Exposure (µg/m³)	Mid-Level Exposure (µg/m³)	Low-Level Exposure (µg/m³)
1,2,4-Trimethylbenzene	1.7	680	610	510
1,2-Dichloroethane	< 2.0	120	98	< 200
1,3,5-Trimethylbenzene	< 2.5	< 250	< 250	1200
2-Butanone {MEK}	2.7	1600	1200	920
4-Ethyltoluene	< 2.5	190	170	130
Acetone	31	9100	9000	7500
Acetonitrile	10	1300	1100	790
Acrolein	6.4	4400	4800	4200
Acrylonitrile	< 2.2	< 220	< 220	< 220
Benzene	1	610	460	350
Butadiene	< 1.1	150	240	220
Carbon disulfide	< 3.1	< 310	< 310	170
Chlorodifluoromethane	1.1	< 180	< 180	< 180
Chloroethane	< 1.3	< 130	< 130	< 130
Chloroform	< 2.4	100	< 240	< 240
Chloromethane	0.97	260	220	170
Dichlorodifluoromethane	2.3	< 250	< 250	< 250
Ethyl acetate	< 1.8	240	230	< 180
Ethylbenzene	2	530	420	370
Hexane	2.2	< 180	74	< 180
Isopropyl alcohol	< 2.5	1200	ND	550
m,p-Xylene	7.1	2000	1600	1400
Methyl methacrylate	< 4.1	< 410	< 410	84
Methylene chloride	7.7	330	300	110
n-Heptane	< 2.0	110	110	< 200
Octane	< 4.7	110	120	110
o-Xylene	2.7	780	600	530
Propylene	2.9	3100	4200	3600
Styrene	< 2.1	290	240	190
Toluene	1.5	2600	2200	1300
Trichlorofluoromethane	1.2	< 280	< 280	< 280
Vinyl chloride	< 1.3	< 130	< 130	< 130

c. Tables 3.1.7 through 3.1.9 contain the tabulated analytical results for repeated dose exposure #6 trials conducted on 9 June 2015.

Table 3.1.7 - Repeated Dose Exposure #6 FTIR Results

Analyte	Average Measured Concentration			
	Chamber Background (ppm)	High Level Exposure (ppm)	Mid-Level Exposure (ppm)	Low-Level Exposure (ppm)
Carbon Dioxide	**454**	**2242**	**3279**	**2280**
Carbon Monoxide	< 5	**141**	**121**	**46.4**
Methane	**1.8**	**9.8**	**8.6**	**4.3**
Acetylene	< 1	**1.0**	**1.3**	< 1
Ethylene	< 1	**2.5**	**2.3**	**1.0**
Nitric Oxide	< 3	**5.3**	**4.9**	< 4
Nitrogen Dioxide	< 1	< 1	< 1	< 1
Sulfur Dioxide	< 3	< 3	< 3	< 3

Table 3.1.8 - Repeated Dose Exposure #6 TO-11 Analysis Results

Analyte	Measured Concentration					
	Chamber Background (ppm)	High Level Exposure (ppm)	Mid-Level Exposure		Low-Level Exposure	
			Med_1 (ppm)	Med_2 (ppm)	Low_1 (ppm)	Low_2 (ppm)
Formaldehyde	**0.17**	**11.3**	**11.8**	**14.0**	**7.97**	**8.02**
Acetaldehyde	< 0.30	**2.53**	**4.31**	**6.23**	**6.06**	**6.11**
Acetone	< 0.23	**0.10**	**0.09**	**0.11**	**1.10**	**1.27**
Acrolein	< 0.23	**1.30**	**1.35**	**1.42**	**0.41**	**0.38**
Propionaldehyde	< 0.23	< 0.24	**0.17**	**0.26**	**0.32**	**0.33**
Crotonaldehyde	< 0.19	**0.45**	**0.53**	**0.63**	**0.38**	**0.38**
Butyraldehyde	< 0.18	< 0.19	< 0.20	< 0.23	**0.35**	**0.40**
Benzaldehyde	< 0.12	**0.05**	**0.05**	**0.05**	< 0.14	< 0.15
Isovaleraldehyde	< 0.15	< 0.16	< 0.17	< 0.19	< 0.17	< 0.19
Valeraldehyde	< 0.15	< 0.16	< 0.17	< 0.19	< 0.17	< 0.19
o,m,p-Tolualdehyde	< 0.11	< 0.12	< 0.12	< 0.14	< 0.12	< 0.14
Hexaldehyde	< 0.13	< 0.14	< 0.15	< 0.17	< 0.15	< 0.16
2,5-DMB	< 0.10	< 0.10	< 0.11	< 0.12	< 0.11	< 0.12

Table 3.1.9 - Repeated Dose Exposure #6 VOC Results

Detected Analytes	Measured Concentration			
	Chamber Background ($\mu g/m^3$)	High Level Exposure ($\mu g/m^3$)	Mid-Level Exposure ($\mu g/m^3$)	Low-Level Exposure ($\mu g/m^3$)
1,2,4-Trimethylbenzene	< 12	< 25	< 25	< 25
1,2-Dichloroethane	< 10	< 20	< 20	< 20
1,3,5-Trimethylbenzene	< 12	< 25	< 25	< 25
2-Butanone {MEK}	< 29	**1300**	**1200**	**290**
4-Ethyltoluene	< 12	< 25	< 25	< 25
Acetone	**73**	**9900**	**9500**	**4700**
Acetonitrile	**120**	**950**	**970**	**200**
Acrolein	**12**	**5800**	**5400**	**2800**
Acrylonitrile	< 11	**33**	**40**	< 22
Benzene	< 8.0	**380**	**450**	**130**
Butadiene	< 5.5	**47**	**93**	**110**
Carbon disulfide	< 16	< 31	< 31	< 31
Chlorodifluoromethane	< 8.8	< 18	< 18	< 18
Chloroethane	< 6.6	< 13	< 13	< 13
Chloroform	< 12	**55**	**65**	**20**
Chloromethane	< 10	**210**	**180**	**70**
Dichlorodifluoromethane	< 12	< 25	< 25	< 25
Ethyl acetate	< 9.0	< 18	< 18	< 18
Ethylbenzene	< 11	**170**	**200**	**54**
Hexane	< 8.8	**13**	**14**	< 18
Isopropyl alcohol	< 12	**19**	**21**	< 25
m,p-Xylene	**5.5**	**550**	**650**	**180**
Methyl methacrylate	< 20	< 41	< 41	< 41
Methylene chloride	**8.8**	**41**	**49**	**22**
n-Heptane	< 10	< 20	**9.1**	ND
Octane	< 23	**11**	< 47	<47
o-Xylene	< 11	**98**	**110**	**36**
Propylene	**2.2**	**3900**	**3900**	**1300**
Styrene	< 11	**9.8**	**17**	< 21
Toluene	< 9.4	**160**	**190**	**55**
Trichlorofluoromethane	< 14	< 28	< 28	< 28
Vinyl chloride	< 6.4	**10**	**9.1**	< 13

d. Tables 3.1.10 through 3.1.12 contain the tabulated analytical results for repeated dose exposure #10 trials conducted on 15 June 2015.

Table 3.1.10 - Repeated Dose Exposure #10 FTIR Results

Analyte	Average Measured Concentration			
	Chamber Background (ppm)	High Level Exposure (ppm)	Mid-Level Exposure (ppm)	Low-Level Exposure (ppm)
Carbon Dioxide	**437**	**2372**	**3933**	**2683**
Carbon Monoxide	< 5	**190**	**163**	**62.4**
Methane	**1.6**	**13.7**	**12.1**	**5.5**
Acetylene	< 1	**1.2**	**1.1**	< 1
Ethylene	< 1	**4.1**	**3.7**	**1.6**
Nitric Oxide	< 3	**8.5**	**6.9**	**3.7**
Nitrogen Dioxide	< 1	< 1	< 1	< 1
Sulfur Dioxide	< 3	< 3	< 3	< 3

Table 3.1.11 - Repeated Dose Exposure #10 TO-11 Analysis Results

Analyte	Measured Concentration						
	Chamber Background (ppm)	High Level Exposure		Mid-Level Exposure		Low-Level Exposure	
		High_1 (ppm)	High_2 (ppm)	Med_1 (ppm)	Med_2 (ppm)	Low_1 (ppm)	Low_2 (ppm)
Formaldehyde	< 0.43	**15.57**	**15.67**	**12.73**	**12.81**	**8.25**	**8.04**
Acetaldehyde	< 0.29	**6.17**	**6.85**	**8.44**	**8.47**	**8.08**	**7.84**
Acetone	< 0.22	< 0.27	< 0.28	< 0.26	< 0.26	**1.24**	**1.46**
Acrolein	< 0.23	**2.05**	**2.12**	**2.01**	**1.98**	**0.79**	**0.76**
Propionaldehyde	< 0.22	**0.39**	**0.40**	**0.45**	**0.45**	**0.42**	**0.40**
Crotonaldehyde	< 0.18	**0.60**	**0.60**	**0.60**	**0.60**	**0.52**	**0.51**
Butyraldehyde	< 0.18	< 0.22	< 0.22	< 0.21	< 0.21	**0.27**	**0.30**
Benzaldehyde	< 0.12	**0.05**	**0.05**	**0.05**	**0.05**	**0.04**	**0.04**
Isovaleraldehyde	< 0.15	< 0.18	< 0.19	< 0.18	< 0.18	< 0.17	< 0.18
Valeraldehyde	< 0.11	< 0.18	< 0.19	< 0.18	< 0.18	< 0.17	< 0.18
o,m,p-Tolualdehyde	< 0.11	< 0.13	< 0.13	< 0.13	< 0.13	< 0.12	< 0.13
Hexaldehyde	< 0.13	< 0.16	< 0.16	< 0.15	< 0.15	< 0.15	< 0.16
2,5-DMB	< 0.10	< 0.12	< 0.12	< 0.11	< 0.11	< 0.11	< 0.12

Table 3.1.12 - Repeated Dose Exposure #10 VOC Results

Detected Analytes	Measured Concentration			
	Chamber Background ($\mu g/m^3$)	High Level Exposure ($\mu g/m^3$)	Mid-Level Exposure ($\mu g/m^3$)	Low-Level Exposure ($\mu g/m^3$)
1,2,4-Trimethylbenzene	< 25	**220**	**230**	< 25
1,2-Dichloroethane	< 20	< 200	< 200	< 20
1,3,5-Trimethylbenzene	< 25	< 250	< 250	< 25
2-Butanone {MEK}	< 59	**1700**	**1300**	**370**
4-Ethyltoluene	< 25	< 250	< 250	< 25
Acetone	**51**	**13000**	**13000**	**6000**
Acetonitrile	**880**	**3200**	**1000**	**320**
Acrolein	< 11	**7900**	**7000**	**3500**
Acrylonitrile	< 22	< 220	< 220	**14**
Benzene	< 16	**930**	**760**	**200**
Butadiene	< 11	**100**	< 110	**80**
Carbon disulfide	< 31	< 310	< 310	< 31
Chlorodifluoromethane	< 18	< 180	< 180	< 18
Chloroethane	< 13	< 130	< 130	< 13
Chloroform	< 24	< 240	< 240	**17**
Chloromethane	< 21	**230**	**200**	**62**
Dichlorodifluoromethane	< 25	< 250	< 250	< 25
Ethyl acetate	< 18	< 180	< 180	< 18
Ethylbenzene	< 22	**300**	**250**	**56**
Hexane	< 18	< 180	< 180	< 180
Isopropyl alcohol	< 25	**850**	**970**	< 25
m,p-Xylene	< 43	**1000**	**800**	**190**
Methyl methacrylate	< 41	< 410	< 410	< 41
Methylene chloride	**15**	**550**	**570**	**27**
n-Heptane	< 20	< 200	< 200	< 20
Octane	< 47	**110**	< 470	< 47
o-Xylene	< 22	**270**	**240**	**40**
Propylene	< 17	**6900**	**1200**	**2500**
Styrene	< 21	**110**	**120**	**9.5**
Toluene	< 19	**710**	**670**	**90**
Trichlorofluoromethane	< 28	< 280	< 280	< 28
Vinyl chloride	< 13	< 130	< 130	< 13

4.1 TECHNICAL ASSESSMENT

Table 4.1.1 contains the 24 compounds measured in the exposure chamber during these experiments to be characterized as the combustion by-products of the pyrotechnic formulation in the red smoke grenades. Although nearly 100 analytes were measured for all three of the analytical methods used, only these analytes were detected in most of the samples collected and are not believed to be laboratory carry-over and/or contaminants. The table also provides the analytical method which provides the most reliable results.

Table 4.1.1 – Characterization of Red Smoke Analytes and Reporting Methodology

Detected Analyte	Analytical Method	Detected Analyte	Analytical Method
Carbon Dioxide	Gas Phase FTIR Spectrometry	Acetonitrile	TO-15 GC/MS
Carbon Monoxide		Acrolein	
Methane		Benzene	
Acetylene		Butadiene	
Ethylene		Chloromethane	
Nitric Oxide		Ethylbenzene	
Formaldehyde	TO-11 HPLC	m,p-Xylene	
Acetaldehyde		Methylene Chloride	
Propionaldehyde		o-Xylene	
Crotonaldehyde		Propylene	
2-Butanone	TO-15 GC/MS	Styrene	
Acetone		Toluene	

Table 4.1.2 contains the concentration results obtained for the single acute level exposure trial.

Tables 4.1.3 through 4.1.5 provide the analyte concentrations obtained for the multiple trials conducted for the repeated dose exposures (high, intermediate, and low levels respectively). These tables also provide a basic statistical analysis of the data which includes the average concentration (AVG), standard deviation (STDEV), and the relative standard deviation (STDEV/AVG, expressed as a percentage) to gauge experimental precision.

Table 4.1.2 – Acute Exposure Analyte Concentrations

ANALYTE	Measured Concentration (ppm)
Carbon Dioxide	1986
Carbon Monoxide	149
Methane	12
Acetylene	1.1
Ethylene	2.6
Nitric Oxide	5.6
Formaldehyde	26
Acetaldehyde	13
Propionaldehyde	0.44
Crotonaldehyde	0.61
2-Butanone	0.71
Acetone	3.96
Acetonitrile	0.83
Acrolein	2.92
Benzene	0.18
Butadiene	0.23
Chloromethane	0.16
Ethylbenzene	0.058
m,p-Xylene	0.21
Methylene Chloride	0.013
o-Xylene	0.041
Propylene	4.42
Styrene	0.0094
Toluene	0.072

Table 4.1.3 – High Level Repeated Dose Exposure Analyte Concentrations

ANALYTE	Measured Concentration			Statistical Analysis		
	RD #2	RD #6	RD #10	AVG	STDEV	RSD
	(ppm)	(ppm)	(ppm)	(ppm)	(ppm)	(%)
Carbon Dioxide	1940	2242	2372	2185	222	10%
Carbon Monoxide	133	141	190	155	31	20%
Methane	9.1	10	14	11	2.5	23%
Acetylene	ND	1.0	1.2	1.1	0.12	11%
Ethylene	2.1	2.5	4.1	2.9	1.0	35%
Nitric Oxide	4.1	5.3	8.5	6.0	2.3	38%
Formaldehyde	23	11	16	17	5.7	34%
Acetaldehyde	13	2.5	6.5	7.5	5.5	73%
Propionaldehyde	0.44	ND	0.40	0.42	0.032	8%
Crotonaldehyde	0.61	0.45	0.60	0.55	0.090	16%
2-Butanone	0.54	0.44	0.58	0.52	0.071	14%
Acetone	3.83	4.17	5.47	4.49	0.87	19%
Acetonitrile	0.77	0.57	1.91	1.08	0.72	67%
Acrolein	1.92	2.53	3.45	2.63	0.77	29%
Benzene	0.19	0.12	0.29	0.20	0.086	43%
Butadiene	0.068	0.021	0.045	0.045	0.023	52%
Chloromethane	0.13	0.10	0.11	0.11	0.012	11%
Ethylbenzene	0.12	0.039	0.069	0.077	0.042	55%
m,p-Xylene	0.46	0.13	0.23	0.27	0.17	63%
Methylene Chloride	0.095	0.012	0.16	0.088	0.073	83%
o-Xylene	0.18	0.023	0.062	0.088	0.082	93%
Propylene	1.80	2.27	4.01	2.69	1.2	43%
Styrene	0.068	0.0023	0.026	0.032	0.033	104%
Toluene	0.69	0.042	0.19	0.31	0.34	111%

Table 4.1.4 – Intermediate (Mid-) Level Repeated Dose Exposure Analyte Concentrations

ANALYTE	Measured Concentration			Statistical Analysis		
	RD #2	RD #6	RD #10	AVG	STDEV	RSD
	(ppm)	(ppm)	(ppm)	(ppm)	(ppm)	(%)
Carbon Dioxide	3312	3279	3933	3508	369	11%
Carbon Monoxide	108	121	163	131	29	22%
Methane	7.6	8.6	12.1	9.5	2.4	25%
Acetylene	ND	1.3	1.1	1.2	0.12	11%
Ethylene	2.0	2.3	3.7	2.7	0.92	35%
Nitric Oxide	3.5	4.9	6.9	5.1	1.7	34%
Formaldehyde	18	13	13	14	2.7	19%
Acetaldehyde	12	5.3	8.5	8.5	3.2	38%
Propionaldehyde	0.54	0.22	0.45	0.40	0.17	42%
Crotonaldehyde	0.66	0.58	0.60	0.61	0.042	7%
2-Butanone	0.41	0.41	0.44	0.42	0.020	5%
Acetone	3.79	4.00	5.47	4.42	0.92	21%
Acetonitrile	0.66	0.58	0.60	0.61	0.041	7%
Acrolein	2.09	2.36	3.05	2.5	0.50	20%
Benzene	0.14	0.14	0.24	0.17	0.055	32%
Butadiene	0.11	0.042	ND	0.075	0.047	62%
Chloromethane	0.11	0.087	0.097	0.097	0.010	10%
Ethylbenzene	0.097	0.046	0.058	0.067	0.027	40%
m,p-Xylene	0.37	0.15	0.18	0.23	0.12	50%
Methylene Chloride	0.086	0.014	0.16	0.088	0.075	85%
o-Xylene	0.14	0.025	0.055	0.073	0.058	80%
Propylene	2.44	2.27	0.70	1.8	0.96	53%
Styrene	0.056	0.0040	0.028	0.030	0.026	89%
Toluene	0.58	0.05	0.18	0.27	0.28	103%

Table 4.1.5 – Low Level Repeated Dose Exposure Analyte Concentrations

ANALYTE	Measured Concentration			Statistical Analysis		
	RD #2	RD #6	RD #10	AVG	STDEV	RSD
	(ppm)	(ppm)	(ppm)	(ppm)	(ppm)	(%)
Carbon Dioxide	3514	2280	2683	2826	629	22%
Carbon Monoxide	75	46	62	61	14	23%
Methane	5.8	4.3	5.5	5.2	0.78	15%
Acetylene	ND	ND	ND	NA	NA	NA
Ethylene	1.6	1.0	1.6	1.4	0.31	22%
Nitric Oxide	3.2	ND	3.7	3.4	0.37	11%
Formaldehyde	13	8.0	8.1	9.6	2.7	28%
Acetaldehyde	11	6.1	8.0	8.2	2.3	28%
Propionaldehyde	0.56	0.33	0.41	0.43	0.12	28%
Crotonaldehyde	0.76	0.38	0.52	0.55	0.19	35%
2-Butanone	0.31	0.098	0.13	0.18	0.12	65%
Acetone	3.2	2.0	2.5	2.6	0.59	23%
Acetonitrile	0.47	0.12	0.19	0.26	0.19	71%
Acrolein	1.8	1.2	1.5	1.5	0.31	20%
Benzene	0.11	0.041	0.063	0.071	0.035	50%
Butadiene	0.099	0.050	0.036	0.062	0.033	54%
Chloromethane	0.082	0.034	0.030	0.049	0.029	60%
Ethylbenzene	0.085	0.012	0.013	0.037	0.042	114%
m,p-Xylene	0.32	0.041	0.044	0.14	0.16	119%
Methylene Chloride	0.032	0.006	0.008	0.015	0.014	93%
o-Xylene	0.12	0.008	0.009	0.047	0.065	141%
Propylene	2.1	0.76	1.5	1.4	0.67	47%
Styrene	0.045	ND	0.0022	0.023	0.030	128%
Toluene	0.34	0.015	0.024	0.13	0.19	147%

5.1 REFERENCES

A. FSAB-IOP-008, Operation and Use Midac Model I-Series FTIR, May 2012.

B. FSAB-IOP-023, Operation and Use of the Oxigraf Model O2 Oxygen Analyzer, May 2012.

C. FSAB-IOP-006, Operation of APEX Model 623 Air Sampling Meter Box, May 2012.

D. FSAB-IOP-019, Sample Media Collection and Handling Procedures, May 2012

E. 2015-CC-292 (Laboratory Report, Red Smoke Inhalation Toxicity Study [Acute] – Carbonyls Analysis), U.S. Army Aberdeen Test Center, Applied Science Test Division – Chemical Sampling and Analysis Team, 21 May 2015.

F. 2015-CC-331 (Laboratory Report, Red Smoke Inhalation Toxicity Study RD#2 – Carbonyls Analysis), U.S. Army Aberdeen Test Center, Applied Science Test Division – Chemical Sampling and Analysis Team, 23 June 2015.

G. 2015-CC-336 (Laboratory Report, Red Smoke Inhalation Toxicity Study RD#6 – Carbonyls Analysis), U.S. Army Aberdeen Test Center, Applied Science Test Division – Chemical Sampling and Analysis Team, 29 June 2015.

H. 2015-CC-337 (Laboratory Report, Red Smoke Inhalation Toxicity Study RD#10 – Carbonyls Analysis), U.S. Army Aberdeen Test Center, Applied Science Test Division – Chemical Sampling and Analysis Team, 30 June 2015.

I. Report Serial # 74192 (Laboratory Report, Red Smoke Inhalation Toxicity Study [Acute] – VOCs Analysis), U.S. Army Institute of Public Health, 26 May 2015.

J. Report Serial # 76035 (Laboratory Report, Red Smoke Inhalation Toxicity Study [RD#2] – VOCs Analysis), U.S. Army Institute of Public Health, 08 July 2015.

K. Report Serial # 76326 (Laboratory Report, Red Smoke Inhalation Toxicity Study [RD#6 and RD#10] – VOCs Analysis), U.S. Army Institute of Public Health, 14 July 2015.

L. Email correspondence from Lee Crouse, AIPH Red Smoke Study – Requested Information Regarding the Test Item, 19 June 2014.

APPENDIX A - FTIR Daily Check Sheets and other Quality Control Information

FTIR Testing Check Sheet

Analyst: M. Chapman

General Test Information: Red Smoke Inhalation Study
Test Name: Red Smoke Test Date: Wed. 4/29/2015 Customer: Mr. Lee Crouse

FTIR Information:

Daily Start-up Checklist			
Instrument Purge ON	✓	Cell Heater ON (set to 121°C)	✓
Check interferometer	✓	Cell Pressure (while sampling)	14.69 psia
Check LN_2 Dewar extender	✓	Clocks Synchronized	✓ w/ Lee's watch

FTIR Serial #	Sampling Position	Pathlength	ZPD	Peak Min	Peak Max
I274	Exposure Chamber	7.13 meters	1031	-19000 (-1.45V)	14100 (1.080V)
I_{4000} = 9880		I_{2000} = 33900		SBR = I_{4000} / I_{2000} = 0.29	

Daily FTIR System Checks:

Daily Calibration Check Results									
Gas Type	Level 1			Level 2			Level 3		
	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff
CO_2	2040	1965	-3.7	1020	990	-3.0	510	506	-0.8
CO	1000	1000	0.0	500	498	-0.4	250	249	-0.4%
NO	49.6	49.8	0.4	24.8	24.9	0.4	12.4	11.9	-4.0
SO_2	9.70	9.33	-3.9	4.85	4.45	-8.2	2.43	2.22	-8.7

NOTE: The acceptable tolerance for the % difference results is ±20%.

Data Acquisition - Test:
AutoQuant Pro Collection File Path --
C:\Documents and Settings\All Users\Shared Documents\AutoQuant\Collect\

Testing Timeline			
Test Scenario	**Test Start Time**	**Stop Time**	**# Scans**
1 Exposure Chamber Background	9:49	9:55	30
2 Acute Exposure	Pumps/VOC 10:13:30	10:42:30	157
3	AQ start ~10:13:55		
4			
5			
6			

ANALYST NOTES:

Environics Model 2040 Gas Mixer: s/n 2919 Cal Exp Date 2/3/2016.

FTIR QC gas mixture: cyl CC107061 CO_2 1.02% CO 498 ppm NO 248 ppm SO_2 48.53 ppm

Smoke grenade popped @ 10:06 am

Animals loaded in chamber @ 10:12 am (start)

FTIR Testing Check Sheet

Analyst: M. CHAPMAN

General Test Information: Red Smoke Inhalation Study
Test Name: RED SMOKE Test Date: 03 June 2015 Customer: Mr. Lee Crouse

FTIR Information:

Daily Start-up Checklist			
Instrument Purge ON	✓	Cell Heater ON (set to 121°C)	✓
Check interferometer	✓	Cell Pressure (while sampling)	14.65 psia
Check LN_2 Dewar extender	✓	Clocks Synchronized	✓ w/Lee's watch

FTIR Serial #	Sampling Position	Pathlength	ZPD	Peak Min	Peak Max
I274	Exposure Chamber	7.13 meters	1025	-19200 (-1.490 V)	14200 (1.080V)
I_{4000} = 9884		I_{2000} = 33898		SBR = I_{4000} / I_{2000} = 0.29	

Daily FTIR System Checks: 121°C 14.85 psia

Daily Calibration Check Results									
Gas Type	Level 1			Level 2			Level 3		
	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff
CO_2	1020	983	-3.6	510	492	-3.6	204	207	1.6
CO	500	474	-5.3	250	238	-4.7	100	98	-1.6
NO	24.8	24.7	-0.2	12.4	11.9	-4.4	5.0	4.82	-3.7
SO_2	4.85	4.36	-10.2	2.43	2.17	-10.8	0.97	0.85	-12.9

NOTE: The acceptable tolerance for the % difference results is ±20%.

Data Acquisition - Test:
AutoQuant Pro Collection File Path --
C:\Documents and Settings\All Users\Shared Documents\AutoQuant\Collect\ KESTREL S/N 581400 EXP DATE 03 DEC 2015

Testing Timeline				
	Test Scenario	Test Start Time	Stop Time	# Scans
1	RD#2 Exposure Chamber Background	0929	0959	185
2	RD#2 HIGH LEVEL EXPOSURE	11:15	11:43	174
3	RD#2 MID LEVEL EXPOSURE	11:54:45 *	12:24	161
4	RD#2 LOW LEVEL EXPOSURE	1:13	1:43	183
5				
6				

1.41 mg/m³
0.51 mg/L

ANALYST NOTES:

SMOKE GRENADE set off @ 10:33.

High → animals loaded (started) @ ~11:13 to 11:15 Stop sampling @ 11:43:30.

MED → start sampling ~11:54:45 STOP sampling @ 12:24

* FTIR AQ @ 11:57:45 (estimated late)

LOW → Animals @ 1:12:45

sample start @ 1:13:45 sample stop @ 1:42

FTIR Testing Check Sheet

Analyst: M Chapman

General Test Information: Red Smoke Inhalation Study
Test Name: Repeated Dose Exp #6 Test Date: 6/9/2015 Customer: Mr. Lee Crouse

FTIR Information:

Daily Start-up Checklist			
Instrument Purge ON	✓	Cell Heater ON (set to 121°C)	✓
Check interferometer	✓	Cell Pressure (while sampling)	14.40 psig
Check LN_2 Dewar extender	✓	Clocks Synchronized	✓

FTIR Serial #	Sampling Position	Pathlength	ZPD	Peak Min	Peak Max
I274	Exposure Chamber	7.13 meters	1026	-19300 (-1.450 V)	14000 (1.065 V)
I_{4000} = 9600		I_{2000} = 33400		SBR = I_{4000} / I_{2000} = 0.287	

Daily FTIR System Checks:

Daily Calibration Check Results									
Gas Type	Level 1			Level 2			Level 3		
	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff
CO_2	1020	975	-4.4	510	496	-2.7	204	207	1.6
CO	500	✓ 481	-3.8	250	✓ 242	-3.0	100	✓ 100	0
NO	24.8	24.7	-0.4	12.4	12.0	-3.5	5.0	4.79	-4.1
SO_2	4.85	4.2	-13.4	2.43	2.09	-14.0	0.97	0.81	-16.3

NOTE: The acceptable tolerance for the % difference results is ±20%.

Data Acquisition - Test:
AutoQuant Pro Collection File Path --
C:\Documents and Settings\All Users\Shared Documents\AutoQuant\Collect\

Testing Timeline			
Test Scenario	**Test Start Time**	**Stop Time**	**# Scans**
1 RD #6 Chamber Background	10:11:30	10:42:56 FTIR 10:41:30 (aldehydes)	192
2 RD #6 - High Level Exp	~11:40:15	12:09 FTIR ~12:08 (Samples)	175
3 RD #6 - Med Level Exp (AQ started @ 12:27:00)	12:26:30	12:55:35	176
4 RD #6 - Low Level Exp	1:28:40	1:57:40	176
5			
6			

ANALYST NOTES:

1. Chamber Background VOC sample started @ 10:17:00 (aldehyde tube started w/FTIR)
   Barom. pressure = 29.61 in Hg, T = 22.5°C, RH = 64.9% (Room (Kestrel)) Chamber T = 71°F RH = 68%
2. Repeated Dose #6 1st grenade was a DUDE
   2nd " SMOKE popped @ 11:04, start loading High animals @ 11:38
   start loading MED animals @ 12:25:35
   Start " Low animals @ 1:28:00

FTIR Testing Check Sheet

Analyst: M. Chapman

General Test Information: Red Smoke Inhalation Study
Test Name: RD#10 Test Date: 6-15-2015 Customer: Mr. Lee Crouse

FTIR Information:

Daily Start-up Checklist			
Instrument Purge ON	✓	Cell Heater ON (set to 121°C)	✓
Check interferometer	✓	Cell Pressure (while sampling)	✓ 14.52 psia
Check LN_2 Dewar extender	✓	Clocks Synchronized	

FTIR Serial #	Sampling Position	Pathlength	ZPD	Peak Min	Peak Max
I274	Exposure Chamber	7.13 meters	1025	-19500 (-1.490V)	14200 (1.090V)
I_{4000} = 10018		I_{2000} = 34270		SBR = I_{4000} / I_{2000} = 0.29	

Daily FTIR System Checks:

Daily Calibration Check Results									
Gas Type	Level 1			Level 2			Level 3		
	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff	Target (ppm)	Result (ppm)	% Diff
CO_2	1020	972	-4.7	510	494	-3.2	204	206	0.9
CO	500	489	-2.2	250	244	-2.5	100	100	0.
NO	24.8	24.8	0	12.4	12.0	-3.6	5.0	4.77	-4.7
SO_2	4.85	4.41	-9.1	2.43	2.23	-8.1	0.97	0.88	-9.5

NOTE: The acceptable tolerance for the % difference results is ±20%.

Data Acquisition - Test:
AutoQuant Pro Collection File Path --
C:\Documents and Settings\All Users\Shared Documents\AutoQuant\Collect\

Testing Timeline			
Test Scenario	**Test Start Time**	**Stop Time**	**# Scans**
1 RD#10_ Chamber Background ①	0942	1042	181
2 RD#10_ High Level Exp	1039	1107	167
3 RD#10_ MED Level Exp	1158	12:27	208
4 RD#10_ Low Level Exp	1258	13:27	
5			
6			

ANALYST NOTES:

1. Sample line from chamber attached to FTIR 1 minute after the start of the chamber background. Several sampling glitches occurred w/computer (AQ) 101-102

Smoke popped @ 10:25
a. Start loading High animals @ 10:37:17
b. " " MED " @ 11:57:10
c. " " Low " @ 12:57:20

Table A.1 – Miscellaneous Equipment Calibration Information

Equipment	Serial Number	Calibration Expiration
Environics Model 2040 Gas Mixer	2619	03 Feb 2016
DryCal Flowmeter	4318	13 Sept 2016

Airgas

Airgas Specialty Gases
600 Union Landing Road
Cinnaminson, NJ 08077
(856) 829-7878 Fax: (856) 829-6576
www.airgas.com

CERTIFICATE OF ANALYSIS
Grade of Product: EPA Protocol

Part Number:	E05NI98E15A0000	Reference Number:	82-124390646-1
Cylinder Number:	CC107061	Cylinder Volume:	144.9 CF
Laboratory:	ASG - Riverton - NJ	Cylinder Pressure:	2015 PSIG
PGVP Number:	B52013	Valve Outlet:	660
Gas Code:	CO,CO2,NO,SO2,BALN	Certification Date:	Sep 05, 2013

Expiration Date: Sep 05, 2017

Certification performed in accordance with "EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (May 2012)" document EPA 600/R-12/531, using the assay procedures listed. Analytical Methodology does not require correction for analytical interference. This cylinder has a total analytical uncertainty as stated below with a confidence level of 95%. There are no significant impurities which affect the use of this calibration mixture. All concentrations are on a volume/volume basis unless otherwise noted.

Do Not Use This Cylinder below 100 psig, i.e. 0.7 megapascals.

ANALYTICAL RESULTS

Component	Requested Concentration	Actual Concentration	Protocol Method	Total Relative Uncertainty	Assay Dates
NOX	250.0 PPM	248.3 PPM	G1	+/- 0.6% NIST Traceable	08/29/2013, 09/05/2013
SULFUR DIOXIDE	50.00 PPM	48.53 PPM	G1	+/- 1.1% NIST Traceable	08/29/2013, 09/05/2013
NITRIC OXIDE	250.0 PPM	248.2 PPM	G1	+/- 0.6% NIST Traceable	08/29/2013, 09/05/2013
CARBON MONOXIDE	5000 PPM	4998 PPM	G1	+/- 1.0% NIST Traceable	09/05/2013
CARBON DIOXIDE	1.000 %	1.020 %	G1	+/- 0.5% NIST Traceable	09/03/2013
NITROGEN	Balance				

CALIBRATION STANDARDS

Type	Lot ID	Cylinder No	Concentration	Uncertainty	Expiration Date
NTRM	12061832	CC352180	50.10 PPM SULFUR DIOXIDE/NITROGEN	+/- 1.0%	Apr 24, 2018
PRM	12312	680179	10.01 PPM NITROGEN DIOXIDE/NITROGEN	+/- 2.0%	Feb 14, 2012
NTRM	12061959	CC367737	250.8 PPM NITRIC OXIDE/NITROGEN	+/- 0.5%	May 04, 2018
GMIS	124206889106	CC322664	4.879 PPM NITROGEN DIOXIDE/NITROGEN	+/- 2.0%	Apr 08, 2016
NTRM	13060232	CC401984	4950 PPM CARBON MONOXIDE/NITROGEN	+/- 0.4%	Feb 15, 2019
NTRM	00060303	XC018380B	1.963 % CARBON DIOXIDE/NITROGEN	+/- 0.4%	Mar 21, 2018

The SRM or PRM noted above is only in reference to the GMIS used in the assay and not part of the analysis.

ANALYTICAL EQUIPMENT

Instrument/Make/Model	Analytical Principle	Last Multipoint Calibration
Siemens Ultramat-6E-CO2-N1-N0-0820	NDIR	Aug 03, 2013
Siemens Ultramat 6 N1C8180 COHIGH	NDIR	Aug 09, 2013
Nicolet 6700 APW1100391 NO	FTIR	Aug 23, 2013
Nicolet 6700 APW1100391 NO2	FTIR	Aug 23, 2013
Nicolet 6700 APW1100391 SO2	FTIR	Aug 10, 2013

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Figure A1 - Calibration Check Gas Certificate of Analysis

APPENDIX B – Aldehyde Analytical Reports

U.S. Army Aberdeen Test Center
Warfighter Directorate
Applied Science Test Division
Chemical Sampling and Analysis Branch
400 Colleran Road, Building 363, Aberdeen Proving Ground, MD 21005-5059

Conducted For:

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ATEC Project #: 2015-DT-ATC-DODSP-G1491

CSAB Test Report #: 2015-CC-292

Report Title: **Red Smoke Inhalation Toxicity Study - Carbonyls Analysis**

Chemical Sampling and Analysis Branch retains all data and report records for a 7 year period beyond the issue date of this report. All retained data and report records can be retrieved during this timeframe. After 7 years all records may be destroyed according to current security protocols. If this is not acceptable, please contact us immediately for alternative arrangements.

Report Prepared By: Katie Arnold

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Date: 21 May 2015

FOUO

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-292
Report Date: 21-May-2015

1.0 Introduction

Five samples from the Red Smoke Inhalation Toxicity Study were submitted, in acceptable condition, to determine the concentration of carbonyls generated during the test.

2.0 Summary

Results are posted in the tables below. No concentrations of carbonyls above the reporting limit were detected in the back tubes or the field blank. It should be noted that acrolein has shown historically low recoveries in the collection media used for this test. All quality control checks performed with this analysis were within the tolerance limits of the laboratory.

3.0 Results/Analysis

Description: Acute Exp_1 (Front)
Position: Acute Exp_1 (Front)
Scenario & Trial #: 1

Sample ID: S-150519-00051
Date Sampled: 29-Apr-15
Date Received: 04-May-15
Air Volume: 10.68 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	26.08 ppm Air	D		05/06/15	Mod TO-11A	
Acetaldehyde	14.64 ppm Air	D		05/06/15	Mod TO-11A	
Acetone	0.28 ppm Air			05/06/15	Mod TO-11A	
Acrolein	0.58 ppm Air	ML		05/06/15	Mod TO-11A	
Propionaldehyde	0.73 ppm Air			05/06/15	Mod TO-11A	
Crotonaldehyde	0.65 ppm Air			05/06/15	Mod TO-11A	
Butyraldehyde	<0.48 ppm Air			05/06/15	Mod TO-11A	
Benzaldehyde	<0.32 ppm Air			05/06/15	Mod TO-11A	
Isovaleraldehyde	<0.40 ppm Air			05/06/15	Mod TO-11A	
Valeraldehyde	<0.40 ppm Air			05/06/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.29 ppm Air			05/06/15	Mod TO-11A	
Hexaldehyde	<0.34 ppm Air			05/06/15	Mod TO-11A	
2,5-DMB	<0.26 ppm Air			05/06/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: Acute Exp_1 (Back)
Position: Acute Exp_1 (Back)
Scenario & Trial #: 1

Sample ID: S-150519-00052
Date Sampled: 29-Apr-15
Date Received: 04-May-15
Air Volume: 10.68 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<1.14 ppm Air			05/06/15	Mod TO-11A	
Acetaldehyde	<0.78 ppm Air			05/06/15	Mod TO-11A	
Acetone	<0.59 ppm Air			05/06/15	Mod TO-11A	
Acrolein	<0.61 ppm Air	ML		05/06/15	Mod TO-11A	
Propionaldehyde	<0.59 ppm Air			05/06/15	Mod TO-11A	
Crotonaldehyde	<0.49 ppm Air			05/06/15	Mod TO-11A	
Butyraldehyde	<0.48 ppm Air			05/06/15	Mod TO-11A	

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-292
Report Date: 21-May-2015

Description: Acute Exp_1 (Back) (continued) **Sample ID: S-150519-00052**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Benzaldehyde	<0.32 ppm Air			05/06/15	Mod TO-11A	
Isovaleraldehyde	<0.40 ppm Air			05/06/15	Mod TO-11A	
Valeraldehyde	<0.40 ppm Air			05/06/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.29 ppm Air			05/06/15	Mod TO-11A	
Hexaldehyde	<0.34 ppm Air			05/06/15	Mod TO-11A	
2,5-DMB	<0.26 ppm Air			05/06/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

Description: Acute Exp_2 (Front)
Position: Acute Exp_2 (Front)
Scenario & Trial #: 2

Sample ID: S-150519-00053
Date Sampled: 29-Apr-15
Date Received: 04-May-15
Air Volume: 11.3 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	26.15 ppm Air	D		05/06/15	Mod TO-11A	
Acetaldehyde	12.04 ppm Air	D		05/06/15	Mod TO-11A	
Acetone	0.77 ppm Air			05/06/15	Mod TO-11A	
Acrolein	<0.58 ppm Air	ML		05/06/15	Mod TO-11A	
Propionaldehyde	0.15 ppm Air			05/06/15	Mod TO-11A	
Crotonaldehyde	0.57 ppm Air			05/06/15	Mod TO-11A	
Butyraldehyde	<0.45 ppm Air			05/06/15	Mod TO-11A	
Benzaldehyde	<0.31 ppm Air			05/06/15	Mod TO-11A	
Isovaleraldehyde	<0.38 ppm Air			05/06/15	Mod TO-11A	
Valeraldehyde	<0.38 ppm Air			05/06/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.27 ppm Air			05/06/15	Mod TO-11A	
Hexaldehyde	<0.32 ppm Air			05/06/15	Mod TO-11A	
2,5-DMB	<0.24 ppm Air			05/06/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: Acute Exp_2 (Back)
Position: Acute Exp_2 (Back)
Scenario & Trial #: 2

Sample ID: S-150519-00054
Date Sampled: 29-Apr-15
Date Received: 04-May-15
Air Volume: 11.3 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<1.08 ppm Air			05/06/15	Mod TO-11A	
Acetaldehyde	<0.74 ppm Air			05/06/15	Mod TO-11A	
Acetone	<0.56 ppm Air			05/06/15	Mod TO-11A	
Acrolein	<0.58 ppm Air	ML		05/06/15	Mod TO-11A	
Propionaldehyde	<0.56 ppm Air			05/06/15	Mod TO-11A	
Crotonaldehyde	<0.46 ppm Air			05/06/15	Mod TO-11A	
Butyraldehyde	<0.45 ppm Air			05/06/15	Mod TO-11A	
Benzaldehyde	<0.31 ppm Air			05/06/15	Mod TO-11A	
Isovaleraldehyde	<0.38 ppm Air			05/06/15	Mod TO-11A	

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-292
Report Date: 21-May-2015

Description: Acute Exp_2 (Back) (continued) **Sample ID: S-150519-00054**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Valeraldehyde	<0.38 ppm Air			05/06/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.27 ppm Air			05/06/15	Mod TO-11A	
Hexaldehyde	<0.32 ppm Air			05/06/15	Mod TO-11A	
2,5-DMB	<0.24 ppm Air			05/06/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

Description: Field Blank **Sample ID: S-150519-00055**
Position: Field Blank
Date Sampled: 29-Apr-15
Date Received: 04-May-15

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Acetaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Acetone	<15.00 ug/sample			05/06/15	Mod TO-11A	
Acrolein	<15.00 ug/sample	ML		05/06/15	Mod TO-11A	
Propionaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Crotonaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Butyraldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Benzaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Isovaleraldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
Valeraldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
o,m,p-Tolualdehyde	<45.00 ug/sample			05/06/15	Mod TO-11A	
Hexaldehyde	<15.00 ug/sample			05/06/15	Mod TO-11A	
2,5-DMB	<15.00 ug/sample			05/06/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491

CSAB Test Report #: 2015-CC-331

Report Title: **Red Smoke Inhalation Toxicity Study RD#2 - Carbonyls Analysis**

Any reproductions or excerpts from this report must reference the entire report or the report number. The results relate only to the specific samples/test item/test scenario identified within the report. The opinions/interpretations expressed in this report are outside the scope of the Chemical Sampling and Analysis Branch's A2LA accreditation.

Chemical Sampling and Analysis Branch retains all data and report records for a 7 year period beyond the issue date of this report. All retained data and report records can be retrieved during this timeframe. After 7 years all records may be destroyed according to current security protocols. If this is not acceptable, please contact us immediately for alternative arrangements.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-331
Report Date: 23-Jun-2015

1.0 Introduction

Ten samples from the Red Smoke Inhalation Toxicity Study were submitted, in acceptable condition, to determine the concentration of carbonyls generated during the test.

2.0 Summary

Results are posted in the tables below. It should be noted that acrolein has shown historically low recoveries in the collection media used for this test. All quality control checks performed with this analysis were within the tolerance limits of the laboratory which the exception of the media spike for butyraldehyde.

3.0 Results/Analysis

Description: RD#2_Chamber Background
Position: Chamber Background
Event #: RD #2

Sample ID: S-150604-00001
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 27.54 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.44 ppm Air			06/04/15	Mod TO-11A	
Acetaldehyde	<0.30 ppm Air			06/04/15	Mod TO-11A	
Acetone	<0.23 ppm Air			06/04/15	Mod TO-11A	
Acrolein	<0.24 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<0.23 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	<0.19 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.18 ppm Air	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<0.13 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.15 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.15 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.11 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.13 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.10 ppm Air			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_High_1 (Front)
Position: High (Front)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00002
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 14.97 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	23.77 ppm Air	D		06/04/15	Mod TO-11A	
Acetaldehyde	14.32 ppm Air	D		06/04/15	Mod TO-11A	
Acetone	0.13 ppm Air			06/04/15	Mod TO-11A	
Acrolein	1.79 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	0.54 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	0.59 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.34 ppm Air	MH		06/04/15	Mod TO-11A	

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Report #: 2015-CC-331
Report Date: 23-Jun-2015

Description: RD#2_High_1 (Front) (continued) **Sample ID: S-150604-00002**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Benzaldehyde	<0.23 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.28 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.28 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.20 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.18 ppm Air			06/04/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_High_1 (Back)
Position: High (Back)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00003
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 14.97 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.82 ppm Air			06/04/15	Mod TO-11A	
Acetaldehyde	<0.56 ppm Air			06/04/15	Mod TO-11A	
Acetone	<0.42 ppm Air			06/04/15	Mod TO-11A	
Acrolein	<0.44 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<0.42 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	<0.35 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.34 ppm Air	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<0.23 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.28 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.28 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.20 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.18 ppm Air			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_High_2 (Front)
Position: High (Front)
Scenario & Trial #: 2
Event #: RD #2

Sample ID: S-150604-00004
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 16.83 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	21.22 ppm Air	D		06/04/15	Mod TO-11A	
Acetaldehyde	12.17 ppm Air	D		06/04/15	Mod TO-11A	
Acetone	<0.38 ppm Air			06/04/15	Mod TO-11A	
Acrolein	1.76 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	0.45 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	0.52 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.30 ppm Air	MH		06/04/15	Mod TO-11A	

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Report #: 2015-CC-331
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Description: RD#2_High_2 (Front) (continued) **Sample ID: S-150604-00004**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Benzaldehyde	<0.21 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.18 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.22 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.16 ppm Air			06/04/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_High_2 (Back)
Position: High (Back)
Scenario & Trial #: 2
Event #: RD #2

Sample ID: S-150604-00005
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 16.83 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.73 ppm Air			06/04/15	Mod TO-11A	
Acetaldehyde	<0.49 ppm Air			06/04/15	Mod TO-11A	
Acetone	<0.38 ppm Air			06/04/15	Mod TO-11A	
Acrolein	<0.39 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<0.38 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	<0.31 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.30 ppm Air	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<0.21 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.18 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.22 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.16 ppm Air			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_Med_1 (Front)
Position: Med (Front)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00006
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 17.01 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	17.57 ppm Air	D		06/04/15	Mod TO-11A	
Acetaldehyde	11.72 ppm Air	D		06/04/15	Mod TO-11A	
Acetone	0.18 ppm Air			06/04/15	Mod TO-11A	
Acrolein	1.57 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	0.54 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	0.66 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.30 ppm Air	MH		06/04/15	Mod TO-11A	

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Report #: 2015-CC-331
Report Date: 23-Jun-2015

Description: RD#2_Med_1 (Front) (continued) **Sample ID: S-150604-00006**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Benzaldehyde	<0.20 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.18 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.22 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.16 ppm Air			06/04/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_Med_1 (Back)
Position: Med (Back)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00007
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 17.01 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.72 ppm Air			06/04/15	Mod TO-11A	
Acetaldehyde	<0.49 ppm Air			06/04/15	Mod TO-11A	
Acetone	<0.37 ppm Air			06/04/15	Mod TO-11A	
Acrolein	<0.38 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<0.37 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	<0.31 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.30 ppm Air	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<0.20 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.25 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.18 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.22 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.16 ppm Air			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_Low_1 (Front)
Position: Low (Front)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00008
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 17.7 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	12.69 ppm Air	D		06/04/15	Mod TO-11A	
Acetaldehyde	10.67 ppm Air	D		06/04/15	Mod TO-11A	
Acetone	1.37 ppm Air			06/04/15	Mod TO-11A	
Acrolein	1.14 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	0.56 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	0.76 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	0.16 ppm Air	MH		06/04/15	Mod TO-11A	

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
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Report #: 2015-CC-331
Report Date: 23-Jun-2015

Description: RD#2_Low_1 (Front) (continued) **Sample ID: S-150604-00008**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Benzaldehyde	0.05 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.17 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.21 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.15 ppm Air			06/04/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_Low_1 (Back)
Position: Low (Back)
Scenario & Trial #: 1
Event #: RD #2

Sample ID: S-150604-00009
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15
Air Volume: 17.7 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.69 ppm Air			06/04/15	Mod TO-11A	
Acetaldehyde	<0.47 ppm Air			06/04/15	Mod TO-11A	
Acetone	<0.36 ppm Air			06/04/15	Mod TO-11A	
Acrolein	<0.37 ppm Air	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<0.36 ppm Air			06/04/15	Mod TO-11A	
Crotonaldehyde	<0.30 ppm Air			06/04/15	Mod TO-11A	
Butyraldehyde	<0.29 ppm Air	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<0.20 ppm Air			06/04/15	Mod TO-11A	
Isovaleraldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
Valeraldehyde	<0.24 ppm Air			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.17 ppm Air			06/04/15	Mod TO-11A	
Hexaldehyde	<0.21 ppm Air			06/04/15	Mod TO-11A	
2,5-DMB	<0.15 ppm Air			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

Description: RD#2_Field Blank
Position: Field Blank
Event #: RD #2

Sample ID: S-150604-00010
Date Sampled: 03-Jun-15
Date Received: 04-Jun-15

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
Acetaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
Acetone	<15.00 ug/sample			06/04/15	Mod TO-11A	
Acrolein	<15.00 ug/sample	ML		06/04/15	Mod TO-11A	
Propionaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
Crotonaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
Butyraldehyde	<15.00 ug/sample	MH		06/04/15	Mod TO-11A	
Benzaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
Isovaleraldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	

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ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-331
Report Date: 23-Jun-2015

Description: RD#2_Field Blank (continued) Sample ID: S-150604-00010

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Valeraldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
o,m,p-Tolualdehyde	<45.00 ug/sample			06/04/15	Mod TO-11A	
Hexaldehyde	<15.00 ug/sample			06/04/15	Mod TO-11A	
2,5-DMB	<15.00 ug/sample			06/04/15	Mod TO-11A	

MH = Result may be biased high due to matrix effects.
ML = Result may be biased low due to matrix effects.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491

CSAB Test Report #: 2015-CC-336

Report Title: **Red Smoke Inhalation Toxicity Study RD#6 - Carbonyl Analysis**

Chemical Sampling and Analysis Branch retains all data and report records for a 7 year period beyond the issue date of this report. All retained data and report records can be retrieved during this timeframe. After 7 years all records may be destroyed according to current security protocols. If this is not acceptable, please contact us immediately for alternative arrangements.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-336
Report Date: 29-Jun-2015

1.0 Introduction

Seven samples from the Red Smoke Inhalation Toxicity Study were submitted, in acceptable condition, to determine the concentration of carbonyls generated during the test.

2.0 Summary

Results are posted in the tables below. It should be noted that acrolein has shown historically low recoveries in the collection media used for this test. All quality control checks performed with this analysis were within the tolerance limits of the laboratory with the exception of the media spikes for acrolein and crotonaldehyde.

3.0 Results/Analysis

Description: RD#6_Chamber Background
Position: Chamber Background
Event #: RD #6

Sample ID: S-150615-00008
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 28.04 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	0.17 ppm Air			06/16/15	Mod TO-11A	
Acetaldehyde	<0.30 ppm Air			06/16/15	Mod TO-11A	
Acetone	<0.23 ppm Air			06/16/15	Mod TO-11A	
Acrolein	<0.23 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	<0.23 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	<0.19 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<0.18 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	<0.12 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.11 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.13 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.10 ppm Air			06/16/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

Description: RD#6_High Level Exp
Position: High Level
Scenario & Trial #: 1
Event #: RD #6

Sample ID: S-150615-00009
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 26.41 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	11.27 ppm Air	D		06/16/15	Mod TO-11A	
Acetaldehyde	2.53 ppm Air			06/16/15	Mod TO-11A	
Acetone	0.10 ppm Air			06/16/15	Mod TO-11A	
Acrolein	1.30 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	<0.24 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	0.45 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<0.19 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/16/15	Mod TO-11A	

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Report #: 2015-CC-336
Report Date: 29-Jun-2015

Description: RD#6_High Level Exp (continued) **Sample ID: S-150615-00009**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Isovaleraldehyde	<0.16 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.16 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.12 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.14 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.10 ppm Air			06/16/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#6_Mid Level Exp #1 **Sample ID: S-150615-00010**
Position: Mid Level
Scenario & Trial #: 1
Event #: RD #6
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 25.09 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	11.83 ppm Air	D		06/16/15	Mod TO-11A	
Acetaldehyde	4.31 ppm Air	D		06/16/15	Mod TO-11A	
Acetone	0.09 ppm Air			06/16/15	Mod TO-11A	
Acrolein	1.35 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	0.17 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	0.53 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<0.20 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.17 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.17 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.12 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.11 ppm Air			06/16/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#6_Mid Level Exp #2 **Sample ID: S-150615-00011**
Position: Mid Level
Scenario & Trial #: 2
Event #: RD #6
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 22.16 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	13.99 ppm Air	D		06/16/15	Mod TO-11A	
Acetaldehyde	6.23 ppm Air	D		06/16/15	Mod TO-11A	
Acetone	0.11 ppm Air			06/16/15	Mod TO-11A	
Acrolein	1.42 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	0.26 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	0.63 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<0.23 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.19 ppm Air			06/16/15	Mod TO-11A	

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Report #: 2015-CC-336
Report Date: 29-Jun-2015

Description: RD#6_Mid Level Exp #2 (continued) **Sample ID: S-150615-00011**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Valeraldehyde	<0.19 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.14 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.17 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.12 ppm Air			06/16/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#6_Low Level Exp #1
Position: Low Level
Scenario & Trial #: 1
Event #: RD #6

Sample ID: S-150615-00012
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 24.43 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	7.97 ppm Air	D		06/16/15	Mod TO-11A	
Acetaldehyde	6.06 ppm Air	D		06/16/15	Mod TO-11A	
Acetone	1.10 ppm Air			06/16/15	Mod TO-11A	
Acrolein	0.41 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	0.32 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	0.38 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	0.35 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	<0.14 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.17 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.17 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.12 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.11 ppm Air			06/16/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#6_Low Level Exp #2
Position: Low Level
Scenario & Trial #: 2
Event #: RD #6

Sample ID: S-150615-00013
Date Sampled: 09-Jun-15
Date Received: 11-Jun-15
Air Volume: 22.51 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	8.02 ppm Air	D		06/16/15	Mod TO-11A	
Acetaldehyde	6.11 ppm Air	D		06/16/15	Mod TO-11A	
Acetone	1.27 ppm Air			06/16/15	Mod TO-11A	
Acrolein	0.38 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	0.33 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	0.38 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	0.40 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.19 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.19 ppm Air			06/16/15	Mod TO-11A	

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Report #: 2015-CC-336
Report Date: 29-Jun-2015

Description: RD#6_Low Level Exp #2 (continued) **Sample ID: S-150615-00013**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
o,m,p-Tolualdehyde	<0.14 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.16 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.12 ppm Air			06/16/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#6_Field Blank **Sample ID: S-150615-00014**
Position: Field Blank Date Sampled: 09-Jun-15
Event #: RD #6 Date Received: 11-Jun-15

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Acetaldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Acetone	<15.00 ug/sample			06/16/15	Mod TO-11A	
Acrolein	<15.00 ug/sample	ML		06/16/15	Mod TO-11A	
Propionaldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Crotonaldehyde	<15.00 ug/sample	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Benzaldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Isovaleraldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
Valeraldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<45.00 ug/sample			06/16/15	Mod TO-11A	
Hexaldehyde	<15.00 ug/sample			06/16/15	Mod TO-11A	
2,5-DMB	<15.00 ug/sample			06/16/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491

CSAB Test Report #: 2015-CC-337

Report Title: **Red Smoke Inhalation Toxicity Study RD#10 - Carbonyl Analysis**

Any reproductions or excerpts from this report must reference the entire report or the report number. The results relate only to the specific samples/test item/test scenario identified within the report. The opinions/interpretations expressed in this report are outside the scope of the Chemical Sampling and Analysis Branch's A2LA accreditation.

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
ATEC Project Title: FY15 DOD General Laboratory Support

Report #: 2015-CC-337
Report Date: 30-Jun-2015

1.0 Introduction

Eight samples from the Red Smoke Inhalation Toxicity Study were submitted, in acceptable condition, to determine the concentration of carbonyls generated during the test.

2.0 Summary

Results are posted in the tables below. It should be noted that acrolein has shown historically low recoveries in the collection media used for this test. All quality control checks performed with this analysis were within the tolerance limits of the laboratory with the exception of the media spikes for acrolein and crotonaldehyde.

3.0 Results/Analysis

Description: RD#10_Chamber Background
Position: Chamber Background
Event #: RD #10

Sample ID: S-150616-00001
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 28.64 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<0.43 ppm Air			06/16/15	Mod TO-11A	
Acetaldehyde	<0.29 ppm Air			06/16/15	Mod TO-11A	
Acetone	<0.22 ppm Air			06/16/15	Mod TO-11A	
Acrolein	<0.23 ppm Air	ML		06/16/15	Mod TO-11A	
Propionaldehyde	<0.22 ppm Air			06/16/15	Mod TO-11A	
Crotonaldehyde	<0.18 ppm Air	ML		06/16/15	Mod TO-11A	
Butyraldehyde	<0.18 ppm Air			06/16/15	Mod TO-11A	
Benzaldehyde	<0.12 ppm Air			06/16/15	Mod TO-11A	
Isovaleraldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
Valeraldehyde	<0.15 ppm Air			06/16/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.11 ppm Air			06/16/15	Mod TO-11A	
Hexaldehyde	<0.13 ppm Air			06/16/15	Mod TO-11A	
2,5-DMB	<0.10 ppm Air			06/16/15	Mod TO-11A	

ML = Result may be biased low due to matrix effects.

Description: RD#10_High Level Exp #1
Position: High Level
Scenario & Trial #: 1
Event #: RD #10

Sample ID: S-150616-00002
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 23.37 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	15.57 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	6.17 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	<0.27 ppm Air			06/17/15	Mod TO-11A	
Acrolein	2.05 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.39 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.60 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	<0.22 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/17/15	Mod TO-11A	

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Description: RD#10_High Level Exp #1 (continued) **Sample ID: S-150616-00002**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Isovaleraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
Valeraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.13 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.16 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.12 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_High Level Exp #2
Position: High Level
Scenario & Trial #: 2
Event #: RD #10

Sample ID: S-150616-00003
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 22.75 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	15.67 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	6.85 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	<0.28 ppm Air			06/17/15	Mod TO-11A	
Acrolein	2.12 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.40 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.60 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	<0.22 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/17/15	Mod TO-11A	
Isovaleraldehyde	<0.19 ppm Air			06/17/15	Mod TO-11A	
Valeraldehyde	<0.19 ppm Air			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.13 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.16 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.12 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_Mid Level Exp #1
Position: Mid Level
Scenario & Trial #: 1
Event #: RD #10

Sample ID: S-150616-00004
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 23.85 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	12.73 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	8.44 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	<0.26 ppm Air			06/17/15	Mod TO-11A	
Acrolein	2.01 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.45 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.60 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	<0.21 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/17/15	Mod TO-11A	
Isovaleraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	

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Report Date: 30-Jun-2015

Description: RD#10_Mid Level Exp #1 (continued) **Sample ID: S-150616-00004**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Valeraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.13 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.15 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.11 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_Mid Level Exp #2
Position: Mid Level
Scenario & Trial #: 2
Event #: RD #10

Sample ID: S-150616-00005
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 23.99 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	12.81 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	8.47 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	<0.26 ppm Air			06/17/15	Mod TO-11A	
Acrolein	1.98 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.45 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.60 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	<0.21 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.05 ppm Air			06/17/15	Mod TO-11A	
Isovaleraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
Valeraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.13 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.15 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.11 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_Low Level Exp #1
Position: Low Level
Scenario & Trial #: 1
Event #: RD #10

Sample ID: S-150616-00006
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 24.53 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	8.25 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	8.08 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	1.24 ppm Air			06/17/15	Mod TO-11A	
Acrolein	0.79 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.42 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.52 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	0.27 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.04 ppm Air			06/17/15	Mod TO-11A	
Isovaleraldehyde	<0.17 ppm Air			06/17/15	Mod TO-11A	
Valeraldehyde	<0.17 ppm Air			06/17/15	Mod TO-11A	

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Description: RD#10_Low Level Exp #1 (continued) Sample ID: S-150616-00006

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
o,m,p-Tolualdehyde	<0.12 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.15 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.11 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_Low Level Exp #2 **Sample ID: S-150616-00007**
Position: Low Level
Scenario & Trial #: 2
Event #: RD #10
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15
Air Volume: 23.3 L Air
Length of Sampling: 30 min

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	8.04 ppm Air	D		06/17/15	Mod TO-11A	
Acetaldehyde	7.84 ppm Air	D		06/17/15	Mod TO-11A	
Acetone	1.46 ppm Air			06/17/15	Mod TO-11A	
Acrolein	0.76 ppm Air	ML		06/17/15	Mod TO-11A	
Propionaldehyde	0.40 ppm Air			06/17/15	Mod TO-11A	
Crotonaldehyde	0.51 ppm Air	ML		06/17/15	Mod TO-11A	
Butyraldehyde	0.30 ppm Air			06/17/15	Mod TO-11A	
Benzaldehyde	0.04 ppm Air			06/17/15	Mod TO-11A	
Isovaleraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
Valeraldehyde	<0.18 ppm Air			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<0.13 ppm Air			06/17/15	Mod TO-11A	
Hexaldehyde	<0.16 ppm Air			06/17/15	Mod TO-11A	
2,5-DMB	<0.12 ppm Air			06/17/15	Mod TO-11A	

D = Sample diluted; results corrected for dilutions.
ML = Result may be biased low due to matrix effects.

Description: RD#10_Field Blank **Sample ID: S-150616-00008**
Position: Field Blank
Event #: RD #10
Date Sampled: 15-Jun-15
Date Received: 16-Jun-15

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification
Formaldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Acetaldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Acetone	<15.00 ug/sample			06/17/15	Mod TO-11A	
Acrolein	<15.00 ug/sample	ML		06/17/15	Mod TO-11A	
Propionaldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Crotonaldehyde	<15.00 ug/sample	ML		06/17/15	Mod TO-11A	
Butyraldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Benzaldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Isovaleraldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
Valeraldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
o,m,p-Tolualdehyde	<45.00 ug/sample			06/17/15	Mod TO-11A	
Hexaldehyde	<15.00 ug/sample			06/17/15	Mod TO-11A	
2,5-DMB	<15.00 ug/sample			06/17/15	Mod TO-11A	

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ATEC Project #: 2015-DT-ATC-DODSP-G1491
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Report #: 2015-CC-337
Report Date: 30-Jun-2015

Description: RD#10_Field Blank (continued) **Sample ID: S-150616-00008**

Test	Result	Qualifier	Uncertainty	Date of Analysis	Test Method	Specification

ML = Result may be biased low due to matrix effects.

APPENDIX C – VOC Analytical Reports

DEPARTMENT OF THE ARMY
US ARMY INSTITUTE OF PUBLIC HEALTH
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MCHB-IP-L 26 May 2015

MEMORANDUM FOR USAPHC, TOX Portfolio (5158 Blackhawk Rd, MCHB-IP-TEP/ Lee Crouse), Building E2100, Gunpowder, MD 21010

SUBJECT: Laboratory Sciences (LS) Final Analytical Report

1. This is LS Final Analytical Report for:

Project Site:	RED SMOKE INHALATION TOX STUDY
Funding:	S.0024589
LS Work Order #:	12833
Report Serial #:	74192

2. Please contact us if this report or any of our services did not meet your needs or expectations.

3. Point of contact for additional information is MAJ Jose Pizarro-Matos,

DSN 584-2208 or commercial 410-436-2208.

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USAPHC

SAMPLE SUMMARY

Workorder: 12833 RED SMOKE INHALATION TOX STUDY

All samples were inspected and observed to conform to our receipt policies, except as noted.

Lab ID	Sample ID	Matrix	Date Collected	Date Received	Cancel Code
128330001	RED SMK_ACUTE EXP (#7107)	Air	4/29/2015	4/29/2015	

AIPH
Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

TERMINOLOGY & ABBREVIATIONS (ENV)

Terms:

AIPH = US Army Institute of Public Health

DF = Dilution Factor

DUP = Duplicate Analysis

HSN = Horizon Sample Number (Lab Number).

J = The reported result is an estimated value; the result is between the method detection limit (MDL) and the limit of quantitation (LOQ).

LCS = Laboratory Control Sample

LCSD = Laboratory Control Sample Duplicate

LOQ = Limit of Quantitation

LS = Laboratory Sciences

MDL = Method Detection Limit

MS = Matrix Spike

MSD = Matrix Spike Duplicate

ND = Not Detected

Qual = Data Qualifier

RPD = Relative Percent Difference

SML = Sample Management Laboratory (AIPH)

(S) = Surrogate Standard (Found in Analytical Results and QC Listings)

U = The analyte/element was not detected at or above the limit of quantitation (LOQ).

Uncert = Measurement Uncertainty (Reported in Radiochemical Analyses Only)

** Indicates QC failure. For example, recoveries or relative percent difference (RPD) out of range.

Units:

% = percent

cc = cubic centimeter

cm = centimeter

cm2 = square centimeter

cpm = counts per minute

dpm = disintegrations per minute

ft2 = square foot

g = gram

USAPHC

AIPH
Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

in2 = square inch
kg = kilogram
L = Liter
m3 = cubic meter
MFL = million fibers per liter
mg = milligram
min = minute
mL = milliliter
mm2 = square millimeter
mm3 = cubic millimeter
MPN = most probable number
ng = nanogram
NTU = Nephelometric Turbidity Units
pCi = picocurie
pg = picogram
ppb = parts per billion
ppm = parts per million
S = siemens
struct = structures
TON = Threshold Odor Number
uCi = microcurie
ug = microgram
uL = microliter
umhos = micromhos (conductivity unit)
umole = micromole

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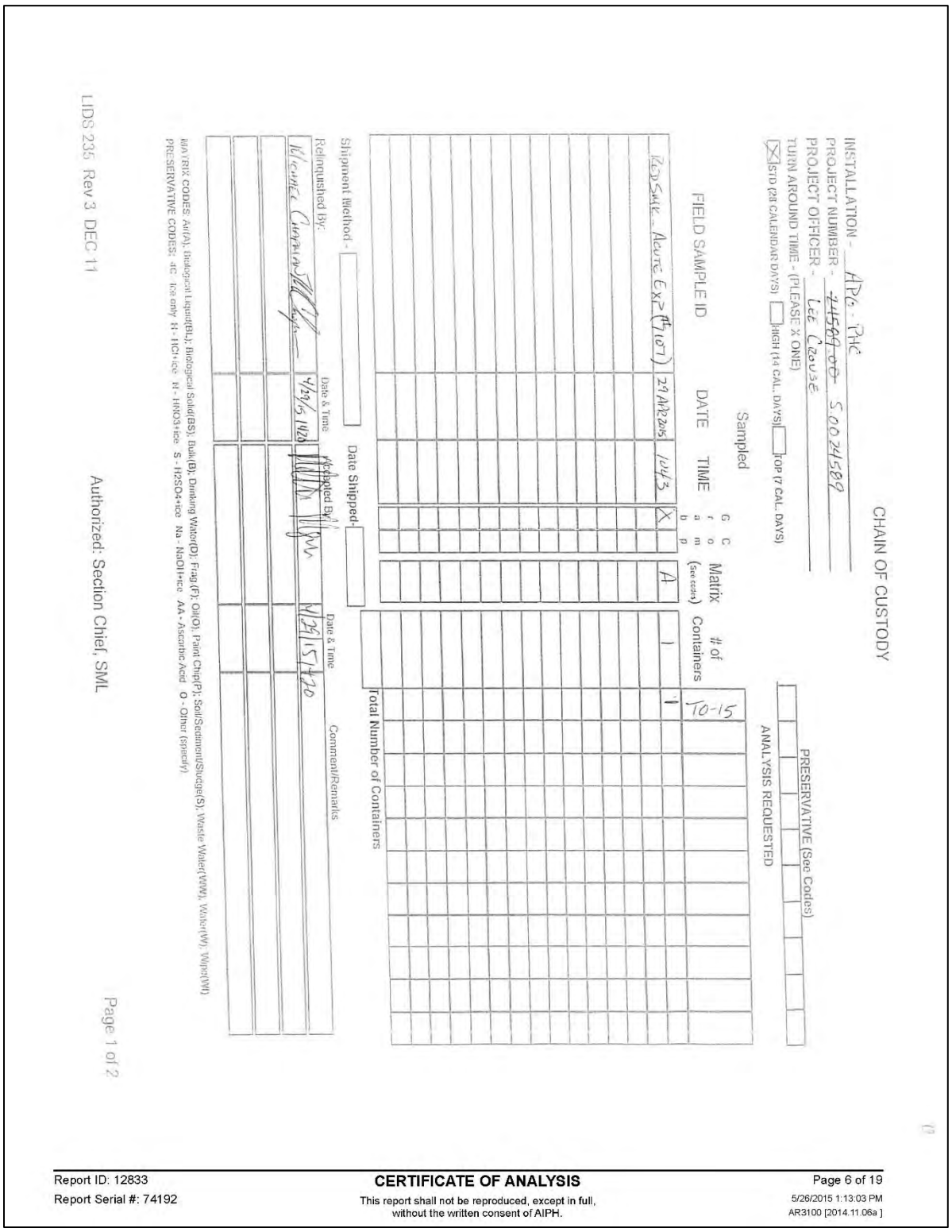
The following page(s) comprise the

SML Documents



CHAIN OF CUSTODY

INSTALLATION - APG - PHC
PROJECT NUMBER - 245889.002 S.00
PROJECT OFFICER - Lee Crouse
TURN AROUND TIME - (PLEASE X ONE)
☒ STD (28 CALENDAR DAYS) ☐ HIGH (14 CAL. DAYS) ☐ TOP (7 CAL. DAYS)

FIELD SAMPLE ID	DATE Sampled	TIME	Grab	Composite	Matrix (see codes)	# of Containers	ANALYSIS REQUESTED	PRESERVATIVE (See Codes)
RedSmk - Acute Exp (107)	29 APR 2015	1443	X		A	1	TO-15	

Total Number of Containers

Shipment Method -
Date Shipped -

Relinquished By: Lee Crouse — Date & Time: 4/29/15 1420
Received By: — Date & Time: 4/29/15 1420
Comment/Remarks

MATRIX CODES: Air(A); Biological Liquid(BL); Biological Solid(BS); Bulk(B); Drinking Water(D); Frag (F); Oil(O); Paint Chip(P); Soil/Sediment/Sludge(S); Waste Water(WW); Water(W); Wipe(W)
PRESERVATIVE CODES: 4C - Ice only H - HCl+Ice N - HNO3+Ice S - H2SO4+Ice Na - NaOH+Ice AA - Ascorbic Acid O - Other (specify)

LIDS 235 Rev 3 DEC 11

Authorized: Section Chief, SML

Page 1 of 2

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The following report(s) comprise the

Contractor Data Report(s) for Analytical Tests

performed at contract laboratories

in support of the US Army Public Health Command.

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Analysis Report

ANALYTICAL RESULTS

Prepared by:

Eurofins Lancaster Laboratories Environmental
2425 New Holland Pike
Lancaster, PA 17601

Prepared for:

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

May 08, 2015

Project: P181D1

Submittal Date: 04/30/2015
Group Number: 1557751
SDG: IP181
PO Number: W91ZLK-14-P-0590
Release Number: P181D1
State of Sample Origin: NA

Client Sample Description	Lancaster Labs (LL) #
128330001 RED SMK_ACUTE EXP Air	7869822

The specific methodologies used in obtaining the enclosed analytical results are indicated on the Laboratory Sample Analysis Record.

Regulatory agencies do not accredit laboratories for all methods, analytes, and matrices. Our scopes of accreditation can be viewed at http://www.eurofinsus.com/environment-testing/laboratories/eurofins-lancaster-laboratories-environmental/resources/certifications/ .

ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Chuck Stoner
ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Heidi Taylor

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Analysis Report

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Respectfully Submitted,

Katherine A. Klinefelter

Katherine A. Klinefelter
Principal Specialist

(717) 556-7256

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Case Narrative

Project Name: P181D1
LL Group #: 1557751

General Comments:

See the Laboratory Sample Analysis Record section of the Analysis Report for the method references.

All QC met criteria unless otherwise noted in an Analysis Specific Comment below. Refer to the QC Summary for specific values and acceptance criteria.

Project specific QC samples are not included in this data set

Matrix QC may not be reported if site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

Surrogate recoveries (if applicable) which are outside of the QC window are confirmed unless attributed to a dilution or otherwise noted in an Analysis Specific Comment below.

The samples were received at the appropriate temperature and in accordance with the chain of custody unless otherwise noted.

Analysis Specific Comments:

EPA TO-15, Volatiles in Air

Sample #s: 7869822

The recovery for a target analyte(s) in the Laboratory Control Spike(s) is outside the QC acceptance limits as noted on the QC Summary. Since the recovery is high and the target analyte(s) was not detected in the sample, the data is reported.

Batch #: D151253OBB (Sample number(s): 7869822)

The recovery(ies) for the following analyte(s) in the LCS and/or LCSD exceeded the acceptance window indicating a positive bias: Acrolein, Vinyl Acetate, cis-1,3-Dichloropropene

v 1.9.2 5/8/2015 12:00:52PM

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Analysis Report

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Sample Description: 128330001 RED SMK_ACUTE EXP Air
12833 / RED SMOKE INHALATION
P181D1 Summa Can # 7107

LL Sample # AQ 7869822
LL Group # 1557751
Account # 04694

Project Name: P181D1

Collected: 04/29/2015 10:43

Submitted: 04/30/2015 20:05
Reported: 05/08/2015 12:00

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

181-1 SDG#: IP181-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	9,400		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	1,400		42	84	84	50
05298	Acrolein	107-02-8	6,700		570	570	570	500
05298	Acrylonitrile	107-13-1	49		11	22	22	10
05298	Benzene	71-43-2	590		6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	510		44	55	55	50
05298	2-Butanone	78-93-3	2,100		74	290	290	50
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	6.3	J	5.3	13	13	10
05298	Chloroform	67-66-3	56		9.8	24	24	10
05298	Chloromethane	74-87-3	330		4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	250		8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	20	U	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

IP181 Page 9 of 345
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Report ID: 12833
Report Serial #: 74192

CERTIFICATE OF ANALYSIS

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AR3100 [2014.11.06a]

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Analysis Report

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Sample Description: 128330001 RED SMK_ACUTE EXP Air
12833 / RED SMOKE INHALATION
P181D1 Summa Can # 7107

LL Sample # AQ 7869822
LL Group # 1557751
Account # 04694

Project Name: P181D1

Collected: 04/29/2015 10:43

Submitted: 04/30/2015 20:05
Reported: 05/08/2015 12:00

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

181-1 SDG#: IP181-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	24		7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	42		12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	45		6.9	35	35	10
05298	Octane	111-65-9	11	J	9.3	47	47	10
05298	Propene	115-07-1	7,600		170	860	860	500
05298	Styrene	100-42-5	40		8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	270		7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	19		5.1	13	13	10
05298	m/p-Xylene	179601-23-1	900		8.7	43	43	10
05298	o-Xylene	95-47-6	180		8.7	22	22	10

The recovery for a target analyte(s) in the Laboratory Control Spike(s) is outside the QC acceptance limits as noted on the QC Summary. Since the recovery is high and the target analyte(s) was not detected in the sample, the data is reported.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1512530BB	05/07/2015 03:50	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1512530BB	05/07/2015 11:57	Jacob E Bailey	50
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1512530BB	05/07/2015 12:40	Jacob E Bailey	500

*=This limit was used in the evaluation of the final result

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH
Group Number: 1557751
Reported: 05/08/2015 12:00

Matrix QC may not be reported if insufficient sample or site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

All Inorganic Initial Calibration and Continuing Calibration Blanks met acceptable method criteria unless otherwise noted on the Analysis Report.

Laboratory Compliance Quality Control

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Batch number: D1512530BB	Sample number(s): 7869822									
Acetone	2.4 U	1.2	2.4	2.4	ug/m3	108	106	58-128	2	25
Acetonitrile	1.7 U	0.84	1.7	1.7	ug/m3					
Acrolein	1.1 U	1.1	1.1	1.1	ug/m3	129*	131*	62-126	2	25
Acrylonitrile	2.2 U	1.1	2.2	2.2	ug/m3					
Benzene	1.6 U	0.64	1.6	1.6	ug/m3	98	98	69-119	1	25
Benzyl Chloride	2.6 U	2.6	2.6	2.6	ug/m3	112	107	50-147	5	25
Bromobenzene	3.2 U	1.3	3.2	3.2	ug/m3					
Bromodichloromethane	3.4 U	1.3	3.4	3.4	ug/m3	96	94	72-128	1	25
Bromoform	5.2 U	2.1	5.2	5.2	ug/m3	91	89	66-139	2	25
Bromomethane	1.9 U	0.78	1.9	1.9	ug/m3	105	104	63-134	2	25
1,3-Butadiene	1.1 U	0.44	1.1	1.1	ug/m3	119	116	66-134	2	25
2-Butanone	2.9 U	1.5	2.9	2.9	ug/m3	108	104	67-130	4	25
tert-Butyl Alcohol	3.0 U	1.5	3.0	3.0	ug/m3					
Carbon Disulfide	3.1 U	1.6	3.1	3.1	ug/m3	112	110	57-134	2	25
Carbon Tetrachloride	3.1 U	1.3	3.1	3.1	ug/m3	99	95	68-132	4	25
Chlorobenzene	2.3 U	0.92	2.3	2.3	ug/m3	92	90	70-119	2	25
Chlorodifluoromethane	1.8 U	0.71	1.8	1.8	ug/m3					
Chloroethane	1.3 U	0.53	1.3	1.3	ug/m3	97	94	63-127	4	25
Chloroform	2.4 U	0.98	2.4	2.4	ug/m3	102	99	68-123	3	25
Chloromethane	2.1 U	0.41	2.1	2.1	ug/m3	89	88	59-132	2	25
3-Chloropropene	1.6 U	0.63	1.6	1.6	ug/m3					

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH
Group Number: 1557751
Reported: 05/08/2015 12:00

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Cumene	4.9 U	0.98	4.9	4.9	ug/m3					
Cyclohexane	1.7 U	0.69	1.7	1.7	ug/m3	109	106	70-117	3	25
Dibromochloromethane	4.3 U	1.7	4.3	4.3	ug/m3	97	95	70-130	2	25
1,2-Dibromoethane	3.8 U	1.5	3.8	3.8	ug/m3	100	98	74-122	1	25
Dibromomethane	3.6 U	1.4	3.6	3.6	ug/m3					
1,2-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	84	81	63-129	4	25
1,3-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	82	79	65-130	4	25
1,4-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	85	81	60-131	4	25
Dichlorodifluoromethane	2.5 U	0.99	2.5	2.5	ug/m3	108	105	59-128	2	25
1,1-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	97	93	68-126	4	25
1,2-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	101	98	65-128	2	25
1,1-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	105	105	61-133	0	25
cis-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	95	92	70-121	4	25
trans-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	100	97	67-124	3	25
Dichlorofluoromethane	2.1 U	0.84	2.1	2.1	ug/m3					
1,2-Dichloropropane	2.3 U	0.92	2.3	2.3	ug/m3	92	93	69-123	1	25
cis-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	130*	130*	70-128	0	25
trans-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	109	109	75-133	1	25
1,4-Dioxane	3.6 U	1.8	3.6	3.6	ug/m3	89	87	71-122	3	25
Ethyl Acetate	1.8 U	0.72	1.8	1.8	ug/m3	89	86	65-128	3	25
Ethyl Acrylate	4.1 U	2.0	4.1	4.1	ug/m3					
Ethyl Methacrylate	4.7 U	2.3	4.7	4.7	ug/m3					
Ethylbenzene	2.2 U	0.87	2.2	2.2	ug/m3	108	105	70-124	2	25
4-Ethyltoluene	2.5 U	0.98	2.5	2.5	ug/m3	99	95	67-129	3	25
Freon 113	3.8 U	1.5	3.8	3.8	ug/m3	93	92	66-126	1	25
Freon 114	3.5 U	1.4	3.5	3.5	ug/m3	102	100	63-121	2	25
Heptane	2.0 U	0.82	2.0	2.0	ug/m3	107	105	69-123	2	25
Hexachlorobutadiene	11	5.3	11	11	ug/m3	77	73	56-138	6	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH Group Number: 1557751
Reported: 05/08/2015 12:00

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Hexachloroethane	9.7 U	4.8	9.7	9.7	ug/m3					
Hexane	1.8 U	0.70	1.8	1.8	ug/m3	104	101	63-120	3	25
2-Hexanone	4.1 U	2.0	4.1	4.1	ug/m3	83	78	62-128	5	25
Isooctane	4.7 U	2.3	4.7	4.7	ug/m3					
Isopropanol	2.5 U	1.2	2.5	2.5	ug/m3	96	93	52-125	2	25
Methyl Acrylate	3.5 U	1.8	3.5	3.5	ug/m3					
Methyl Iodide	2.9 U	1.2	2.9	2.9	ug/m3					
Methyl Methacrylate	4.1 U	2.0	4.1	4.1	ug/m3	113	111	70-128	2	25
Alpha Methyl Styrene	4.8 U	0.97	4.8	4.8	ug/m3					
Methyl t-Butyl Ether	1.8 U	0.72	1.8	1.8	ug/m3	108	107	66-126	1	25
4-Methyl-2-pentanone	4.1 U	2.0	4.1	4.1	ug/m3	90	87	67-130	3	25
Methylene Chloride	3.5 U	1.7	3.5	3.5	ug/m3	110	107	62-115	3	25
Octane	4.7 U	2.3	4.7	4.7	ug/m3					
Propene	1.7 U	0.86	1.7	1.7	ug/m3	106	104	57-136	2	25
Styrene	2.1 U	0.85	2.1	2.1	ug/m3	108	107	73-127	1	25
1,1,1,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3					
1,1,2,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3	87	84	65-127	4	25
Tetrachloroethene	3.4 U	1.4	3.4	3.4	ug/m3	88	87	66-124	1	25
Tetrahydrofuran	1.5 U	0.59	1.5	1.5	ug/m3	112	111	64-123	2	25
Toluene	1.9 U	0.75	1.9	1.9	ug/m3	104	103	66-119	1	25
1,2,4-Trichlorobenzene	7.4 U	3.7	7.4	7.4	ug/m3	73	67	55-142	9	25
1,1,1-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	98	94	68-125	4	25
1,1,2-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	92	91	73-119	1	25
Trichloroethene	2.7 U	1.1	2.7	2.7	ug/m3	95	92	71-123	2	25
Trichlorofluoromethane	2.8 U	1.1	2.8	2.8	ug/m3	105	103	62-126	2	25
1,2,3-Trichloropropane	3.0 U	1.2	3.0	3.0	ug/m3					
1,2,4-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	94	90	66-132	4	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH
Group Number: 1557751
Reported: 05/08/2015 12:00

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
1,3,5-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	100	97	67-130	3	25
Vinyl Acetate	3.5 U	1.8	3.5	3.5	ug/m3	156*	159*	56-139	2	25
Vinyl Chloride	1.3 U	0.51	1.3	1.3	ug/m3	114	111	64-127	2	25
m/p-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	111	109	61-134	2	25
o-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	116	114	67-125	1	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP181

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

Sample #	Client ID	DF	Comments
7869822	128330001	10; 50; 500	

See QC Reference List for Associated Batch QC Samples

SAMPLE RECEIPT:

Samples were received in good condition and within temperature requirements.

HOLDING TIME:

All holding times were met.

CALIBRATION/STANDARDIZATION:

(Sample number(s): 7869822: Analysis: 05298)
A target analyte(s) in the continuing calibration verification standard is outside the QC acceptance limits. Since the result is high and the target analyte(s) is not detected in the sample, the data is reported.

QUALITY CONTROL AND NONCONFORMANCE SUMMARY:

LCS/LCSD

(Sample number(s): 7869822: Analysis: 05298)
The recovery for a target analyte(s) in the Laboratory Control Spike(s) is outside the QC acceptance limits as noted on the QC Summary. Since the recovery is high and the target analyte(s) was not detected in the sample, the data is reported.

Batch#: D151253CBA
The recovery(ies) for the following analyte(s) in the LCS and LCSD exceeds the acceptance window indicating a positive bias: Acrolein, cis-1,3-Dichloropropene, Vinyl Acetate
Refer to the QC Summary forms for more information.

SAMPLE ANALYSIS:

No problems were encountered with the analysis of the samples.

5/15/2015 8:21:59 AM

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP181

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

Abbreviation Key

LOQ = Limit of Quantitation	LCS = Lab Control Sample
MDL = Method Detection Limit	LCSD = Lab Control Sample Duplicate
ND = Not Detected	RE = Repreparation/Reanalysis
J = Estimated Value	* = Out of Specification
E= out of calibration range	

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Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	**BMQL**	Below Minimum Quantitation Level
N.D.	none detected	**MPN**	Most Probable Number
TNTC	Too Numerous To Count	**CP Units**	cobalt-chloroplatinate units
IU	International Units	**NTU**	nephelometric turbidity units
umhos/cm	micromhos/cm	**ng**	nanogram(s)
C	degrees Celsius	**F**	degrees Fahrenheit
meq	milliequivalents	**lb.**	pound(s)
g	gram(s)	**kg**	kilogram(s)
µg	microgram(s)	**mg**	milligram(s)
mL	milliliter(s)	**L**	liter(s)
m3	cubic meter(s)	**µL**	microliter(s)
		pg/L	picogram/liter

<	less than
>	greater than
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.
ppb	parts per billion
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.

Laboratory Data Qualifiers:

B - Analyte detected in the blank
C - Result confirmed by reanalysis
E - Concentration exceeds the calibration range
J (or G, I, X) - estimated value ≥ the Method Detection Limit (MDL or DL) and the < Limit of Quantitation (LOQ or RL)
P - Concentration difference between the primary and confirmation column >40%. The lower result is reported.
U - Analyte was not detected at the value indicated
V - Concentration difference between the primary and confirmation column >100%. The reporting limit is raised due to this disparity and evident interference…

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods.
Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

WARRANTY AND LIMITS OF LIABILITY - In accepting analytical work, we warrant the accuracy of test results for the sample as submitted. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. WE DISCLAIM ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF FITNESS FOR PARTICULAR PURPOSE AND WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL, LLC BE LIABLE FOR INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFIT OR GOODWILL REGARDLESS OF (A) THE NEGLIGENCE (EITHER SOLE OR CONCURRENT) OF EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL AND (B) WHETHER EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. We accept no legal responsibility for the purposes for which the client uses the test results. No purchase order or other order for work shall be accepted by Eurofins Lancaster Laboratories Environmental which includes any conditions that vary from the Standard Terms and Conditions, and Eurofins Lancaster Laboratories Environmental hereby objects to any conflicting terms contained in any acceptance or order submitted by client.

DEPARTMENT OF THE ARMY
US ARMY INSTITUTE OF PUBLIC HEALTH
5158 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MARYLAND 21010-5403

MCHB-IP-L 08 July 2015

MEMORANDUM FOR USAPHC, TOX Portfolio (5158 Blackhawk Rd, MCHB-IP-TEP/ Lee Crouse), Building E2100, Gunpowder, MD 21010

SUBJECT: Laboratory Sciences (LS) Final Analytical Report

1. This is LS Final Analytical Report for:

Project Site:	RED SMOKE INHALATION TOX STUDY
Funding:	S.0024589
LS Work Order #:	13079
Report Serial #:	76035

2. Please contact us if this report or any of our services did not meet your needs or expectations.

3. Point of contact for additional information is MAJ Jose Pizarro-Matos,

DSN 584-2208 or commercial 410-436-2208.

MISER.CRAIG.S.1229386391

Digitally signed by MISER.CRAIG.S.1229386391
DN: CN = MISER.CRAIG.S.1229386391 C = US O = U.S. Government OU = DoD
Date: 2015.07.08 11:23:47 -04'00'

CRAIG MISER
Chief, Laboratory Analytical Division - Inorganic

AIPH
Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5403

SAMPLE SUMMARY

Workorder: 13079 RED SMOKE INHALATION TOX STUDY

All samples were inspected and observed to conform to our receipt policies, except as noted.

Lab ID	Sample ID	Matrix	Date Collected	Date Received	Cancel Code
130790001	RED SMK_RD#2_CHAMBER BKG_7102	Air	6/3/2015 09:59	6/3/2015 14:30	
130790002	RED SMK_RD#2_HIGH EXP_7110	Air	6/3/2015 11:43	6/3/2015 14:30	
130790003	RED SMK_RD#2_MED EXP_7093	Air	6/3/2015 12:24	6/3/2015 14:30	
130790004	RED SMK_RD#2_LOW EXP_7099	Air	6/3/2015 13:43	6/3/2015 14:30	

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Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

USAPHC

PROJECT SUMMARY

Workorder: 13079 RED SMOKE INHALATION TOX STUDY

Batch Comments

Batch: ELLE/1208 - Subcontract Data for ELLE

In the contractor's case narrative/conformance summary calibration/standardization section, the correct sample number for the sample with the positive hit for carbon disulfide is 7915824 instead of 791824.

USAPHC

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Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

TERMINOLOGY & ABBREVIATIONS (ENV)

Terms:

AIPH = US Army Institute of Public Health

DF = Dilution Factor

DUP = Duplicate Analysis

HSN = Horizon Sample Number (Lab Number).

J = The reported result is an estimated value; the result is between the method detection limit (MDL) and the limit of quantitation (LOQ).

LCS = Laboratory Control Sample

LCSD = Laboratory Control Sample Duplicate

LOQ = Limit of Quantitation

LS = Laboratory Sciences

MDL = Method Detection Limit

MS = Matrix Spike

MSD = Matrix Spike Duplicate

ND = Not Detected

Qual = Data Qualifier

RPD = Relative Percent Difference

SML = Sample Management Laboratory (AIPH)

(S) = Surrogate Standard (Found in Analytical Results and QC Listings)

U = The analyte/element was not detected at or above the limit of quantitation (LOQ).

Uncert = Measurement Uncertainty (Reported in Radiochemical Analyses Only)

** Indicates QC failure. For example, recoveries or relative percent difference (RPD) out of range.

Units:

% = percent

cc = cubic centimeter

cm = centimeter

cm2 = square centimeter

cpm = counts per minute

dpm = disintegrations per minute

ft2 = square foot

g = gram

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in2 = square inch
kg = kilogram
L = Liter
m3 = cubic meter
MFL = million fibers per liter
mg = milligram
min = minute
mL = milliliter
mm2 = square millimeter
mm3 = cubic millimeter
MPN = most probable number
ng = nanogram
NTU = Nephelometric Turbidity Units
pCi = picocurie
pg = picogram
ppb = parts per billion
ppm = parts per million
S = siemens
struct = structures
TON = Threshold Odor Number
uCi = microcurie
ug = microgram
uL = microliter
umhos = micromhos (conductivity unit)
umole = micromole

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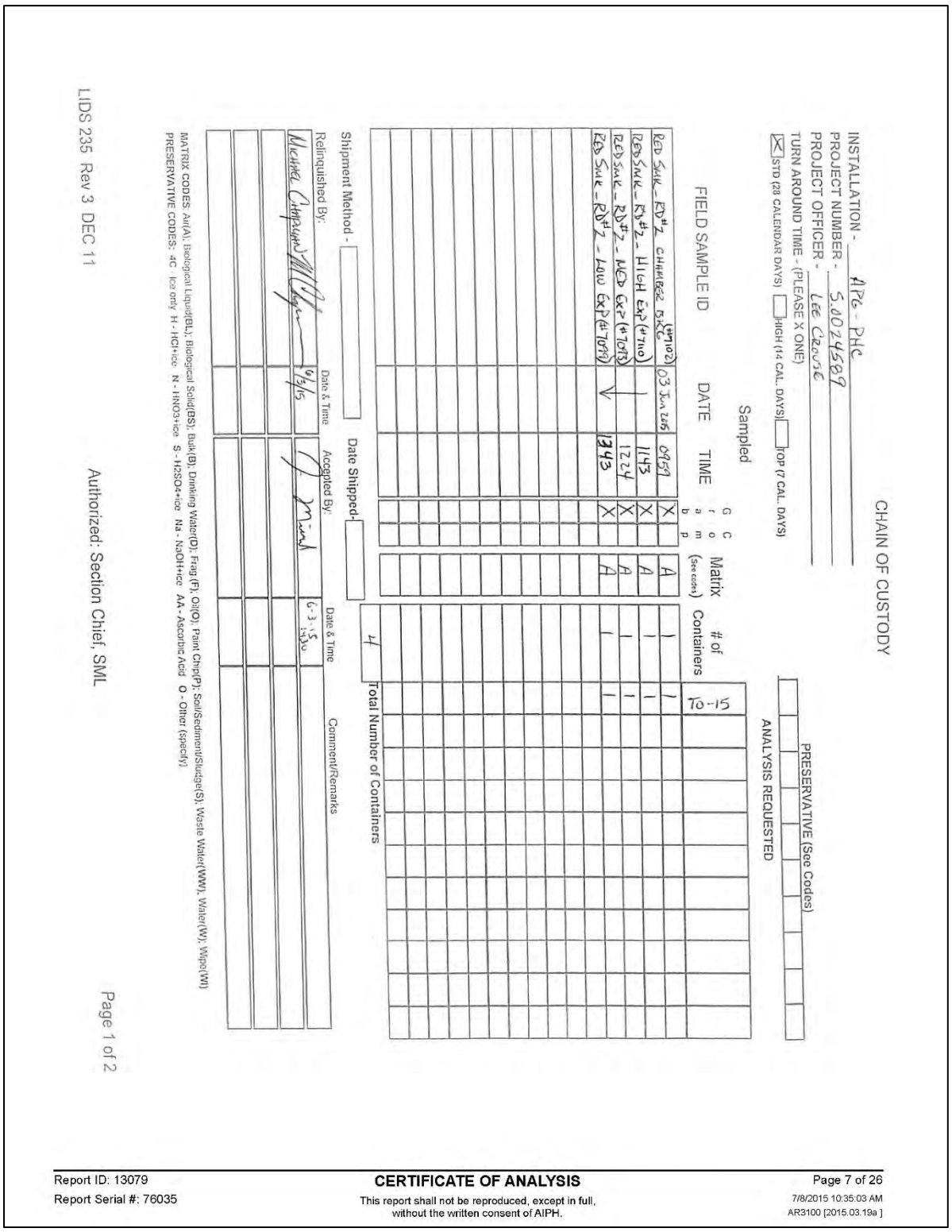
The following page(s) comprise the

SML Documents



CHAIN OF CUSTODY

INSTALLATION - APG - PHC
PROJECT NUMBER - 5.80245897
PROJECT OFFICER - Lee Crouse
TURN AROUND TIME - (PLEASE X ONE)
☒ STD (28 CALENDAR DAYS) ☐ HIGH (14 CAL. DAYS) ☐ TOP (7 CAL. DAYS)

FIELD SAMPLE ID	Sampled DATE	Sampled TIME	Grab	Comp	Matrix (See codes)	# of Containers
RED SMK - RD#2 CHAMBER BLKC (#1102)	03 JUN 2015	0959	X		A	1
RED SMK - RD#2 - HIGH EXP (#1110)		1143	X		A	1
RED SMK - RD#2 - MED EXP (#1043)		1224	X		A	1
RED SMK - RD#2 - LOW EXP (#1070)	V	1343	X		A	1

Total Number of Containers: 4

ANALYSIS REQUESTED

PRESERVATIVE (See Codes)

10-15	

Shipment Method - [ ] Date Shipped - [ ]

Relinquished By:	Date & Time	Accepted By:	Date & Time	Comment/Remarks
Michael Chapman	6/3/15	[illegible]	6-3-15 1430	

MATRIX CODES: Air(A); Biological Liquid(BL); Biological Solid(BS); Bulk(B); Drinking Water(D); Frag (F); Oil(O); Paint Chip(P); Soil/Sediment/Sludge(S); Waste Water(WW); Water(W); Wipe(WI)
PRESERVATIVE CODES: 4C - Ice only H - HCl+Ice N - HNO3+Ice S - H2SO4+Ice Na - NaOH+Ice AA - Ascorbic Acid O - Other (specify)

LIDS 235 Rev 3 DEC 11

Authorized: Section Chief, SML

Page 1 of 2

AIPH
Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

The following report(s) comprise the

Contractor Data Report(s) for Analytical Tests

performed at contract laboratories

in support of the US Army Public Health Command.

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Analysis Report

REVISED

ANALYTICAL RESULTS

Prepared by:

Eurofins Lancaster Laboratories Environmental
2425 New Holland Pike
Lancaster, PA 17601

Prepared for:

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

July 02, 2015

Project: P212D1

Submittal Date: 06/04/2015
Group Number: 1566579
SDG: IP212
PO Number: W91ZLK-14-P-0590
Release Number: P212D1
State of Sample Origin: NA

Client Sample Description	Lancaster Labs (LL) #
130790001 RED SMK_RD#2_CHAMBER Air	7915821
130790002 RED SMK_RD#2_HIGH Air	7915822
130790003 RED SMK_RD#2_MED Air	7915823
130790004 RED SMK_RD#2_LOW Air	7915824

The specific methodologies used in obtaining the enclosed analytical results are indicated on the Laboratory Sample Analysis Record.

Regulatory agencies do not accredit laboratories for all methods, analytes, and matrices. Our scopes of accreditation can be viewed at http://www.eurofinsus.com/environment-testing/laboratories/eurofins-lancaster-laboratories-environmental/resources/certifications/ .

ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Chuck Stoner
ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Heidi Taylor

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Analysis Report

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REVISED

Respectfully Submitted,

Katherine A Klinefelter

Katherine A. Klinefelter
Principal Specialist

(717) 556-7256

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Case Narrative

Project Name: P212D1
LL Group #: 1566579

General Comments:
All analyses have been performed in accordance with DOD QSM Version 5.0 unless otherwise noted below.

See the Laboratory Sample Analysis Record section of the Analysis Report for the method references.

All QC met criteria unless otherwise noted in an Analysis Specific Comment below. Refer to the QC Summary for specific values and acceptance criteria.

Project specific QC samples are not included in this data set

Matrix QC may not be reported if site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

Surrogate recoveries (if applicable) which are outside of the QC window are confirmed unless attributed to a dilution or otherwise noted in an Analysis Specific Comment below.

The samples were received at the appropriate temperature and in accordance with the chain of custody unless otherwise noted.

Analysis Specific Comments:

EPA TO-15, Volatiles in Air
Batch #: D151683OBA (Sample number(s): 7915821-7915824)

The recovery(ies) for the following analyte(s) in the LCS and/or LCSD exceeded the acceptance window indicating a positive bias: Vinyl Acetate

v 1.9.3 7/2/2015 1:23:33PM

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Analysis Report

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REVISED

Sample Description: 130790001 RED SMK_RD#2_CHAMBER Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7102

LL Sample # AQ 7915821
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 09:59

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D1 SDG#: IP212-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air EPA TO-15			ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	31		1.2	4.8	4.8	1
05298	Acetonitrile	75-05-8	10		0.84	1.7	1.7	1
05298	Acrolein	107-02-8	6.4		1.1	1.1	1.1	1
05298	Acrylonitrile	107-13-1	2.2	U	1.1	2.2	2.2	1
05298	Benzene	71-43-2	1.0	J	0.64	1.6	1.6	1
05298	Benzyl Chloride	100-44-7	2.6	U	2.6	2.6	2.6	1
05298	Bromobenzene	108-86-1	3.2	U	1.3	3.2	3.2	1
05298	Bromodichloromethane	75-27-4	3.4	U	1.3	3.4	3.4	1
05298	Bromoform	75-25-2	5.2	U	2.1	5.2	5.2	1
05298	Bromomethane	74-83-9	1.9	U	0.78	1.9	1.9	1
05298	1,3-Butadiene	106-99-0	1.1	U	0.88	1.1	1.1	1
05298	2-Butanone	78-93-3	2.7	J	1.5	5.9	5.9	1
05298	tert-Butyl Alcohol	75-65-0	3.0	U	1.5	3.0	3.0	1
05298	Carbon Disulfide	75-15-0	3.1	U	1.6	3.1	3.1	1
05298	Carbon Tetrachloride	56-23-5	3.1	U	1.3	3.1	3.1	1
05298	Chlorobenzene	108-90-7	2.3	U	0.92	2.3	2.3	1
05298	Chlorodifluoromethane	75-45-6	1.1	J	0.71	1.8	1.8	1
05298	Chloroethane	75-00-3	1.3	U	0.53	1.3	1.3	1
05298	Chloroform	67-66-3	2.4	U	0.98	2.4	2.4	1
05298	Chloromethane	74-87-3	0.97	J	0.41	2.1	2.1	1
05298	3-Chloropropene	107-05-1	1.6	U	0.63	1.6	1.6	1
05298	Cumene	98-82-8	4.9	U	0.98	4.9	4.9	1
05298	Cyclohexane	110-82-7	1.7	U	0.69	1.7	1.7	1
05298	Dibromochloromethane	124-48-1	4.3	U	1.7	4.3	4.3	1
05298	1,2-Dibromoethane	106-93-4	3.8	U	1.5	3.8	3.8	1
05298	Dibromomethane	74-95-3	3.6	U	1.4	3.6	3.6	1
05298	1,2-Dichlorobenzene	95-50-1	3.0	U	1.2	3.0	3.0	1
05298	1,3-Dichlorobenzene	541-73-1	3.0	U	1.2	3.0	3.0	1
05298	1,4-Dichlorobenzene	106-46-7	3.0	U	1.2	3.0	3.0	1
05298	Dichlorodifluoromethane	75-71-8	2.3	J	0.99	2.5	2.5	1
05298	1,1-Dichloroethane	75-34-3	2.0	U	0.81	2.0	2.0	1
05298	1,2-Dichloroethane	107-06-2	2.0	U	0.81	2.0	2.0	1
05298	1,1-Dichloroethene	75-35-4	2.0	U	0.79	2.0	2.0	1
05298	cis-1,2-Dichloroethene	156-59-2	2.0	U	0.79	2.0	2.0	1
05298	trans-1,2-Dichloroethene	156-60-5	2.0	U	0.79	2.0	2.0	1
05298	Dichlorofluoromethane	75-43-4	2.1	U	0.84	2.1	2.1	1
05298	1,2-Dichloropropane	78-87-5	2.3	U	0.92	2.3	2.3	1
05298	cis-1,3-Dichloropropene	10061-01-5	2.3	U	0.91	2.3	2.3	1
05298	trans-1,3-Dichloropropene	10061-02-6	2.3	U	0.91	2.3	2.3	1
05298	1,4-Dioxane	123-91-1	3.6	U	1.8	3.6	3.6	1
05298	Ethyl Acetate	141-78-6	1.8	U	1.8	1.8	1.8	1
05298	Ethyl Acrylate	140-88-5	4.1	U	0.82	4.1	4.1	1
05298	Ethyl Methacrylate	97-63-2	4.7	U	0.93	4.7	4.7	1
05298	Ethylbenzene	100-41-4	2.0	J	0.87	2.2	2.2	1
05298	4-Ethyltoluene	622-96-8	2.5	U	0.98	2.5	2.5	1
05298	Freon 113	76-13-1	3.8	U	3.8	3.8	3.8	1
05298	Freon 114	76-14-2	3.5	U	1.4	3.5	3.5	1
05298	Heptane	142-82-5	2.0	U	0.82	2.0	2.0	1
05298	Hexachlorobutadiene	87-68-3	21	U	4.3	21	21	1
05298	Hexachloroethane	67-72-1	9.7	U	1.9	9.7	9.7	1

*=This limit was used in the evaluation of the final result

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Report ID: 13079
Report Serial #: 76035

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

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REVISED

Sample Description: 130790001 RED SMK_RD#2_CHAMBER Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7102

LL Sample # AQ 7915821
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 09:59

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D1 SDG#: IP212-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	2.2		0.70	1.8	1.8	1
05298	2-Hexanone	591-78-6	8.2	U	2.0	8.2	8.2	1
05298	Isooctane	540-84-1	4.7	U	0.93	4.7	4.7	1
05298	Isopropanol	67-63-0	2.5	U	1.2	2.5	2.5	1
05298	Methyl Acrylate	96-33-3	3.5	U	0.70	3.5	3.5	1
05298	Methyl Iodide	74-88-4	2.9	U	1.2	2.9	2.9	1
05298	Methyl Methacrylate	80-62-6	4.1	U	0.82	4.1	4.1	1
05298	Alpha Methyl Styrene	98-83-9	4.8	U	0.97	4.8	4.8	1
05298	Methyl t-Butyl Ether	1634-04-4	1.8	U	0.72	1.8	1.8	1
05298	4-Methyl-2-pentanone	108-10-1	8.2	U	2.0	8.2	8.2	1
05298	Methylene Chloride	75-09-2	7.7		0.69	3.5	3.5	1
05298	Octane	111-65-9	4.7	U	0.93	4.7	4.7	1
05298	Propene	115-07-1	2.9		0.34	1.7	1.7	1
05298	Styrene	100-42-5	2.1	U	0.85	2.1	2.1	1
05298	1,1,1,2-Tetrachloroethane	630-20-6	3.4	U	1.4	3.4	3.4	1
05298	1,1,2,2-Tetrachloroethane	79-34-5	3.4	U	1.4	3.4	3.4	1
05298	Tetrachloroethene	127-18-4	3.4	U	1.4	3.4	3.4	1
05298	Tetrahydrofuran	109-99-9	1.5	U	0.59	1.5	1.5	1
05298	Toluene	108-88-3	1.5	J	0.75	1.9	1.9	1
05298	1,2,4-Trichlorobenzene	120-82-1	15	U	3.7	15	15	1
05298	1,1,1-Trichloroethane	71-55-6	2.7	U	1.1	2.7	2.7	1
05298	1,1,2-Trichloroethane	79-00-5	2.7	U	1.1	2.7	2.7	1
05298	Trichloroethene	79-01-6	2.7	U	1.1	2.7	2.7	1
05298	Trichlorofluoromethane	75-69-4	1.2	J	1.1	2.8	2.8	1
05298	1,2,3-Trichloropropane	96-18-4	3.0	U	1.2	3.0	3.0	1
05298	1,2,4-Trimethylbenzene	95-63-6	1.7	J	0.98	2.5	2.5	1
05298	1,3,5-Trimethylbenzene	108-67-8	2.5	U	0.98	2.5	2.5	1
05298	Vinyl Acetate	108-05-4	3.5	U	1.8	3.5	3.5	1
05298	Vinyl Chloride	75-01-4	1.3	U	0.51	1.3	1.3	1
05298	m/p-Xylene	179601-23-1	7.1		0.87	4.3	4.3	1
05298	o-Xylene	95-47-6	2.7		0.87	2.2	2.2	1

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 14:15	Jacob E Bailey	1

*-This limit was used in the evaluation of the final result

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Analysis Report

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REVISED

Sample Description: 130790002 RED SMK_RD#2_HIGH Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7110

LL Sample # AQ 7915822
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 11:43

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D2 SDG#: IP212-02

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	9,100		1,200	4,800	4,800	1000
05298	Acetonitrile	75-05-8	1,300		84	170	170	100
05298	Acrolein	107-02-8	4,400		1,100	1,100	1,100	1000
05298	Acrylonitrile	107-13-1	220	U	110	220	220	100
05298	Benzene	71-43-2	610		64	160	160	100
05298	Benzyl Chloride	100-44-7	260	U	260	260	260	100
05298	Bromobenzene	108-86-1	320	U	130	320	320	100
05298	Bromodichloromethane	75-27-4	340	U	130	340	340	100
05298	Bromoform	75-25-2	520	U	210	520	520	100
05298	Bromomethane	74-83-9	190	U	78	190	190	100
05298	1,3-Butadiene	106-99-0	150		88	110	110	100
05298	2-Butanone	78-93-3	1,600		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	300	U	150	300	300	100
05298	Carbon Disulfide	75-15-0	310	U	160	310	310	100
05298	Carbon Tetrachloride	56-23-5	310	U	130	310	310	100
05298	Chlorobenzene	108-90-7	230	U	92	230	230	100
05298	Chlorodifluoromethane	75-45-6	180	U	71	180	180	100
05298	Chloroethane	75-00-3	130	U	53	130	130	100
05298	Chloroform	67-66-3	100	J	98	240	240	100
05298	Chloromethane	74-87-3	260		41	210	210	100
05298	3-Chloropropene	107-05-1	160	U	63	160	160	100
05298	Cumene	98-82-8	490	U	98	490	490	100
05298	Cyclohexane	110-82-7	170	U	69	170	170	100
05298	Dibromochloromethane	124-48-1	430	U	170	430	430	100
05298	1,2-Dibromoethane	106-93-4	380	U	150	380	380	100
05298	Dibromomethane	74-95-3	360	U	140	360	360	100
05298	1,2-Dichlorobenzene	95-50-1	300	U	120	300	300	100
05298	1,3-Dichlorobenzene	541-73-1	300	U	120	300	300	100
05298	1,4-Dichlorobenzene	106-46-7	300	U	120	300	300	100
05298	Dichlorodifluoromethane	75-71-8	250	U	99	250	250	100
05298	1,1-Dichloroethane	75-34-3	200	U	81	200	200	100
05298	1,2-Dichloroethane	107-06-2	120	J	81	200	200	100
05298	1,1-Dichloroethene	75-35-4	200	U	79	200	200	100
05298	cis-1,2-Dichloroethene	156-59-2	200	U	79	200	200	100
05298	trans-1,2-Dichloroethene	156-60-5	200	U	79	200	200	100
05298	Dichlorofluoromethane	75-43-4	210	U	84	210	210	100
05298	1,2-Dichloropropane	78-87-5	230	U	92	230	230	100
05298	cis-1,3-Dichloropropene	10061-01-5	230	U	91	230	230	100
05298	trans-1,3-Dichloropropene	10061-02-6	230	U	91	230	230	100
05298	1,4-Dioxane	123-91-1	360	U	180	360	360	100
05298	Ethyl Acetate	141-78-6	240		180	180	180	100
05298	Ethyl Acrylate	140-88-5	410	U	82	410	410	100
05298	Ethyl Methacrylate	97-63-2	470	U	93	470	470	100
05298	Ethylbenzene	100-41-4	530		87	220	220	100
05298	4-Ethyltoluene	622-96-8	190	J	98	250	250	100
05298	Freon 113	76-13-1	380	U	380	380	380	100
05298	Freon 114	76-14-2	350	U	140	350	350	100
05298	Heptane	142-82-5	110	J	82	200	200	100
05298	Hexachlorobutadiene	87-68-3	2,100	U	430	2,100	2,100	100
05298	Hexachloroethane	67-72-1	970	U	190	970	970	100

*=This limit was used in the evaluation of the final result

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Analysis Report

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REVISED

Sample Description: 130790002 RED SMK_RD#2_HIGH Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7110

LL Sample # AQ 7915822
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 11:43

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D2 SDG#: IP212-02

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	180	U	70	180	180	100
05298	2-Hexanone	591-78-6	820	U	200	820	820	100
05298	Isooctane	540-84-1	470	U	93	470	470	100
05298	Isopropanol	67-63-0	1,200		120	250	250	100
05298	Methyl Acrylate	96-33-3	350	U	70	350	350	100
05298	Methyl Iodide	74-88-4	290	U	120	290	290	100
05298	Methyl Methacrylate	80-62-6	410	U	82	410	410	100
05298	Alpha Methyl Styrene	98-83-9	480	U	97	480	480	100
05298	Methyl t-Butyl Ether	1634-04-4	180	U	72	180	180	100
05298	4-Methyl-2-pentanone	108-10-1	820	U	200	820	820	100
05298	Methylene Chloride	75-09-2	330	J	69	350	350	100
05298	Octane	111-65-9	110	J	93	470	470	100
05298	Propene	115-07-1	3,100		340	1,700	1,700	1000
05298	Styrene	100-42-5	290		85	210	210	100
05298	1,1,1,2-Tetrachloroethane	630-20-6	340	U	140	340	340	100
05298	1,1,2,2-Tetrachloroethane	79-34-5	340	U	140	340	340	100
05298	Tetrachloroethene	127-18-4	340	U	140	340	340	100
05298	Tetrahydrofuran	109-99-9	150	U	59	150	150	100
05298	Toluene	108-88-3	2,600		75	190	190	100
05298	1,2,4-Trichlorobenzene	120-82-1	1,500	U	370	1,500	1,500	100
05298	1,1,1-Trichloroethane	71-55-6	270	U	110	270	270	100
05298	1,1,2-Trichloroethane	79-00-5	270	U	110	270	270	100
05298	Trichloroethene	79-01-6	270	U	110	270	270	100
05298	Trichlorofluoromethane	75-69-4	280	U	110	280	280	100
05298	1,2,3-Trichloropropane	96-18-4	300	U	120	300	300	100
05298	1,2,4-Trimethylbenzene	95-63-6	680		98	250	250	100
05298	1,3,5-Trimethylbenzene	108-67-8	250	U	98	250	250	100
05298	Vinyl Acetate	108-05-4	350	U	180	350	350	100
05298	Vinyl Chloride	75-01-4	130	U	51	130	130	100
05298	m/p-Xylene	179601-23-1	2,000		87	430	430	100
05298	o-Xylene	95-47-6	780		87	220	220	100

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 08:27	Jacob E Bailey	1000
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 15:03	Jacob E Bailey	100

*-This limit was used in the evaluation of the final result

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Analysis Report

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REVISED

Sample Description: 130790003 RED SMK_RD#2_MED Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7093

LL Sample # AQ 7915823
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 12:24

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D3 SDG#: IP212-03

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	9,000		1,200	4,800	4,800	1000
05298	Acetonitrile	75-05-8	1,100		84	170	170	100
05298	Acrolein	107-02-8	4,800		1,100	1,100	1,100	1000
05298	Acrylonitrile	107-13-1	220	U	110	220	220	100
05298	Benzene	71-43-2	460		64	160	160	100
05298	Benzyl Chloride	100-44-7	260	U	260	260	260	100
05298	Bromobenzene	108-86-1	320	U	130	320	320	100
05298	Bromodichloromethane	75-27-4	340	U	130	340	340	100
05298	Bromoform	75-25-2	520	U	210	520	520	100
05298	Bromomethane	74-83-9	190	U	78	190	190	100
05298	1,3-Butadiene	106-99-0	240		88	110	110	100
05298	2-Butanone	78-93-3	1,200		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	300	U	150	300	300	100
05298	Carbon Disulfide	75-15-0	310	U	160	310	310	100
05298	Carbon Tetrachloride	56-23-5	310	U	130	310	310	100
05298	Chlorobenzene	108-90-7	230	U	92	230	230	100
05298	Chlorodifluoromethane	75-45-6	180	U	71	180	180	100
05298	Chloroethane	75-00-3	130	U	53	130	130	100
05298	Chloroform	67-66-3	240	U	98	240	240	100
05298	Chloromethane	74-87-3	220		41	210	210	100
05298	3-Chloropropene	107-05-1	160	U	63	160	160	100
05298	Cumene	98-82-8	490	U	98	490	490	100
05298	Cyclohexane	110-82-7	170	U	69	170	170	100
05298	Dibromochloromethane	124-48-1	430	U	170	430	430	100
05298	1,2-Dibromoethane	106-93-4	380	U	150	380	380	100
05298	Dibromomethane	74-95-3	360	U	140	360	360	100
05298	1,2-Dichlorobenzene	95-50-1	300	U	120	300	300	100
05298	1,3-Dichlorobenzene	541-73-1	300	U	120	300	300	100
05298	1,4-Dichlorobenzene	106-46-7	300	U	120	300	300	100
05298	Dichlorodifluoromethane	75-71-8	250	U	99	250	250	100
05298	1,1-Dichloroethane	75-34-3	200	U	81	200	200	100
05298	1,2-Dichloroethane	107-06-2	98	J	81	200	200	100
05298	1,1-Dichloroethene	75-35-4	200	U	79	200	200	100
05298	cis-1,2-Dichloroethene	156-59-2	200	U	79	200	200	100
05298	trans-1,2-Dichloroethene	156-60-5	200	U	79	200	200	100
05298	Dichlorofluoromethane	75-43-4	210	U	84	210	210	100
05298	1,2-Dichloropropane	78-87-5	230	U	92	230	230	100
05298	cis-1,3-Dichloropropene	10061-01-5	230	U	91	230	230	100
05298	trans-1,3-Dichloropropene	10061-02-6	230	U	91	230	230	100
05298	1,4-Dioxane	123-91-1	360	U	180	360	360	100
05298	Ethyl Acetate	141-78-6	230		180	180	180	100
05298	Ethyl Acrylate	140-88-5	410	U	82	410	410	100
05298	Ethyl Methacrylate	97-63-2	470	U	93	470	470	100
05298	Ethylbenzene	100-41-4	420		87	220	220	100
05298	4-Ethyltoluene	622-96-8	170	J	98	250	250	100
05298	Freon 113	76-13-1	380	U	380	380	380	100
05298	Freon 114	76-14-2	350	U	140	350	350	100
05298	Heptane	142-82-5	110	J	82	200	200	100
05298	Hexachlorobutadiene	87-68-3	2,100	U	430	2,100	2,100	100
05298	Hexachloroethane	67-72-1	970	U	190	970	970	100

*=This limit was used in the evaluation of the final result

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Report ID: 13079
Report Serial #: 76035

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

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REVISED

Sample Description: 130790003 RED SMK_RD#2_MED Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7093

LL Sample # AQ 7915823
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 12:24

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D3 SDG#: IP212-03

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	74	J	70	180	180	100
05298	2-Hexanone	591-78-6	820	U	200	820	820	100
05298	Isooctane	540-84-1	470	U	93	470	470	100
05298	Isopropanol	67-63-0	250	U	120	250	250	100
05298	Methyl Acrylate	96-33-3	350	U	70	350	350	100
05298	Methyl Iodide	74-88-4	290	U	120	290	290	100
05298	Methyl Methacrylate	80-62-6	410	U	82	410	410	100
05298	Alpha Methyl Styrene	98-83-9	480	U	97	480	480	100
05298	Methyl t-Butyl Ether	1634-04-4	180	U	72	180	180	100
05298	4-Methyl-2-pentanone	108-10-1	820	U	200	820	820	100
05298	Methylene Chloride	75-09-2	300	J	69	350	350	100
05298	Octane	111-65-9	120	J	93	470	470	100
05298	Propene	115-07-1	4,200		34	170	170	100
05298	Styrene	100-42-5	240		85	210	210	100
05298	1,1,1,2-Tetrachloroethane	630-20-6	340	U	140	340	340	100
05298	1,1,2,2-Tetrachloroethane	79-34-5	340	U	140	340	340	100
05298	Tetrachloroethene	127-18-4	340	U	140	340	340	100
05298	Tetrahydrofuran	109-99-9	150	U	59	150	150	100
05298	Toluene	108-88-3	2,200		75	190	190	100
05298	1,2,4-Trichlorobenzene	120-82-1	1,500	U	370	1,500	1,500	100
05298	1,1,1-Trichloroethane	71-55-6	270	U	110	270	270	100
05298	1,1,2-Trichloroethane	79-00-5	270	U	110	270	270	100
05298	Trichloroethene	79-01-6	270	U	110	270	270	100
05298	Trichlorofluoromethane	75-69-4	280	U	110	280	280	100
05298	1,2,3-Trichloropropane	96-18-4	300	U	120	300	300	100
05298	1,2,4-Trimethylbenzene	95-63-6	610		98	250	250	100
05298	1,3,5-Trimethylbenzene	108-67-8	250	U	98	250	250	100
05298	Vinyl Acetate	108-05-4	350	U	180	350	350	100
05298	Vinyl Chloride	75-01-4	130	U	51	130	130	100
05298	m/p-Xylene	179601-23-1	1,600		87	430	430	100
05298	o-Xylene	95-47-6	600		87	220	220	100

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 09:10	Jacob E Bailey	1000
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 15:51	Jacob E Bailey	100

*-This limit was used in the evaluation of the final result

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Report ID: 13079
Report Serial #: 76035

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

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REVISED

Sample Description: 130790004 RED SMK_RD#2_LOW Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7099

LL Sample # AQ 7915824
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 13:43

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D4 SDG#: IP212-04

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	7,500		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	790		84	170	170	100
05298	Acrolein	107-02-8	4,200		570	570	570	500
05298	Acrylonitrile	107-13-1	220	U	110	220	220	100
05298	Benzene	71-43-2	350		64	160	160	100
05298	Benzyl Chloride	100-44-7	260	U	260	260	260	100
05298	Bromobenzene	108-86-1	320	U	130	320	320	100
05298	Bromodichloromethane	75-27-4	340	U	130	340	340	100
05298	Bromoform	75-25-2	520	U	210	520	520	100
05298	Bromomethane	74-83-9	190	U	78	190	190	100
05298	1,3-Butadiene	106-99-0	220		88	110	110	100
05298	2-Butanone	78-93-3	920		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	300	U	150	300	300	100
05298	Carbon Disulfide	75-15-0	170	J	160	310	310	100
05298	Carbon Tetrachloride	56-23-5	310	U	130	310	310	100
05298	Chlorobenzene	108-90-7	230	U	92	230	230	100
05298	Chlorodifluoromethane	75-45-6	180	U	71	180	180	100
05298	Chloroethane	75-00-3	130	U	53	130	130	100
05298	Chloroform	67-66-3	240	U	98	240	240	100
05298	Chloromethane	74-87-3	170	J	41	210	210	100
05298	3-Chloropropene	107-05-1	160	U	63	160	160	100
05298	Cumene	98-82-8	490	U	98	490	490	100
05298	Cyclohexane	110-82-7	170	U	69	170	170	100
05298	Dibromochloromethane	124-48-1	430	U	170	430	430	100
05298	1,2-Dibromoethane	106-93-4	380	U	150	380	380	100
05298	Dibromomethane	74-95-3	360	U	140	360	360	100
05298	1,2-Dichlorobenzene	95-50-1	300	U	120	300	300	100
05298	1,3-Dichlorobenzene	541-73-1	300	U	120	300	300	100
05298	1,4-Dichlorobenzene	106-46-7	300	U	120	300	300	100
05298	Dichlorodifluoromethane	75-71-8	250	U	99	250	250	100
05298	1,1-Dichloroethane	75-34-3	200	U	81	200	200	100
05298	1,2-Dichloroethane	107-06-2	200	U	81	200	200	100
05298	1,1-Dichloroethene	75-35-4	200	U	79	200	200	100
05298	cis-1,2-Dichloroethene	156-59-2	200	U	79	200	200	100
05298	trans-1,2-Dichloroethene	156-60-5	200	U	79	200	200	100
05298	Dichlorofluoromethane	75-43-4	210	U	84	210	210	100
05298	1,2-Dichloropropane	78-87-5	230	U	92	230	230	100
05298	cis-1,3-Dichloropropene	10061-01-5	230	U	91	230	230	100
05298	trans-1,3-Dichloropropene	10061-02-6	230	U	91	230	230	100
05298	1,4-Dioxane	123-91-1	360	U	180	360	360	100
05298	Ethyl Acetate	141-78-6	180	U	180	180	180	100
05298	Ethyl Acrylate	140-88-5	410	U	82	410	410	100
05298	Ethyl Methacrylate	97-63-2	470	U	93	470	470	100
05298	Ethylbenzene	100-41-4	370		87	220	220	100
05298	4-Ethyltoluene	622-96-8	130	J	98	250	250	100
05298	Freon 113	76-13-1	380	U	380	380	380	100
05298	Freon 114	76-14-2	350	U	140	350	350	100
05298	Heptane	142-82-5	200	U	82	200	200	100
05298	Hexachlorobutadiene	87-68-3	2,100	U	430	2,100	2,100	100
05298	Hexachloroethane	67-72-1	970	U	190	970	970	100

*=This limit was used in the evaluation of the final result

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Report ID: 13079
Report Serial #: 76035

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

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REVISED

Sample Description: 130790004 RED SMK_RD#2_LOW Air
13079 / RED SMOKE INHALATION
P212D1 Summa Can # B7099

LL Sample # AQ 7915824
LL Group # 1566579
Account # 04694

Project Name: P212D1

Collected: 06/03/2015 13:43

Submitted: 06/04/2015 18:45
Reported: 07/02/2015 13:23

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

212D4 SDG#: IP212-04

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	180	U	70	180	180	100
05298	2-Hexanone	591-78-6	820	U	200	820	820	100
05298	Isooctane	540-84-1	470	U	93	470	470	100
05298	Isopropanol	67-63-0	550		120	250	250	100
05298	Methyl Acrylate	96-33-3	350	U	70	350	350	100
05298	Methyl Iodide	74-88-4	290	U	120	290	290	100
05298	Methyl Methacrylate	80-62-6	84	J	82	410	410	100
05298	Alpha Methyl Styrene	98-83-9	480	U	97	480	480	100
05298	Methyl t-Butyl Ether	1634-04-4	180	U	72	180	180	100
05298	4-Methyl-2-pentanone	108-10-1	820	U	200	820	820	100
05298	Methylene Chloride	75-09-2	110	J	69	350	350	100
05298	Octane	111-65-9	110	J	93	470	470	100
05298	Propene	115-07-1	3,600		34	170	170	100
05298	Styrene	100-42-5	190	J	85	210	210	100
05298	1,1,1,2-Tetrachloroethane	630-20-6	340	U	140	340	340	100
05298	1,1,2,2-Tetrachloroethane	79-34-5	340	U	140	340	340	100
05298	Tetrachloroethene	127-18-4	340	U	140	340	340	100
05298	Tetrahydrofuran	109-99-9	150	U	59	150	150	100
05298	Toluene	108-88-3	1,300		75	190	190	100
05298	1,2,4-Trichlorobenzene	120-82-1	1,500	U	370	1,500	1,500	100
05298	1,1,1-Trichloroethane	71-55-6	270	U	110	270	270	100
05298	1,1,2-Trichloroethane	79-00-5	270	U	110	270	270	100
05298	Trichloroethene	79-01-6	270	U	110	270	270	100
05298	Trichlorofluoromethane	75-69-4	280	U	110	280	280	100
05298	1,2,3-Trichloropropane	96-18-4	300	U	120	300	300	100
05298	1,2,4-Trimethylbenzene	95-63-6	510		98	250	250	100
05298	1,3,5-Trimethylbenzene	108-67-8	1,200		98	250	250	100
05298	Vinyl Acetate	108-05-4	350	U	180	350	350	100
05298	Vinyl Chloride	75-01-4	130	U	51	130	130	100
05298	m/p-Xylene	179601-23-1	1,400		87	430	430	100
05298	o-Xylene	95-47-6	530		87	220	220	100

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 16:39	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1516830BA	06/18/2015 18:05	Jacob E Bailey	500

*-This limit was used in the evaluation of the final result

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Report ID: 13079
Report Serial #: 76035

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

REVISED

Quality Control Summary

Client Name: USAPHC/AIPH Group Number: 1566579
Reported: 07/02/2015 13:23

Matrix QC may not be reported if insufficient sample or site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

All Inorganic Initial Calibration and Continuing Calibration Blanks met acceptable method criteria unless otherwise noted on the Analysis Report.

Laboratory Compliance Quality Control

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Batch number: D1516830BA	Sample number(s): 7915821-7915824									
Acetone	2.4 U	1.2	2.4	2.4	ug/m3	94	95	58-128	1	25
Acetonitrile	1.7 U	0.84	1.7	1.7	ug/m3					
Acrolein	1.1 U	1.1	1.1	1.1	ug/m3	121	126	62-126	4	25
Acrylonitrile	2.2 U	1.1	2.2	2.2	ug/m3					
Benzene	1.6 U	0.64	1.6	1.6	ug/m3	84	90	69-119	7	25
Benzyl Chloride	2.6 U	2.6	2.6	2.6	ug/m3	109	108	50-147	1	25
Bromobenzene	3.2 U	1.3	3.2	3.2	ug/m3					
Bromodichloromethane	3.4 U	1.3	3.4	3.4	ug/m3	86	88	72-128	3	25
Bromoform	5.2 U	2.1	5.2	5.2	ug/m3	89	92	66-139	3	25
Bromomethane	1.9 U	0.78	1.9	1.9	ug/m3	75	80	63-134	7	25
1,3-Butadiene	1.1 U	0.44	1.1	1.1	ug/m3	76	85	66-134	10	25
2-Butanone	2.9 U	1.5	2.9	2.9	ug/m3	93	94	67-130	0	25
tert-Butyl Alcohol	3.0 U	1.5	3.0	3.0	ug/m3					
Carbon Disulfide	3.1 U	1.6	3.1	3.1	ug/m3	78	83	57-134	7	25
Carbon Tetrachloride	3.1 U	1.3	3.1	3.1	ug/m3	88	89	68-132	2	25
Chlorobenzene	2.3 U	0.92	2.3	2.3	ug/m3	81	85	70-119	5	25
Chlorodifluoromethane	1.8 U	0.71	1.8	1.8	ug/m3					
Chloroethane	1.3 U	0.53	1.3	1.3	ug/m3	76	80	63-127	5	25
Chloroform	2.4 U	0.98	2.4	2.4	ug/m3	88	93	68-123	5	25
Chloromethane	2.1 U	0.41	2.1	2.1	ug/m3	60	62	59-132	4	25
3-Chloropropene	1.6 U	0.63	1.6	1.6	ug/m3					

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

REVISED

Quality Control Summary

Client Name: USAPHC/AIPH
Group Number: 1566579
Reported: 07/02/2015 13:23

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Cumene	4.9 U	0.98	4.9	4.9	ug/m3					
Cyclohexane	1.7 U	0.69	1.7	1.7	ug/m3	85	88	70-117	4	25
Dibromochloromethane	4.3 U	1.7	4.3	4.3	ug/m3	87	91	70-130	4	25
1,2-Dibromoethane	3.8 U	1.5	3.8	3.8	ug/m3	92	93	74-122	1	25
Dibromomethane	3.6 U	1.4	3.6	3.6	ug/m3					
1,2-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	87	85	63-129	2	25
1,3-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	81	80	65-130	1	25
1,4-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	83	82	60-131	2	25
Dichlorodifluoromethane	2.5 U	0.99	2.5	2.5	ug/m3	87	85	59-128	3	25
1,1-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	83	88	68-126	5	25
1,2-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	90	94	65-128	4	25
1,1-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	80	86	61-133	7	25
cis-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	82	88	70-121	8	25
trans-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	81	88	67-124	8	25
Dichlorofluoromethane	2.1 U	0.84	2.1	2.1	ug/m3					
1,2-Dichloropropane	2.3 U	0.92	2.3	2.3	ug/m3	81	86	69-123	7	25
cis-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	120	120	70-128	0	25
trans-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	102	102	75-133	1	25
1,4-Dioxane	3.6 U	1.8	3.6	3.6	ug/m3	86	88	71-122	2	25
Ethyl Acetate	1.8 U	0.72	1.8	1.8	ug/m3	80	80	65-128	0	25
Ethyl Acrylate	4.1 U	2.0	4.1	4.1	ug/m3					
Ethyl Methacrylate	4.7 U	2.3	4.7	4.7	ug/m3					
Ethylbenzene	2.2 U	0.87	2.2	2.2	ug/m3	94	97	70-124	2	25
4-Ethyltoluene	2.5 U	0.98	2.5	2.5	ug/m3	95	95	67-129	1	25
Freon 113	3.8 U	1.5	3.8	3.8	ug/m3	77	79	66-126	3	25
Freon 114	3.5 U	1.4	3.5	3.5	ug/m3	73	79	63-121	8	25
Heptane	2.0 U	0.82	2.0	2.0	ug/m3	85	93	69-123	9	25
Hexachlorobutadiene	11	5.3	11	11	ug/m3	81	66	56-138	20	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

REVISED

Quality Control Summary

Client Name: USAPHC/AIPH
Reported: 07/02/2015 13:23

Group Number: 1566579

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Hexachloroethane	9.7 U	4.8	9.7	9.7	ug/m3					
Hexane	1.8 U	0.70	1.8	1.8	ug/m3	84	88	63-120	4	25
2-Hexanone	4.1 U	2.0	4.1	4.1	ug/m3	71	74	62-128	5	25
Isooctane	4.7 U	2.3	4.7	4.7	ug/m3					
Isopropanol	2.5 U	1.2	2.5	2.5	ug/m3	77	79	52-125	2	25
Methyl Acrylate	3.5 U	1.8	3.5	3.5	ug/m3					
Methyl Iodide	2.9 U	1.2	2.9	2.9	ug/m3					
Methyl Methacrylate	4.1 U	2.0	4.1	4.1	ug/m3	98	98	70-128	0	25
Alpha Methyl Styrene	4.8 U	0.97	4.8	4.8	ug/m3					
Methyl t-Butyl Ether	1.8 U	0.72	1.8	1.8	ug/m3	91	93	66-126	3	25
4-Methyl-2-pentanone	4.1 U	2.0	4.1	4.1	ug/m3	73	75	67-130	3	25
Methylene Chloride	3.5 U	1.7	3.5	3.5	ug/m3	84	89	62-115	6	25
Octane	4.7 U	2.3	4.7	4.7	ug/m3					
Propene	1.7 U	0.86	1.7	1.7	ug/m3	74	76	57-136	3	25
Styrene	2.1 U	0.85	2.1	2.1	ug/m3	101	104	73-127	2	25
1,1,1,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3					
1,1,2,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3	82	82	65-127	0	25
Tetrachloroethene	3.4 U	1.4	3.4	3.4	ug/m3	71	76	66-124	7	25
Tetrahydrofuran	1.5 U	0.59	1.5	1.5	ug/m3	108	109	64-123	1	25
Toluene	1.9 U	0.75	1.9	1.9	ug/m3	88	93	66-119	5	25
1,2,4-Trichlorobenzene	7.4 U	3.7	7.4	7.4	ug/m3	73	60	55-142	20	25
1,1,1-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	84	88	68-125	4	25
1,1,2-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	80	84	73-119	4	25
Trichloroethene	2.7 U	1.1	2.7	2.7	ug/m3	82	84	71-123	3	25
Trichlorofluoromethane	2.8 U	1.1	2.8	2.8	ug/m3	79	82	62-126	4	25
1,2,3-Trichloropropane	3.0 U	1.2	3.0	3.0	ug/m3					
1,2,4-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	90	91	66-132	0	25

*- Outside of specification
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(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

REVISED

Quality Control Summary

Client Name: USAPHC/AIPH
Reported: 07/02/2015 13:23

Group Number: 1566579

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
1,3,5-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	97	98	67-130	1	25
Vinyl Acetate	3.5 U	1.8	3.5	3.5	ug/m3	140*	148*	56-139	6	25
Vinyl Chloride	1.3 U	0.51	1.3	1.3	ug/m3	79	84	64-127	6	25
m/p-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	99	101	61-134	2	25
o-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	107	109	67-125	2	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP212

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

Sample #	Client ID	DF	Comments
7915821	130790001	1	
7915822	130790002	100; 1000	
7915823	130790003	100; 1000	
7915824	130790004	100; 500	

See QC Reference List for Associated Batch QC Samples

SAMPLE RECEIPT:

Samples were received in good condition and within temperature requirements.

HOLDING TIME:

All holding times were met.

CALIBRATION/STANDARDIZATION:

(Sample number(s): 7915821: Analysis: 05298)
A non-conformance was identified for the initial calibration on instrument 10145 performed on 6/17/2015. The calibration contained three compounds above 30%RSD, carbon disulfide at 37%, acetonitrile at 44%, and hexachlorobutadiene at 36%. Samples 7915821,7915822, 7915823, and 7915824 all reported positive results for acetonitrile and sample 791824 reported a postive result for carbon disulfide; therefore these results should be considered estimated values. Hexachlorobutadiene was not detected in any of the four samples, therefore there is no impact upon this result.

QUALITY CONTROL AND NONCONFORMANCE SUMMARY:

LCS/LCSD

(Sample number(s): 7915821-7915824: Analysis: 05298)
The recovery for a target analyte(s) in the Laboratory Control Spike(s) is outside the QC acceptance limits as noted on the QC Summary. Since the recovery is high and the target analyte(s) was not detected in the sample, the data is reported.

Batch#: D1516830BA (Sample number(s): 7915821-7915824)
The recovery(ies) for the following analyte(s) in the LCS and LCSD exceeds the acceptance window indicating a positive bias: Vinyl Acetate
Refer to the QC Summary forms for more information.

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP212

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

SAMPLE ANALYSIS:

No problems were encountered with the analysis of the samples.

Abbreviation Key

LOQ = Limit of Quantitation	LCS = Lab Control Sample
MDL = Method Detection Limit	LCSD = Lab Control Sample Duplicate
ND = Not Detected	RE = Repreparation/Reanalysis
J = Estimated Value	* = Out of Specification
E= out of calibration range	

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Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	**BMQL**	Below Minimum Quantitation Level
N.D.	none detected	**MPN**	Most Probable Number
TNTC	Too Numerous To Count	**CP Units**	cobalt-chloroplatinate units
IU	International Units	**NTU**	nephelometric turbidity units
umhos/cm	micromhos/cm	**ng**	nanogram(s)
C	degrees Celsius	**F**	degrees Fahrenheit
meq	milliequivalents	**lb.**	pound(s)
g	gram(s)	**kg**	kilogram(s)
µg	microgram(s)	**mg**	milligram(s)
mL	milliliter(s)	**L**	liter(s)
m3	cubic meter(s)	**µL**	microliter(s)
		pg/L	picogram/liter

<	less than
>	greater than
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.
ppb	parts per billion
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.

Laboratory Data Qualifiers:

B - Analyte detected in the blank
C - Result confirmed by reanalysis
E - Concentration exceeds the calibration range
J (or G, I, X) - estimated value ≥ the Method Detection Limit (MDL or DL) and the < Limit of Quantitation (LOQ or RL)
P - Concentration difference between the primary and confirmation column >40%. The lower result is reported.
U - Analyte was not detected at the value indicated
V - Concentration difference between the primary and confirmation column >100%. The reporting limit is raised due to this disparity and evident interference…

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods. Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

WARRANTY AND LIMITS OF LIABILITY - In accepting analytical work, we warrant the accuracy of test results for the sample as submitted. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. WE DISCLAIM ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF FITNESS FOR PARTICULAR PURPOSE AND WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL, LLC BE LIABLE FOR INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFIT OR GOODWILL REGARDLESS OF (A) THE NEGLIGENCE (EITHER SOLE OR CONCURRENT) OF EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL AND (B) WHETHER EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. We accept no legal responsibility for the purposes for which the client uses the test results. No purchase order or other order for work shall be accepted by Eurofins Lancaster Laboratories Environmental which includes any conditions that vary from the Standard Terms and Conditions, and Eurofins Lancaster Laboratories Environmental hereby objects to any conflicting terms contained in any acceptance or order submitted by client.

DEPARTMENT OF THE ARMY
US ARMY INSTITUTE OF PUBLIC HEALTH
5158 BLACKHAWK ROAD
ABERDEEN PROVING GROUND MARYLAND 21010-5403

MCHB-IP-L 14 July 2015

MEMORANDUM FOR USAPHC, TOX Portfolio (5158 Blackhawk Rd, MCHB-IP-TEP/ Lee Crouse), Building E2100, Gunpowder, MD 21010

SUBJECT: Laboratory Sciences (LS) Final Analytical Report

1. This is LS Final Analytical Report for:

Project Site:	RED SMOKE INHALATION TOX STUDY
Funding:	S.0024589
LS Work Order #:	13177
Report Serial #:	76326

2. Please contact us if this report or any of our services did not meet your needs or expectations.

3. Point of contact for additional information is MAJ Jose Pizarro-Matos,

DSN 584-2208 or commercial 410-436-2208.

MILLER.WALTER.E.1275869933

Digitally signed by: MILLER.WALTER.E.1275869933
DN: CN = MILLER.WALTER.E.1275869933 C = US O = U.S. Government OU = DoD
Date: 2015.07.14 12:45:19 -04'00'

WALTER E. MILLER
Chief, Laboratory Analytical Division - Organic

AIPH
Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

SAMPLE SUMMARY

Workorder: 13177 RED SMOKE INHALATION TOX STUDY

All samples were inspected and observed to conform to our receipt policies, except as noted.

Lab ID	Sample ID	Matrix	Date Collected	Date Received	Cancel Code
131770001	RedSMK_RD#6_Chamber BKG_(7101)	Air	6/9/2015 10:42	6/9/2015 14:35	
131770002	RedSMK_RD#6_High Exp_(7096)	Air	6/9/2015 12:08	6/9/2015 14:35	
131770003	RedSMK_RD#6_Med Exp_(7103)	Air	6/9/2015 12:55	6/9/2015 14:35	
131770004	RedSMK_RD#6_Low Exp_(7091)	Air	6/9/2015 13:57	6/9/2015 14:35	
131770005	RedSMK_RD#10_ChamberBKG_(7100)	Air	6/15/2015	6/15/2015	
131770006	RedSMK_RD#10_High Exp_(7108)	Air	6/15/2015 11:07	6/15/2015	
131770007	RedSMK_RD#10_Med Exp_(7113)	Air	6/15/2015	6/15/2015	
131770008	RedSMK_RD#10_Low Exp_(6489)	Air	6/15/2015	6/15/2015	

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Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

TERMINOLOGY & ABBREVIATIONS (ENV)

Terms:

AIPH = US Army Institute of Public Health

DF = Dilution Factor

DUP = Duplicate Analysis

HSN = Horizon Sample Number (Lab Number).

J = The reported result is an estimated value; the result is between the method detection limit (MDL) and the limit of quantitation (LOQ).

LCS = Laboratory Control Sample

LCSD = Laboratory Control Sample Duplicate

LOQ = Limit of Quantitation

LS = Laboratory Sciences

MDL = Method Detection Limit

MS = Matrix Spike

MSD = Matrix Spike Duplicate

ND = Not Detected

Qual = Data Qualifier

RPD = Relative Percent Difference

SML = Sample Management Laboratory (AIPH)

(S) = Surrogate Standard (Found in Analytical Results and QC Listings)

U = The analyte/element was not detected at or above the limit of quantitation (LOQ).

Uncert = Measurement Uncertainty (Reported in Radiochemical Analyses Only)

** Indicates QC failure. For example, recoveries or relative percent difference (RPD) out of range.

Units:

% = percent

cc = cubic centimeter

cm = centimeter

cm2 = square centimeter

cpm = counts per minute

dpm = disintegrations per minute

ft2 = square foot

g = gram

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USAPHC

in2 = square inch
kg = kilogram
L = Liter
m3 = cubic meter
MFL = million fibers per liter
mg = milligram
min = minute
mL = milliliter
mm2 = square millimeter
mm3 = cubic millimeter
MPN = most probable number
ng = nanogram
NTU = Nephelometric Turbidity Units
pCi = picocurie
pg = picogram
ppb = parts per billion
ppm = parts per million
S = siemens
struct = structures
TON = Threshold Odor Number
uCi = microcurie
ug = microgram
uL = microliter
umhos = micromhos (conductivity unit)
umole = micromole

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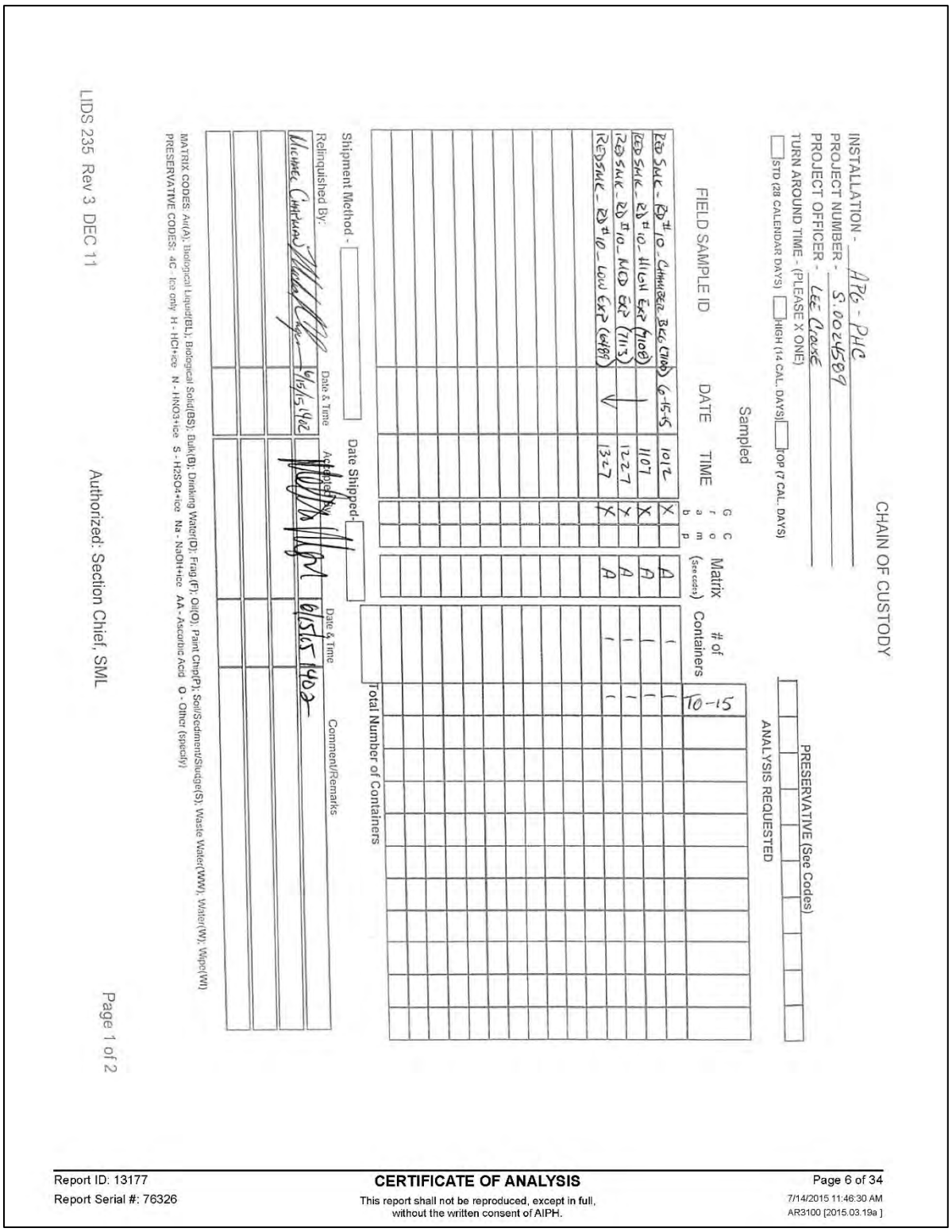
The following page(s) comprise the

SML Documents



CHAIN OF CUSTODY

INSTALLATION - APG - PHC
PROJECT NUMBER - S.0024589
PROJECT OFFICER - Lee Crouse
TURN AROUND TIME - (PLEASE X ONE)
☐ STD (28 CALENDAR DAYS) ☐ HIGH (14 CAL. DAYS) ☐ TOP (7 CAL. DAYS)

FIELD SAMPLE ID	Sampled DATE	Sampled TIME	Grab	Composite	Matrix (See codes)	# of Containers
Exp Smk - Exp #10 - Chamber Bkg (Tank)	6-15-15	1017	X		A	1
Exp Smk - Exp #10 - High Exp (Tank)		1107	X		A	1
Exp Smk - Exp #10 - Mid Exp (Tank)		1227	X		A	1
Exp Smk - Exp #10 - Low Exp (Tank)	✓	1327	X		A	1
						10-15

Total Number of Containers

PRESERVATIVE (See Codes)

ANALYSIS REQUESTED

Shipment Method - ☐ Date Shipped -

Relinquished By:	Date & Time	Accepted By:	Date & Time	Comment/Remarks
Michael Chapman	6/15/15 1402		6/15/15 1402	

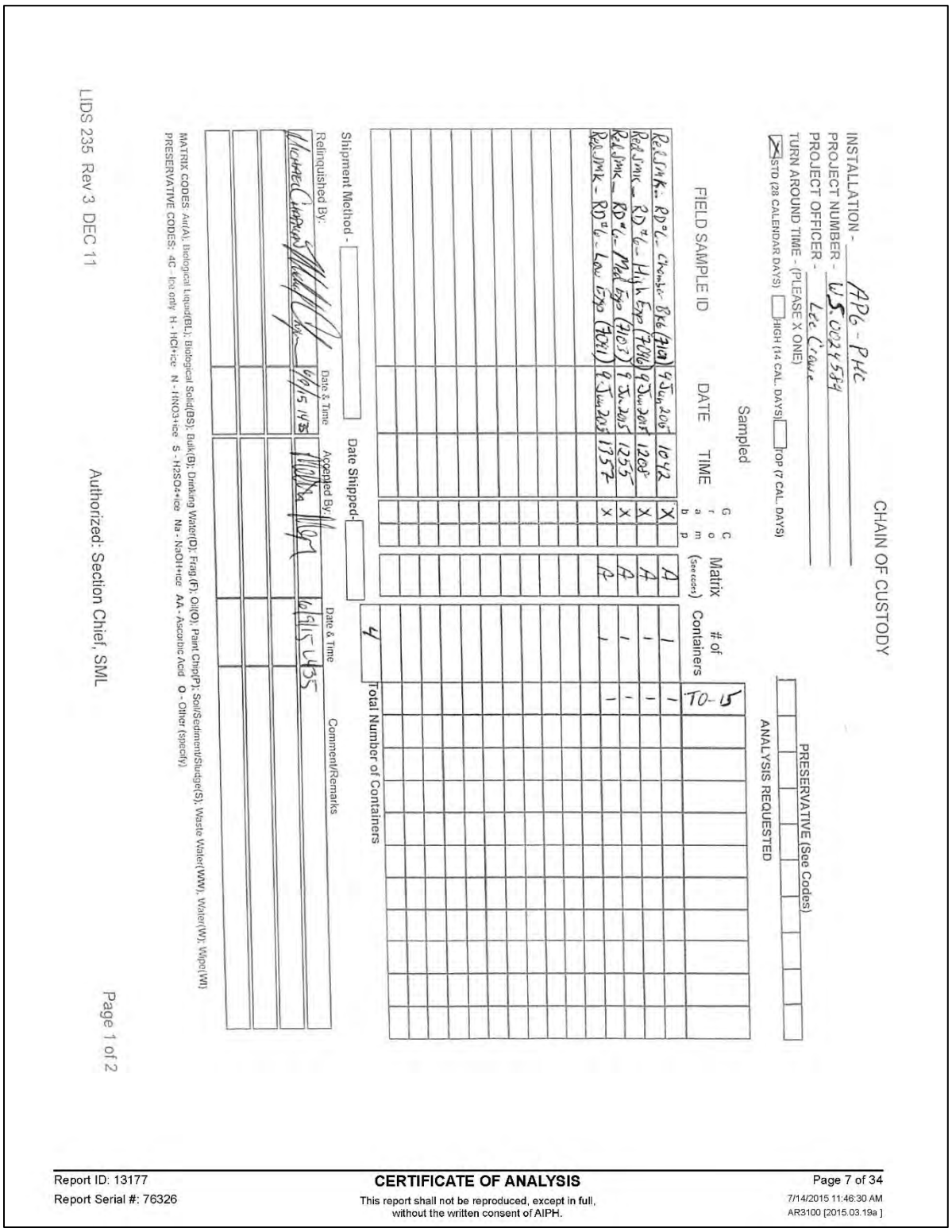
MATRIX CODES: Air(A); Biological Liquid(BL); Biological Solid(BS); Bulk(B); Drinking Water(D); Frag (F); Oil(O); Paint Chip(P); Soil/Sediment/Sludge(S); Waste Water(WW); Water(W); Wipe(WI)

PRESERVATIVE CODES: 4C - Ice only H - HCl+Ice N - HNO3+Ice S - H2SO4+Ice Na - NaOH+Ice AA - Ascorbic Acid O - Other (specify)

LIDS 235 Rev 3 DEC 11

Authorized: Section Chief, SML

Page 1 of 2



CHAIN OF CUSTODY

INSTALLATION - APG - PHC
PROJECT NUMBER - W5.0224534
PROJECT OFFICER - Lee Crouse (PLEASE X ONE)
TURN AROUND TIME - ☒STD (28 CALENDAR DAYS) ☐HIGH (14 CAL. DAYS) ☐TOP (7 CAL. DAYS)

FIELD SAMPLE ID	Sampled DATE	Sampled TIME	Grab	Composite	Matrix (See codes)	# of Containers	TO-5	PRESERVATIVE (See Codes)
Remark: RD#6 Chronic Rat (Air)	9 Jun 2015	1042	X		A	1	1	
Remark: RD#6 - High Exp (Air)	9 Jun 2015	1208	X		A	1	1	
Remark: RD#6 - Med Exp (Air)	9 Jun 2015	1255	X		A	1	1	
Remark - RD#6 - Low Exp (Air)	9 Jun 2015	1352	X		A	1	1	

ANALYSIS REQUESTED

Total Number of Containers: 4

Shipment Method - [ ] Date Shipped - [ ]

Relinquished By:	Date & Time	Accepted By:	Date & Time	Comment/Remarks
[illegible]	9/6/15 1435	[illegible]	9/6/15 1435	

MATRIX CODES: Air(A); Biological Liquid(BL); Biological Solid(BS); Bulk(B); Drinking Water(D); Frag (F); Oil(O); Paint Chip(P); Soil/Sediment/Sludge(S); Waste Water(WW); Water(W); Wipe(WI)
PRESERVATIVE CODES: 4C - Ice only H - HCl+ice N - HNO3+ice S - H2SO4+ice Na - NaOH+ice AA - Ascorbic Acid O - Other (specify)

LIDS 235 Rev 3 DEC 11

Authorized: Section Chief, SML

Page 1 of 2

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Laboratory Sciences
5158 Blackhawk Road, Aberdeen Proving Ground MD 21010-5403

The following report(s) comprise the

Contractor Data Report(s) for Analytical Tests

performed at contract laboratories

in support of the US Army Public Health Command.

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2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Analysis Report

ANALYTICAL RESULTS

Prepared by:

Eurofins Lancaster Laboratories Environmental
2425 New Holland Pike
Lancaster, PA 17601

Prepared for:

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

July 10, 2015

Project: P232D1

Submittal Date: 06/16/2015
Group Number: 1569487
SDG: IP232
PO Number: W91ZLK-14-P-0590
Release Number: P232D1
State of Sample Origin: NA

Client Sample Description	Lancaster Labs (LL) #
131770001 RedSMK_RD#6_Chamber Air	7930850
131770002 RedSMK_RD#6_High Air	7930851
131770003 RedSMK_RD#6_Med Air	7930852
131770004 RedSMK_RD#6_Low Air	7930853
131770005 RedSMK_RD#10_ChamberBK Air	7930854
131770006 RedSMK_RD#10_High Air	7930855
131770007 RedSMK_RD#10_Med Air	7930856
131770008 RedSMK_RD#10_Low Air	7930857

The specific methodologies used in obtaining the enclosed analytical results are indicated on the Laboratory Sample Analysis Record.

Regulatory agencies do not accredit laboratories for all methods, analytes, and matrices. Our scopes of accreditation can be viewed at http://www.eurofinsus.com/environment-testing/laboratories/eurofins-lancaster-laboratories-environmental/resources/certifications/ .

ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Chuck Stoner
ELECTRONIC COPY TO	USAPHC/AIPH	Attn: Heidi Taylor

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Analysis Report

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Respectfully Submitted,

Katherine A Klinefelter

Katherine A. Klinefelter
Principal Specialist

(717) 556-7256

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Case Narrative

Project Name: P232D1
LL Group #: 1569487

General Comments:
All analyses have been performed in accordance with DOD QSM Version 5.0 unless otherwise noted below.

See the Laboratory Sample Analysis Record section of the Analysis Report for the method references.

All QC met criteria unless otherwise noted in an Analysis Specific Comment below. Refer to the QC Summary for specific values and acceptance criteria.

Project specific QC samples are not included in this data set

Matrix QC may not be reported if site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

Surrogate recoveries (if applicable) which are outside of the QC window are confirmed unless attributed to a dilution or otherwise noted in an Analysis Specific Comment below.

The samples were received at the appropriate temperature and in accordance with the chain of custody unless otherwise noted.

Analysis Specific Comments:

EPA TO-15, Volatiles in Air

Sample #s: 7930850, 7930851, 7930852, 7930853, 7930854, 7930855, 7930856, 7930857
Reporting limits were raised due to interference from the sample matrix.

Batch #: D1518930BA (Sample number(s): 7930850-7930857)

The recovery(ies) for the following analyte(s) in the LCS and/or LCSD exceeded the acceptance window indicating a positive bias: Vinyl Acetate

v 1.9.3 7/10/2015 4:32:31PM

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770001 RedSMK_RD#6_Chamber Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7101

LL Sample # AQ 7930850
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 10:42

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D1 SDG#: IP232-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	73		5.9	24	24	5
05298	Acetonitrile	75-05-8	120		4.2	8.4	8.4	5
05298	Acrolein	107-02-8	12		5.7	5.7	5.7	5
05298	Acrylonitrile	107-13-1	11	U	5.4	11	11	5
05298	Benzene	71-43-2	8.0	U	3.2	8.0	8.0	5
05298	Benzyl Chloride	100-44-7	13	U	13	13	13	5
05298	Bromobenzene	108-86-1	16	U	6.4	16	16	5
05298	Bromodichloromethane	75-27-4	17	U	6.7	17	17	5
05298	Bromoform	75-25-2	26	U	10	26	26	5
05298	Bromomethane	74-83-9	9.7	U	3.9	9.7	9.7	5
05298	1,3-Butadiene	106-99-0	5.5	U	4.4	5.5	5.5	5
05298	2-Butanone	78-93-3	29	U	7.4	29	29	5
05298	tert-Butyl Alcohol	75-65-0	15	U	7.6	15	15	5
05298	Carbon Disulfide	75-15-0	16	U	7.8	16	16	5
05298	Carbon Tetrachloride	56-23-5	16	U	6.3	16	16	5
05298	Chlorobenzene	108-90-7	12	U	4.6	12	12	5
05298	Chlorodifluoromethane	75-45-6	8.8	U	3.5	8.8	8.8	5
05298	Chloroethane	75-00-3	6.6	U	2.6	6.6	6.6	5
05298	Chloroform	67-66-3	12	U	4.9	12	12	5
05298	Chloromethane	74-87-3	10	U	2.1	10	10	5
05298	3-Chloropropene	107-05-1	7.8	U	3.1	7.8	7.8	5
05298	Cumene	98-82-8	25	U	4.9	25	25	5
05298	Cyclohexane	110-82-7	8.6	U	3.4	8.6	8.6	5
05298	Dibromochloromethane	124-48-1	21	U	8.5	21	21	5
05298	1,2-Dibromoethane	106-93-4	19	U	7.7	19	19	5
05298	Dibromomethane	74-95-3	18	U	7.1	18	18	5
05298	1,2-Dichlorobenzene	95-50-1	15	U	6.0	15	15	5
05298	1,3-Dichlorobenzene	541-73-1	15	U	6.0	15	15	5
05298	1,4-Dichlorobenzene	106-46-7	15	U	6.0	15	15	5
05298	Dichlorodifluoromethane	75-71-8	12	U	4.9	12	12	5
05298	1,1-Dichloroethane	75-34-3	10	U	4.0	10	10	5
05298	1,2-Dichloroethane	107-06-2	10	U	4.0	10	10	5
05298	1,1-Dichloroethene	75-35-4	9.9	U	4.0	9.9	9.9	5
05298	cis-1,2-Dichloroethene	156-59-2	9.9	U	4.0	9.9	9.9	5
05298	trans-1,2-Dichloroethene	156-60-5	9.9	U	4.0	9.9	9.9	5
05298	Dichlorofluoromethane	75-43-4	11	U	4.2	11	11	5
05298	1,2-Dichloropropane	78-87-5	12	U	4.6	12	12	5
05298	cis-1,3-Dichloropropene	10061-01-5	11	U	4.5	11	11	5
05298	trans-1,3-Dichloropropene	10061-02-6	11	U	4.5	11	11	5
05298	1,4-Dioxane	123-91-1	18	U	9.0	18	18	5
05298	Ethyl Acetate	141-78-6	9.0	U	9.0	9.0	9.0	5
05298	Ethyl Acrylate	140-88-5	20	U	4.1	20	20	5
05298	Ethyl Methacrylate	97-63-2	23	U	4.7	23	23	5
05298	Ethylbenzene	100-41-4	11	U	4.3	11	11	5
05298	4-Ethyltoluene	622-96-8	12	U	4.9	12	12	5
05298	Freon 113	76-13-1	19	U	19	19	19	5
05298	Freon 114	76-14-2	17	U	7.0	17	17	5
05298	Heptane	142-82-5	10	U	4.1	10	10	5
05298	Hexachlorobutadiene	87-68-3	110	U	21	110	110	5
05298	Hexachloroethane	67-72-1	48	U	9.7	48	48	5

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770001 RedSMK_RD#6_Chamber Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7101

LL Sample # AQ 7930850
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 10:42

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D1 SDG#: IP232-01

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	8.8	U	3.5	8.8	8.8	5
05298	2-Hexanone	591-78-6	41	U	10	41	41	5
05298	Isooctane	540-84-1	23	U	4.7	23	23	5
05298	Isopropanol	67-63-0	12	U	6.1	12	12	5
05298	Methyl Acrylate	96-33-3	18	U	3.5	18	18	5
05298	Methyl Iodide	74-88-4	15	U	5.8	15	15	5
05298	Methyl Methacrylate	80-62-6	20	U	4.1	20	20	5
05298	Alpha Methyl Styrene	98-83-9	24	U	4.8	24	24	5
05298	Methyl t-Butyl Ether	1634-04-4	9.0	U	3.6	9.0	9.0	5
05298	4-Methyl-2-pentanone	108-10-1	41	U	10	41	41	5
05298	Methylene Chloride	75-09-2	8.8	J	3.5	17	17	5
05298	Octane	111-65-9	23	U	4.7	23	23	5
05298	Propene	115-07-1	2.2	J	1.7	8.6	8.6	5
05298	Styrene	100-42-5	11	U	4.3	11	11	5
05298	1,1,1,2-Tetrachloroethane	630-20-6	17	U	6.9	17	17	5
05298	1,1,2,2-Tetrachloroethane	79-34-5	17	U	6.9	17	17	5
05298	Tetrachloroethene	127-18-4	17	U	6.8	17	17	5
05298	Tetrahydrofuran	109-99-9	7.4	U	2.9	7.4	7.4	5
05298	Toluene	108-88-3	9.4	U	3.8	9.4	9.4	5
05298	1,2,4-Trichlorobenzene	120-82-1	74	U	19	74	74	5
05298	1,1,1-Trichloroethane	71-55-6	14	U	5.5	14	14	5
05298	1,1,2-Trichloroethane	79-00-5	14	U	5.5	14	14	5
05298	Trichloroethene	79-01-6	13	U	5.4	13	13	5
05298	Trichlorofluoromethane	75-69-4	14	U	5.6	14	14	5
05298	1,2,3-Trichloropropane	96-18-4	15	U	6.0	15	15	5
05298	1,2,4-Trimethylbenzene	95-63-6	12	U	4.9	12	12	5
05298	1,3,5-Trimethylbenzene	108-67-8	12	U	4.9	12	12	5
05298	Vinyl Acetate	108-05-4	18	U	8.8	18	18	5
05298	Vinyl Chloride	75-01-4	6.4	U	2.6	6.4	6.4	5
05298	m/p-Xylene	179601-23-1	5.5	J	4.3	22	22	5
05298	o-Xylene	95-47-6	11	U	4.3	11	11	5

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 02:26	Jacob E Bailey	5

*-This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770002 RedSMK_RD#6_High Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7096

LL Sample # AQ 7930851
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 12:08

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D2 SDG#: IP232-02

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	9,900		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	950		84	170	170	100
05298	Acrolein	107-02-8	5,800		570	570	570	500
05298	Acrylonitrile	107-13-1	33		11	22	22	10
05298	Benzene	71-43-2	380		6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	47		8.8	11	11	10
05298	2-Butanone	78-93-3	1,300		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	13	U	5.3	13	13	10
05298	Chloroform	67-66-3	55		9.8	24	24	10
05298	Chloromethane	74-87-3	210		4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	170		8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	20	U	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770002 RedSMK_RD#6_High Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7096

LL Sample # AQ 7930851
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 12:08

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D2 SDG#: IP232-02

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	13	J	7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	19	J	12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	41		6.9	35	35	10
05298	Octane	111-65-9	11	J	9.3	47	47	10
05298	Propene	115-07-1	3,900		34	170	170	100
05298	Styrene	100-42-5	9.8	J	8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	160		7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	10	J	5.1	13	13	10
05298	m/p-Xylene	179601-23-1	550		8.7	43	43	10
05298	o-Xylene	95-47-6	98		8.7	22	22	10

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 19:37	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 20:25	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BB	07/09/2015 18:09	Jacob E Bailey	500

*=This limit was used in the evaluation of the final result

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Report ID: 13177
Report Serial #: 76326

CERTIFICATE OF ANALYSIS

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7/14/2015 11:46:30 AM
AR3100 [2015.03.19a]

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770003 RedSMK_RD#6_Med Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7103

LL Sample # AQ 7930852
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 12:55

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D3 SDG#: IP232-03

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	9,500		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	970		84	170	170	100
05298	Acrolein	107-02-8	5,400		570	570	570	500
05298	Acrylonitrile	107-13-1	40		11	22	22	10
05298	Benzene	71-43-2	450		6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	93		8.8	11	11	10
05298	2-Butanone	78-93-3	1,200		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	13	U	5.3	13	13	10
05298	Chloroform	67-66-3	65		9.8	24	24	10
05298	Chloromethane	74-87-3	180		4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	200		8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	9.1	J	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

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Analysis Report

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Sample Description: 131770003 RedSMK_RD#6_Med Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7103

LL Sample # AQ 7930852
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 12:55

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D3 SDG#: IP232-03

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	14	J	7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	21	J	12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	49		6.9	35	35	10
05298	Octane	111-65-9	47	U	9.3	47	47	10
05298	Propene	115-07-1	3,900		34	170	170	100
05298	Styrene	100-42-5	17	J	8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	190		7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	9.1	J	5.1	13	13	10
05298	m/p-Xylene	179601-23-1	650		8.7	43	43	10
05298	o-Xylene	95-47-6	110		8.7	22	22	10

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 21:09	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 21:57	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 09:12	Jacob E Bailey	500

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770004 RedSMK_RD#6_Low Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7091

LL Sample # AQ 7930853
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 13:57

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D4 SDG#: IP232-04

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	4,700		120	480	480	100
05298	Acetonitrile	75-05-8	200		8.4	17	17	10
05298	Acrolein	107-02-8	2,800		110	110	110	100
05298	Acrylonitrile	107-13-1	22	U	11	22	22	10
05298	Benzene	71-43-2	130		6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	110		8.8	11	11	10
05298	2-Butanone	78-93-3	290		15	59	59	10
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	13	U	5.3	13	13	10
05298	Chloroform	67-66-3	20	J	9.8	24	24	10
05298	Chloromethane	74-87-3	70		4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	54		8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	20	U	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770004 RedSMK_RD#6_Low Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7091

LL Sample # AQ 7930853
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/09/2015 13:57

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D4 SDG#: IP232-04

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	18	U	7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	25	U	12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	22	J	6.9	35	35	10
05298	Octane	111-65-9	47	U	9.3	47	47	10
05298	Propene	115-07-1	1,300		34	170	170	100
05298	Styrene	100-42-5	21	U	8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	55		7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	13	U	5.1	13	13	10
05298	m/p-Xylene	179601-23-1	180		8.7	43	43	10
05298	o-Xylene	95-47-6	36		8.7	22	22	10

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 22:40	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 09:53	Jacob E Bailey	100

*-This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770005 RedSMK_RD#10_ChamberBK Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7100

LL Sample # AQ 7930854
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 10:12

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D5 SDG#: IP232-05

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air EPA TO-15			ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	51		12	48	48	10
05298	Acetonitrile	75-05-8	880		42	84	84	50
05298	Acrolein	107-02-8	11	U	11	11	11	10
05298	Acrylonitrile	107-13-1	22	U	11	22	22	10
05298	Benzene	71-43-2	16	U	6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	11	U	8.8	11	11	10
05298	2-Butanone	78-93-3	59	U	15	59	59	10
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	13	U	5.3	13	13	10
05298	Chloroform	67-66-3	24	U	9.8	24	24	10
05298	Chloromethane	74-87-3	21	U	4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	22	U	8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	20	U	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

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Report ID: 13177
Report Serial #: 76326

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770005 RedSMK_RD#10_ChamberBK Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7100

LL Sample # AQ 7930854
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 10:12

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D5 SDG#: IP232-05

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	18	U	7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	25	U	12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	15	J	6.9	35	35	10
05298	Octane	111-65-9	47	U	9.3	47	47	10
05298	Propene	115-07-1	17	U	3.4	17	17	10
05298	Styrene	100-42-5	21	U	8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	19	U	7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	13	U	5.1	13	13	10
05298	m/p-Xylene	179601-23-1	43	U	8.7	43	43	10
05298	o-Xylene	95-47-6	22	U	8.7	22	22	10

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/08/2015 23:24	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BB	07/09/2015 19:05	Jacob E Bailey	50

*=This limit was used in the evaluation of the final result

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Report ID: 13177
Report Serial #: 76326

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a]

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770006 RedSMK_RD#10_High Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7108

LL Sample # AQ 7930855
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 11:07

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D6 SDG#: IP232-06

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air EPA TO-15			ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	13,000		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	3,200		84	170	170	100
05298	Acrolein	107-02-8	7,900		570	570	570	500
05298	Acrylonitrile	107-13-1	220	U	110	220	220	100
05298	Benzene	71-43-2	930		64	160	160	100
05298	Benzyl Chloride	100-44-7	260	U	260	260	260	100
05298	Bromobenzene	108-86-1	320	U	130	320	320	100
05298	Bromodichloromethane	75-27-4	340	U	130	340	340	100
05298	Bromoform	75-25-2	520	U	210	520	520	100
05298	Bromomethane	74-83-9	190	U	78	190	190	100
05298	1,3-Butadiene	106-99-0	100	J	88	110	110	100
05298	2-Butanone	78-93-3	1,700		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	300	U	150	300	300	100
05298	Carbon Disulfide	75-15-0	310	U	160	310	310	100
05298	Carbon Tetrachloride	56-23-5	310	U	130	310	310	100
05298	Chlorobenzene	108-90-7	230	U	92	230	230	100
05298	Chlorodifluoromethane	75-45-6	180	U	71	180	180	100
05298	Chloroethane	75-00-3	130	U	53	130	130	100
05298	Chloroform	67-66-3	240	U	98	240	240	100
05298	Chloromethane	74-87-3	230		41	210	210	100
05298	3-Chloropropene	107-05-1	160	U	63	160	160	100
05298	Cumene	98-82-8	490	U	98	490	490	100
05298	Cyclohexane	110-82-7	170	U	69	170	170	100
05298	Dibromochloromethane	124-48-1	430	U	170	430	430	100
05298	1,2-Dibromoethane	106-93-4	380	U	150	380	380	100
05298	Dibromomethane	74-95-3	360	U	140	360	360	100
05298	1,2-Dichlorobenzene	95-50-1	300	U	120	300	300	100
05298	1,3-Dichlorobenzene	541-73-1	300	U	120	300	300	100
05298	1,4-Dichlorobenzene	106-46-7	300	U	120	300	300	100
05298	Dichlorodifluoromethane	75-71-8	250	U	99	250	250	100
05298	1,1-Dichloroethane	75-34-3	200	U	81	200	200	100
05298	1,2-Dichloroethane	107-06-2	200	U	81	200	200	100
05298	1,1-Dichloroethene	75-35-4	200	U	79	200	200	100
05298	cis-1,2-Dichloroethene	156-59-2	200	U	79	200	200	100
05298	trans-1,2-Dichloroethene	156-60-5	200	U	79	200	200	100
05298	Dichlorofluoromethane	75-43-4	210	U	84	210	210	100
05298	1,2-Dichloropropane	78-87-5	230	U	92	230	230	100
05298	cis-1,3-Dichloropropene	10061-01-5	230	U	91	230	230	100
05298	trans-1,3-Dichloropropene	10061-02-6	230	U	91	230	230	100
05298	1,4-Dioxane	123-91-1	360	U	180	360	360	100
05298	Ethyl Acetate	141-78-6	180	U	180	180	180	100
05298	Ethyl Acrylate	140-88-5	410	U	82	410	410	100
05298	Ethyl Methacrylate	97-63-2	470	U	93	470	470	100
05298	Ethylbenzene	100-41-4	300		87	220	220	100
05298	4-Ethyltoluene	622-96-8	250	U	98	250	250	100
05298	Freon 113	76-13-1	380	U	380	380	380	100
05298	Freon 114	76-14-2	350	U	140	350	350	100
05298	Heptane	142-82-5	200	U	82	200	200	100
05298	Hexachlorobutadiene	87-68-3	2,100	U	430	2,100	2,100	100
05298	Hexachloroethane	67-72-1	970	U	190	970	970	100

*=This limit was used in the evaluation of the final result

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Report ID: 13177
Report Serial #: 76326

CERTIFICATE OF ANALYSIS

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AR3100 [2015.03.19a.]

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770006 RedSMK_RD#10_High Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7108

LL Sample # AQ 7930855
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 11:07

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D6 SDG#: IP232-06

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	180	U	70	180	180	100
05298	2-Hexanone	591-78-6	820	U	200	820	820	100
05298	Isooctane	540-84-1	470	U	93	470	470	100
05298	Isopropanol	67-63-0	850		120	250	250	100
05298	Methyl Acrylate	96-33-3	350	U	70	350	350	100
05298	Methyl Iodide	74-88-4	290	U	120	290	290	100
05298	Methyl Methacrylate	80-62-6	410	U	82	410	410	100
05298	Alpha Methyl Styrene	98-83-9	480	U	97	480	480	100
05298	Methyl t-Butyl Ether	1634-04-4	180	U	72	180	180	100
05298	4-Methyl-2-pentanone	108-10-1	820	U	200	820	820	100
05298	Methylene Chloride	75-09-2	550		69	350	350	100
05298	Octane	111-65-9	110	J	93	470	470	100
05298	Propene	115-07-1	6,900		170	860	860	500
05298	Styrene	100-42-5	110	J	85	210	210	100
05298	1,1,1,2-Tetrachloroethane	630-20-6	340	U	140	340	340	100
05298	1,1,2,2-Tetrachloroethane	79-34-5	340	U	140	340	340	100
05298	Tetrachloroethene	127-18-4	340	U	140	340	340	100
05298	Tetrahydrofuran	109-99-9	150	U	59	150	150	100
05298	Toluene	108-88-3	710		75	190	190	100
05298	1,2,4-Trichlorobenzene	120-82-1	1,500	U	370	1,500	1,500	100
05298	1,1,1-Trichloroethane	71-55-6	270	U	110	270	270	100
05298	1,1,2-Trichloroethane	79-00-5	270	U	110	270	270	100
05298	Trichloroethene	79-01-6	270	U	110	270	270	100
05298	Trichlorofluoromethane	75-69-4	280	U	110	280	280	100
05298	1,2,3-Trichloropropane	96-18-4	300	U	120	300	300	100
05298	1,2,4-Trimethylbenzene	95-63-6	220	J	98	250	250	100
05298	1,3,5-Trimethylbenzene	108-67-8	250	U	98	250	250	100
05298	Vinyl Acetate	108-05-4	350	U	180	350	350	100
05298	Vinyl Chloride	75-01-4	130	U	51	130	130	100
05298	m/p-Xylene	179601-23-1	1,000		87	430	430	100
05298	o-Xylene	95-47-6	270		87	220	220	100

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 00:12	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 11:24	Jacob E Bailey	500

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770007 RedSMK_RD#10_Med Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7113

LL Sample # AQ 7930856
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 12:27

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D7 SDG#: IP232-07

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	13,000		590	2,400	2,400	500
05298	Acetonitrile	75-05-8	1,000		84	170	170	100
05298	Acrolein	107-02-8	7,000		570	570	570	500
05298	Acrylonitrile	107-13-1	220	U	110	220	220	100
05298	Benzene	71-43-2	760		64	160	160	100
05298	Benzyl Chloride	100-44-7	260	U	260	260	260	100
05298	Bromobenzene	108-86-1	320	U	130	320	320	100
05298	Bromodichloromethane	75-27-4	340	U	130	340	340	100
05298	Bromoform	75-25-2	520	U	210	520	520	100
05298	Bromomethane	74-83-9	190	U	78	190	190	100
05298	1,3-Butadiene	106-99-0	110	U	88	110	110	100
05298	2-Butanone	78-93-3	1,300		150	590	590	100
05298	tert-Butyl Alcohol	75-65-0	300	U	150	300	300	100
05298	Carbon Disulfide	75-15-0	310	U	160	310	310	100
05298	Carbon Tetrachloride	56-23-5	310	U	130	310	310	100
05298	Chlorobenzene	108-90-7	230	U	92	230	230	100
05298	Chlorodifluoromethane	75-45-6	180	U	71	180	180	100
05298	Chloroethane	75-00-3	130	U	53	130	130	100
05298	Chloroform	67-66-3	240	U	98	240	240	100
05298	Chloromethane	74-87-3	200	J	41	210	210	100
05298	3-Chloropropene	107-05-1	160	U	63	160	160	100
05298	Cumene	98-82-8	490	U	98	490	490	100
05298	Cyclohexane	110-82-7	170	U	69	170	170	100
05298	Dibromochloromethane	124-48-1	430	U	170	430	430	100
05298	1,2-Dibromoethane	106-93-4	380	U	150	380	380	100
05298	Dibromomethane	74-95-3	360	U	140	360	360	100
05298	1,2-Dichlorobenzene	95-50-1	300	U	120	300	300	100
05298	1,3-Dichlorobenzene	541-73-1	300	U	120	300	300	100
05298	1,4-Dichlorobenzene	106-46-7	300	U	120	300	300	100
05298	Dichlorodifluoromethane	75-71-8	250	U	99	250	250	100
05298	1,1-Dichloroethane	75-34-3	200	U	81	200	200	100
05298	1,2-Dichloroethane	107-06-2	200	U	81	200	200	100
05298	1,1-Dichloroethene	75-35-4	200	U	79	200	200	100
05298	cis-1,2-Dichloroethene	156-59-2	200	U	79	200	200	100
05298	trans-1,2-Dichloroethene	156-60-5	200	U	79	200	200	100
05298	Dichlorofluoromethane	75-43-4	210	U	84	210	210	100
05298	1,2-Dichloropropane	78-87-5	230	U	92	230	230	100
05298	cis-1,3-Dichloropropene	10061-01-5	230	U	91	230	230	100
05298	trans-1,3-Dichloropropene	10061-02-6	230	U	91	230	230	100
05298	1,4-Dioxane	123-91-1	360	U	180	360	360	100
05298	Ethyl Acetate	141-78-6	180	U	180	180	180	100
05298	Ethyl Acrylate	140-88-5	410	U	82	410	410	100
05298	Ethyl Methacrylate	97-63-2	470	U	93	470	470	100
05298	Ethylbenzene	100-41-4	250		87	220	220	100
05298	4-Ethyltoluene	622-96-8	250	U	98	250	250	100
05298	Freon 113	76-13-1	380	U	380	380	380	100
05298	Freon 114	76-14-2	350	U	140	350	350	100
05298	Heptane	142-82-5	200	U	82	200	200	100
05298	Hexachlorobutadiene	87-68-3	2,100	U	430	2,100	2,100	100
05298	Hexachloroethane	67-72-1	970	U	190	970	970	100

*=This limit was used in the evaluation of the final result

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Report ID: 13177
Report Serial #: 76326

CERTIFICATE OF ANALYSIS

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7/14/2015 11:46:30 AM
AR3100 [2015.03.19a]

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770007 RedSMK_RD#10_Med Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 7113

LL Sample # AQ 7930856
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 12:27

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D7 SDG#: IP232-07

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	180	U	70	180	180	100
05298	2-Hexanone	591-78-6	820	U	200	820	820	100
05298	Isooctane	540-84-1	470	U	93	470	470	100
05298	Isopropanol	67-63-0	970		120	250	250	100
05298	Methyl Acrylate	96-33-3	350	U	70	350	350	100
05298	Methyl Iodide	74-88-4	290	U	120	290	290	100
05298	Methyl Methacrylate	80-62-6	410	U	82	410	410	100
05298	Alpha Methyl Styrene	98-83-9	480	U	97	480	480	100
05298	Methyl t-Butyl Ether	1634-04-4	180	U	72	180	180	100
05298	4-Methyl-2-pentanone	108-10-1	820	U	200	820	820	100
05298	Methylene Chloride	75-09-2	570		69	350	350	100
05298	Octane	111-65-9	470	U	93	470	470	100
05298	Propene	115-07-1	1,200		34	170	170	100
05298	Styrene	100-42-5	120	J	85	210	210	100
05298	1,1,1,2-Tetrachloroethane	630-20-6	340	U	140	340	340	100
05298	1,1,2,2-Tetrachloroethane	79-34-5	340	U	140	340	340	100
05298	Tetrachloroethene	127-18-4	340	U	140	340	340	100
05298	Tetrahydrofuran	109-99-9	150	U	59	150	150	100
05298	Toluene	108-88-3	670		75	190	190	100
05298	1,2,4-Trichlorobenzene	120-82-1	1,500	U	370	1,500	1,500	100
05298	1,1,1-Trichloroethane	71-55-6	270	U	110	270	270	100
05298	1,1,2-Trichloroethane	79-00-5	270	U	110	270	270	100
05298	Trichloroethene	79-01-6	270	U	110	270	270	100
05298	Trichlorofluoromethane	75-69-4	280	U	110	280	280	100
05298	1,2,3-Trichloropropane	96-18-4	300	U	120	300	300	100
05298	1,2,4-Trimethylbenzene	95-63-6	230	J	98	250	250	100
05298	1,3,5-Trimethylbenzene	108-67-8	250	U	98	250	250	100
05298	Vinyl Acetate	108-05-4	350	U	180	350	350	100
05298	Vinyl Chloride	75-01-4	130	U	51	130	130	100
05298	m/p-Xylene	179601-23-1	800		87	430	430	100
05298	o-Xylene	95-47-6	240		87	220	220	100

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 01:00	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 12:07	Jacob E Bailey	500

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770008 RedSMK_RD#10_Low Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 6489

LL Sample # AQ 7930857
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 13:27

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D8 SDG#: IP232-08

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air	**EPA TO-15**		ug/m3		ug/m3	ug/m3	ug/m3	
05298	Acetone	67-64-1	6,000		300	1,200	1,200	250
05298	Acetonitrile	75-05-8	320		8.4	17	17	10
05298	Acrolein	107-02-8	3,500		110	110	110	100
05298	Acrylonitrile	107-13-1	14	J	11	22	22	10
05298	Benzene	71-43-2	200		6.4	16	16	10
05298	Benzyl Chloride	100-44-7	26	U	26	26	26	10
05298	Bromobenzene	108-86-1	32	U	13	32	32	10
05298	Bromodichloromethane	75-27-4	34	U	13	34	34	10
05298	Bromoform	75-25-2	52	U	21	52	52	10
05298	Bromomethane	74-83-9	19	U	7.8	19	19	10
05298	1,3-Butadiene	106-99-0	80		8.8	11	11	10
05298	2-Butanone	78-93-3	370		15	59	59	10
05298	tert-Butyl Alcohol	75-65-0	30	U	15	30	30	10
05298	Carbon Disulfide	75-15-0	31	U	16	31	31	10
05298	Carbon Tetrachloride	56-23-5	31	U	13	31	31	10
05298	Chlorobenzene	108-90-7	23	U	9.2	23	23	10
05298	Chlorodifluoromethane	75-45-6	18	U	7.1	18	18	10
05298	Chloroethane	75-00-3	13	U	5.3	13	13	10
05298	Chloroform	67-66-3	17	J	9.8	24	24	10
05298	Chloromethane	74-87-3	62		4.1	21	21	10
05298	3-Chloropropene	107-05-1	16	U	6.3	16	16	10
05298	Cumene	98-82-8	49	U	9.8	49	49	10
05298	Cyclohexane	110-82-7	17	U	6.9	17	17	10
05298	Dibromochloromethane	124-48-1	43	U	17	43	43	10
05298	1,2-Dibromoethane	106-93-4	38	U	15	38	38	10
05298	Dibromomethane	74-95-3	36	U	14	36	36	10
05298	1,2-Dichlorobenzene	95-50-1	30	U	12	30	30	10
05298	1,3-Dichlorobenzene	541-73-1	30	U	12	30	30	10
05298	1,4-Dichlorobenzene	106-46-7	30	U	12	30	30	10
05298	Dichlorodifluoromethane	75-71-8	25	U	9.9	25	25	10
05298	1,1-Dichloroethane	75-34-3	20	U	8.1	20	20	10
05298	1,2-Dichloroethane	107-06-2	20	U	8.1	20	20	10
05298	1,1-Dichloroethene	75-35-4	20	U	7.9	20	20	10
05298	cis-1,2-Dichloroethene	156-59-2	20	U	7.9	20	20	10
05298	trans-1,2-Dichloroethene	156-60-5	20	U	7.9	20	20	10
05298	Dichlorofluoromethane	75-43-4	21	U	8.4	21	21	10
05298	1,2-Dichloropropane	78-87-5	23	U	9.2	23	23	10
05298	cis-1,3-Dichloropropene	10061-01-5	23	U	9.1	23	23	10
05298	trans-1,3-Dichloropropene	10061-02-6	23	U	9.1	23	23	10
05298	1,4-Dioxane	123-91-1	36	U	18	36	36	10
05298	Ethyl Acetate	141-78-6	18	U	18	18	18	10
05298	Ethyl Acrylate	140-88-5	41	U	8.2	41	41	10
05298	Ethyl Methacrylate	97-63-2	47	U	9.3	47	47	10
05298	Ethylbenzene	100-41-4	56		8.7	22	22	10
05298	4-Ethyltoluene	622-96-8	25	U	9.8	25	25	10
05298	Freon 113	76-13-1	38	U	38	38	38	10
05298	Freon 114	76-14-2	35	U	14	35	35	10
05298	Heptane	142-82-5	20	U	8.2	20	20	10
05298	Hexachlorobutadiene	87-68-3	210	U	43	210	210	10
05298	Hexachloroethane	67-72-1	97	U	19	97	97	10

*=This limit was used in the evaluation of the final result

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Analysis Report

2425 New Holland Pike, Lancaster, PA 17601 • 717-656-2300 • Fax: 717-656-2681 • www.LancasterLabs.com

Sample Description: 131770008 RedSMK_RD#10_Low Air
13177 / RED SMOKE INHALATION
P232D1 Summa Can # 6489

LL Sample # AQ 7930857
LL Group # 1569487
Account # 04694

Project Name: P232D1

Collected: 06/15/2015 13:27

Submitted: 06/16/2015 17:00
Reported: 07/10/2015 16:31

USAPHC/AIPH
DFAS-IN VP GFEBS - HQ0490
8899 E 56TH ST
Indianapolis IN 46249-3800

232D8 SDG#: IP232-08

CAT No.	Analysis Name	CAS Number	Result		Detection Limit*	Limit of Detection	Limit of Quantitation	DF
Volatiles in Air EPA TO-15			ug/m3		ug/m3	ug/m3	ug/m3	
05298	Hexane	110-54-3	18	U	7.0	18	18	10
05298	2-Hexanone	591-78-6	82	U	20	82	82	10
05298	Isooctane	540-84-1	47	U	9.3	47	47	10
05298	Isopropanol	67-63-0	25	U	12	25	25	10
05298	Methyl Acrylate	96-33-3	35	U	7.0	35	35	10
05298	Methyl Iodide	74-88-4	29	U	12	29	29	10
05298	Methyl Methacrylate	80-62-6	41	U	8.2	41	41	10
05298	Alpha Methyl Styrene	98-83-9	48	U	9.7	48	48	10
05298	Methyl t-Butyl Ether	1634-04-4	18	U	7.2	18	18	10
05298	4-Methyl-2-pentanone	108-10-1	82	U	20	82	82	10
05298	Methylene Chloride	75-09-2	27	J	6.9	35	35	10
05298	Octane	111-65-9	47	U	9.3	47	47	10
05298	Propene	115-07-1	2,500		34	170	170	100
05298	Styrene	100-42-5	9.5	J	8.5	21	21	10
05298	1,1,1,2-Tetrachloroethane	630-20-6	34	U	14	34	34	10
05298	1,1,2,2-Tetrachloroethane	79-34-5	34	U	14	34	34	10
05298	Tetrachloroethene	127-18-4	34	U	14	34	34	10
05298	Tetrahydrofuran	109-99-9	15	U	5.9	15	15	10
05298	Toluene	108-88-3	90		7.5	19	19	10
05298	1,2,4-Trichlorobenzene	120-82-1	150	U	37	150	150	10
05298	1,1,1-Trichloroethane	71-55-6	27	U	11	27	27	10
05298	1,1,2-Trichloroethane	79-00-5	27	U	11	27	27	10
05298	Trichloroethene	79-01-6	27	U	11	27	27	10
05298	Trichlorofluoromethane	75-69-4	28	U	11	28	28	10
05298	1,2,3-Trichloropropane	96-18-4	30	U	12	30	30	10
05298	1,2,4-Trimethylbenzene	95-63-6	25	U	9.8	25	25	10
05298	1,3,5-Trimethylbenzene	108-67-8	25	U	9.8	25	25	10
05298	Vinyl Acetate	108-05-4	35	U	18	35	35	10
05298	Vinyl Chloride	75-01-4	13	U	5.1	13	13	10
05298	m/p-Xylene	179601-23-1	190		8.7	43	43	10
05298	o-Xylene	95-47-6	40		8.7	22	22	10

Reporting limits were raised due to interference from the sample matrix.

General Sample Comments

All QC is compliant unless otherwise noted. Please refer to the Quality Control Summary for overall QC performance data and associated samples.

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BA	07/09/2015 01:43	Jacob E Bailey	10
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BB	07/09/2015 19:52	Jacob E Bailey	100
05298	TO 15 VOA Ext. List	EPA TO-15	1	D1518930BB	07/10/2015 11:10	Jacob E Bailey	250

*=This limit was used in the evaluation of the final result

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH Group Number: 1569487
Reported: 07/10/2015 16:31

Matrix QC may not be reported if insufficient sample or site-specific QC samples were not submitted. In these situations, to demonstrate precision and accuracy at a batch level, a LCS/LCSD was performed, unless otherwise specified in the method.

All Inorganic Initial Calibration and Continuing Calibration Blanks met acceptable method criteria unless otherwise noted on the Analysis Report.

Laboratory Compliance Quality Control

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Batch number: D1518930BA	Sample number(s): 7930850-7930857									
Acetone	2.4 U	1.2	2.4	2.4	ug/m3	91	82	58-128	10	25
Acetonitrile	1.7 U	0.84	1.7	1.7	ug/m3					
Acrolein	1.1 U	1.1	1.1	1.1	ug/m3	122	108	62-126	12	25
Acrylonitrile	2.2 U	1.1	2.2	2.2	ug/m3					
Benzene	1.6 U	0.64	1.6	1.6	ug/m3	91	85	69-119	7	25
Benzyl Chloride	2.6 U	2.6	2.6	2.6	ug/m3	114	101	50-147	13	25
Bromobenzene	3.2 U	1.3	3.2	3.2	ug/m3					
Bromodichloromethane	3.4 U	1.3	3.4	3.4	ug/m3	90	83	72-128	8	25
Bromoform	5.2 U	2.1	5.2	5.2	ug/m3	96	85	66-139	13	25
Bromomethane	1.9 U	0.78	1.9	1.9	ug/m3	86	82	63-134	4	25
1,3-Butadiene	1.1 U	0.44	1.1	1.1	ug/m3	87	83	66-134	4	25
2-Butanone	2.9 U	1.5	2.9	2.9	ug/m3	95	82	67-130	15	25
tert-Butyl Alcohol	3.0 U	1.5	3.0	3.0	ug/m3					
Carbon Disulfide	3.1 U	1.6	3.1	3.1	ug/m3	81	81	57-134	1	25
Carbon Tetrachloride	3.1 U	1.3	3.1	3.1	ug/m3	97	92	68-132	4	25
Chlorobenzene	2.3 U	0.92	2.3	2.3	ug/m3	86	77	70-119	11	25
Chlorodifluoromethane	1.8 U	0.71	1.8	1.8	ug/m3					
Chloroethane	1.3 U	0.53	1.3	1.3	ug/m3	85	79	63-127	7	25
Chloroform	2.4 U	0.98	2.4	2.4	ug/m3	92	86	68-123	7	25
Chloromethane	2.1 U	0.41	2.1	2.1	ug/m3	69	63	59-132	8	25
3-Chloropropene	1.6 U	0.63	1.6	1.6	ug/m3					

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH Group Number: 1569487
Reported: 07/10/2015 16:31

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Cumene	4.9 U	0.98	4.9	4.9	ug/m3					
Cyclohexane	1.7 U	0.69	1.7	1.7	ug/m3	90	87	70-117	4	25
Dibromochloromethane	4.3 U	1.7	4.3	4.3	ug/m3	93	83	70-130	11	25
1,2-Dibromoethane	3.8 U	1.5	3.8	3.8	ug/m3	95	83	74-122	14	25
Dibromomethane	3.6 U	1.4	3.6	3.6	ug/m3					
1,2-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	85	78	63-129	8	25
1,3-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	82	76	65-130	7	25
1,4-Dichlorobenzene	3.0 U	1.2	3.0	3.0	ug/m3	84	77	60-131	9	25
Dichlorodifluoromethane	2.5 U	0.99	2.5	2.5	ug/m3	90	81	59-128	11	25
1,1-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	89	83	68-126	6	25
1,2-Dichloroethane	2.0 U	0.81	2.0	2.0	ug/m3	95	88	65-128	7	25
1,1-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	88	86	61-133	3	25
cis-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	89	85	70-121	4	25
trans-1,2-Dichloroethene	2.0 U	0.79	2.0	2.0	ug/m3	87	85	67-124	2	25
Dichlorofluoromethane	2.1 U	0.84	2.1	2.1	ug/m3					
1,2-Dichloropropane	2.3 U	0.92	2.3	2.3	ug/m3	85	80	69-123	7	25
cis-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	118	107	70-128	10	25
trans-1,3-Dichloropropene	2.3 U	0.91	2.3	2.3	ug/m3	103	89	75-133	14	25
1,4-Dioxane	3.6 U	1.8	3.6	3.6	ug/m3	94	80	71-122	15	25
Ethyl Acetate	1.8 U	0.72	1.8	1.8	ug/m3	78	66	65-128	16	25
Ethyl Acrylate	4.1 U	2.0	4.1	4.1	ug/m3					
Ethyl Methacrylate	4.7 U	2.3	4.7	4.7	ug/m3					
Ethylbenzene	2.2 U	0.87	2.2	2.2	ug/m3	95	83	70-124	13	25
4-Ethyltoluene	2.5 U	0.98	2.5	2.5	ug/m3	98	83	67-129	17	25
Freon 113	3.8 U	1.5	3.8	3.8	ug/m3	87	84	66-126	3	25
Freon 114	3.5 U	1.4	3.5	3.5	ug/m3	84	80	63-121	5	25
Heptane	2.0 U	0.82	2.0	2.0	ug/m3	90	85	69-123	6	25
Hexachlorobutadiene	11	5.3	11	11	ug/m3	81	65	56-138	22	25

*- Outside of specification
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(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

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Reported: 07/10/2015 16:31

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
Hexachloroethane	9.7 U	4.8	9.7	9.7	ug/m3					
Hexane	1.8 U	0.70	1.8	1.8	ug/m3	90	86	63-120	4	25
2-Hexanone	4.1 U	2.0	4.1	4.1	ug/m3	87	76	62-128	14	25
Isooctane	4.7 U	2.3	4.7	4.7	ug/m3					
Isopropanol	2.5 U	1.2	2.5	2.5	ug/m3	82	77	52-125	7	25
Methyl Acrylate	3.5 U	1.8	3.5	3.5	ug/m3					
Methyl Iodide	2.9 U	1.2	2.9	2.9	ug/m3					
Methyl Methacrylate	4.1 U	2.0	4.1	4.1	ug/m3	96	82	70-128	15	25
Alpha Methyl Styrene	4.8 U	0.97	4.8	4.8	ug/m3					
Methyl t-Butyl Ether	1.8 U	0.72	1.8	1.8	ug/m3	93	87	66-126	7	25
4-Methyl-2-pentanone	4.1 U	2.0	4.1	4.1	ug/m3	84	75	67-130	11	25
Methylene Chloride	3.5 U	1.7	3.5	3.5	ug/m3	90	87	62-115	4	25
Octane	4.7 U	2.3	4.7	4.7	ug/m3					
Propene	1.7 U	0.86	1.7	1.7	ug/m3	76	67	57-136	12	25
Styrene	2.1 U	0.85	2.1	2.1	ug/m3	100	86	73-127	15	25
1,1,1,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3					
1,1,2,2-Tetrachloroethane	3.4 U	1.4	3.4	3.4	ug/m3	90	77	65-127	16	25
Tetrachloroethene	3.4 U	1.4	3.4	3.4	ug/m3	82	75	66-124	9	25
Tetrahydrofuran	1.5 U	0.59	1.5	1.5	ug/m3	96	84	64-123	13	25
Toluene	1.9 U	0.75	1.9	1.9	ug/m3	91	83	66-119	10	25
1,2,4-Trichlorobenzene	7.4 U	3.7	7.4	7.4	ug/m3	70	58	55-142	18	25
1,1,1-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	93	88	68-125	5	25
1,1,2-Trichloroethane	2.7 U	1.1	2.7	2.7	ug/m3	86	77	73-119	11	25
Trichloroethene	2.7 U	1.1	2.7	2.7	ug/m3	90	82	71-123	9	25
Trichlorofluoromethane	2.8 U	1.1	2.8	2.8	ug/m3	91	87	62-126	4	25
1,2,3-Trichloropropane	3.0 U	1.2	3.0	3.0	ug/m3					
1,2,4-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	85	79	66-132	7	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Analysis Report

Quality Control Summary

Client Name: USAPHC/AIPH
Group Number: 1569487
Reported: 07/10/2015 16:31

Analysis Name	Blank Result	Blank DL**	Blank LOD	Blank LOQ	Report Units	LCS %REC	LCSD %REC	LCS/LCSD Limits	RPD	RPD Max
1,3,5-Trimethylbenzene	2.5 U	0.98	2.5	2.5	ug/m3	99	84	67-130	17	25
Vinyl Acetate	3.5 U	1.8	3.5	3.5	ug/m3	140*	123	56-139	13	25
Vinyl Chloride	1.3 U	0.51	1.3	1.3	ug/m3	87	83	64-127	4	25
m/p-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	94	82	61-134	14	25
o-Xylene	2.2 U	0.87	2.2	2.2	ug/m3	104	90	67-125	14	25
Batch number: D1518930BB	Sample number(s): 7930851,7930854,7930857									
Acetone	2.4 U	1.2	2.4	2.4	ug/m3	91	82	58-128	10	25
Acetonitrile	1.7 U	0.84	1.7	1.7	ug/m3					
Acrolein	1.1 U	1.1	1.1	1.1	ug/m3	122	108	62-126	12	25
Propene	1.7 U	0.86	1.7	1.7	ug/m3	76	67	57-136	12	25

*- Outside of specification
**-This limit was used in the evaluation of the final result for the blank
(1) The result for one or both determinations was less than five times the LOQ.
(2) The unspiked result was more than four times the spike added.
(3) The surrogate spike amount was less than the LOD.

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP232

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

Sample #	Client ID	DF	Comments
7930850	131770001	5	
7930851	131770002	10; 100; 500	
7930852	131770003	10; 100; 500	
7930853	131770004	10; 100	
7930854	131770005	10; 50	
7930855	131770006	100; 500	
7930856	131770007	100; 500	
7930857	131770008	10; 100; 250	

See QC Reference List for Associated Batch QC Samples

SAMPLE RECEIPT:

Samples were received in good condition and within temperature requirements.

HOLDING TIME:

All holding times were met.

CALIBRATION/STANDARDIZATION:

All criteria were met.

QUALITY CONTROL AND NONCONFORMANCE SUMMARY:

LCS/LCSD

(Sample number(s): 7930850-7930857: Analysis: 05298)
The recovery for a target analyte(s) in the Laboratory Control Spike(s) is outside the QC acceptance limits as noted on the QC Summary. Since the recovery is high and the target analyte(s) was not detected in the sample, the data is reported.

Batch#: D151893CBA (Sample number(s): 7930850-7930857)
The recovery(ies) for the following analyte(s) in the LCS exceeds the acceptance window indicating a positive bias: Vinyl Acetate

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Case Narrative/Conformance Summary

CLIENT: USAPHC/AIPH
SDG: IP232

Volatiles in Air

Fraction: Volatile Organics in Air by GC/MS

Sample Duplicate

(Sample number(s): 7930850: Analysis: 05298)
Please note that US EPA Methods for organic compounds do not require action by the laboratory based on out-of-specification matrix QC results.

SAMPLE ANALYSIS:

(Sample number(s): 7930850-7930857: Analysis: 05298)
Reporting limits were raised due to interference from the sample matrix.

Abbreviation Key

LOQ – Limit of Quantitation	LCS – Lab Control Sample
MDL = Method Detection Limit	LCSD = Lab Control Sample Duplicate
ND = Not Detected	RE = Repreparation/Reanalysis
J = Estimated Value	* = Out of Specification
E= out of calibration range	

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Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	**BMQL**	Below Minimum Quantitation Level
N.D.	none detected	**MPN**	Most Probable Number
TNTC	Too Numerous To Count	**CP Units**	cobalt-chloroplatinate units
IU	International Units	**NTU**	nephelometric turbidity units
umhos/cm	micromhos/cm	**ng**	nanogram(s)
C	degrees Celsius	**F**	degrees Fahrenheit
meq	milliequivalents	**lb.**	pound(s)
g	gram(s)	**kg**	kilogram(s)
µg	microgram(s)	**mg**	milligram(s)
mL	milliliter(s)	**L**	liter(s)
m3	cubic meter(s)	**µL**	microliter(s)
		pg/L	picogram/liter

<	less than
>	greater than
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.
ppb	parts per billion
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.

Laboratory Data Qualifiers:

B - Analyte detected in the blank
C - Result confirmed by reanalysis
E - Concentration exceeds the calibration range
J (or G, I, X) - estimated value ≥ the Method Detection Limit (MDL or DL) and the < Limit of Quantitation (LOQ or RL)
P - Concentration difference between the primary and confirmation column >40%. The lower result is reported.
U - Analyte was not detected at the value indicated
V - Concentration difference between the primary and confirmation column >100%. The reporting limit is raised due to this disparity and evident interference…

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods. Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

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Appendix S

Benchmark Dose Data

Table S-1
Protocol No. 35-15-01-01
Acute and Subacute Inhalation Toxicity Study in Rats
Exposed to Pyrotechnically Disseminated M18 Red Smoke

Benchmark Dose Output
Male Rats

Model Name	Gamma*	Logistic*	LogLogistic*	LogProbit*	Multistage 2	Multistage 3*	Probit*	Weibull*	Quantal-Linear
BMD	0.98454	1.35091	1.27404	1.10264	0.509751	0.701681	1.2218	1.30757	0.238949
BMDL	0.31521	0.490699	0.326282	0.33534	0.182693	0.235426	0.4475	0.30944	0.113642
P-value	1	1	1	1	0.856	0.9693	1	1	0.482
AIC	9.64003	11.6382	11.6382	11.6382	11.006	10.1132	11.638	11.6382	13.4514
Scaled residual for dose group nearest the BMD	-0.03	0	0	0	-0.8	-0.483	0	0	-0.425
Scaled residual for control group	0	0	0	0	0	0	0	0	0

* Model selected with an appropriate fit

Female Rats

Model Name	Gamma*	Logistic	LogLogistic	LogProbit	Multistage 2*	Multistage 3*	Probit	Weibull*	Quantal-Linear*
BMD	0.09568	0.291399	0.0878013	0.187717	0.101495	0.104962	0.274	0.09568	0.095683
BMDL	0.05351	0.16069	0.0268433	0.087194	0.0535612	0.053705	0.1613	0.05351	0.05351
P-value	0.9246	0.6911	0.6882	0.5893	0.7866	0.7928	0.7009	0.9246	0.9246
AIC	20.8971	23.6409	23.2082	23.6918	22.8875	22.861	23.574	20.8971	20.8971
Scaled residual for dose group nearest the BMD	0.5	0.362	0.4	0.734	0.559	0.593	0.4	0.5	0.5
Scaled residual for control group	0	-0.718	0	-0.551	0	0	-0.688	0	0

* Model selected with an appropriate fit

Appendix T

Study Protocol with Modifications

ANIMAL USE PROTOCOL
U.S. ARMY PUBLIC HEALTH COMMAND
ABERDEEN PROVING GROUND MD 21010-5403

PROTOCOL TITLE: Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke

PROTOCOL NUMBER: 35-15-01-01

DATE OF APPROVAL: 27 JAN 2015

STUDY DIRECTOR/PRINCIPAL INVESTIGATOR (SD/PI):

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ACRONYMS:

AEHA: Army Environmental Hygiene Agency
AEQT: Army Environmental Quality Technology
AIPH: Army Institute of Public Health
ALB: albumin
ALKP: alkaline phosphatase
ALT: alanine aminotransferase
AMYL: amylase
ANCOVA: Analysis of Covariance
ANOVA: Analysis of Variance
AST: aspartate aminotransferase
ASTM: American Society for Testing and Materials
AV: Attending Veterinarian
BRD: Biomedical Research Database
BUN: blood urea nitrogen
CA: calcium
CFR: Code of Federal Regulations
CHOL: cholesterol
CHPPM: Center for Health Promotion and Preventive Medicine
CO: carbon monoxide
CO_2: carbon dioxide
COT: Committee on Toxicology
CREA: creatinine
Crl(CD): Charles River Laboratories (Sprague-Dawley)
DTIC: Defense Technical Information Service
EDTA: Ethylenediaminetetraacetic acid
GLOB: globulin
GLP: Good Laboratory Practices
HEPA: high efficiency particulate air
GLU: Glucose
IACUC: Institutional Animal Care and Use Committee
IAW: in accordance with
LC_{50}: median lethal concentration
LDH: lactate dehydrogenase
LPM: liters per minute
LS: Laboratory Sciences Portfolio, AIPH

mg/L: milligrams per liter
mg/m^3: milligrams per cubic meter
mL: milliliters
N/A: not applicable
NIOSH: National Institute of Occupational Safety and Health
NO_x: nitrogen oxides
NRC: National Research Council
NTIS: National Technical Information Service
NYU: New York University
OECD: Organisation for Economic Co-operation and Development
OEP: Ordnance Environmental Program
PHOS: inorganic phosphate
PI/SD: Principal Investigator/Study Director
PPE: personal protective equipment
PVC: polyvinyl chloride
SAS: Statistical Analysis System
SOP: Standing Operating Procedure
SPSS: Statistical Package for the Social Sciences
TBIL: total bilirubin
TOX: Toxicology Portfolio, AIPH
TP: total protein
TSCA: Toxic Substances Control Act
USAIPH: United States Army Institute of Public Health
USAPHC: United States Army Public Health Command
USEPA: United States Environmental Protection Agency
VMD: Veterinary Medicine Division

I. NON-TECHNICAL SYNOPSIS

The inhalation toxicity of a pyrotechnically disseminated red smoke formulation proposed for military use will be determined in two phases of testing. The first phase will evaluate the acute (single exposure) inhalation toxicity of the red smoke formulation in rats. The second phase will evaluate the subacute (repeated exposure) inhalation toxicity of the red smoke formulation by exposing the rats for a total of 10 days. Rats will be exposed (head-only) to emissions from the smoke grenade and monitored for the appropriate observation periods for body weight, food consumption (repeated-exposure only), and clinical signs of toxicity. At the conclusion of each phase of the study, the rats will be euthanized and the tissues observed for possible compound-related lesions. Only animals from the subacute phase will be anesthetized to obtain blood samples for clinical chemistry and hematology analysis and selected tissues will be weighed and processed for histopathology.

II. BACKGROUND

II.1. Background:

The U.S. Military uses colored smokes in a variety of ways including identification of potential targets and friendly troops, simulation of battlefield events, and as a means of communication. Previously-used colored smoke formulations were developed strictly based on their ability to produce the desired color for a specified period of time. Recent changes made to the smoke formulations and dissemination systems used in M18 colored smoke grenades have focused more on soldier safety during training and deployed scenarios as well as the public living or working near military training facilities. The primary changes made to the colored smoke formulations involved the use of sugar instead of sulfur as the fuel and the replacement of sodium bicarbonate by magnesium carbonate as the coolant; however, additional changes have also been made to refine burn times and the colors produced.

At the onset of the transition, the Army requested the NRC to independently review the available toxicity data on certain smokes and obscurants and recommend exposure guidance levels for each. In response to this request, the NRC's COT convened the Subcommittee on Military Smokes and Obscurants, which published three volumes on the toxicity of military smokes and obscurants. Volume 3 of this series assesses toxicity data for seven old and new colored smoke formulations (NRC, 1999). In short, the Subcommittee found that the database for all seven smoke formulations, including the old and new red smokes, was inadequate for assessing the potential toxicity of the combustion products. They further recommended that acute inhalation studies be conducted in experimental animals to evaluate the toxicity of the combusted smoke formulations for emergency and short-term exposure guidance levels. Repeated exposure inhalation toxicity studies were recommended for military training instructors and people living in communities near military training facilities. Since the time of this review, the red dye proposed for use in the new red smoke formulation has changed from a mixture of solvent red 1 (α-meth-oxybenzenazo-β-naphthol) and disperse red 11 (1,4-diamino-2-methoxyanthraquionone) to solvent red 169 ((1-(isopropylamino) anthraquinone) only (E-mail, 2013). Neat solvent red 169 was evaluated by this Institute for acute inhalation toxicity and was found to be non-toxic in rats up to 2.4 mg/L (USACHPPM, 2009). The toxicity of the combusted red smoke formulation has not been evaluated.

II.2. Literature Search for Duplication:

II.2.1. Literature Source(s) Searched: BRD, National Technical Information Service, PubMed, Web of Science, DTIC

II.2.2. Date of Search: 30 June 2014

II.2.3. Period of Search: 1900-2014

II.2.4. Key Words of Search: ("colored smoke*" or "m-18 smoke grenade" or "m18 smoke grenade" or "m 18 smoke grenade" or "red smoke" or "red dye") and (toxic or toxicity) and ("lethal concentration 50" or "median lethal concentration" or mlc or lc50 or lc-50 or "lc 50" or "lethal dose 50" or "median lethal dose" or mld or ld50 or ld-50 or "ld 50" or inhal* or lung or pulmo* or pneumo* or aerosol* or respir* or alveol* or bronchi*) and (rat or rats)

II.2.5. Results of Search: A total of 275 references resulted from the literature search that was performed using the key words and databases listed above. All of the relevant references were performed on the old smoke formulations/dyes used by the Military prior to the transition to sugar-based formulation. In addition, none of these studies evaluated the toxicity of the pyrotechnically-disseminated smoke. They only evaluated the toxicity of the neat dyes used in the smoke grenade formulations. Therefore, no references were found that would suggest that this study would be a duplicate effort.

III. OBJECTIVE/HYPOTHESIS

The objectives of this study are to evaluate the acute inhalation toxicity of the dissemination products from the red M18 smoke grenade in the rat and to determine the effects of repetitive inhalation exposures in male and female rats.

IV. MILITARY RELEVANCE

Pyrotechnic colored smoke M18 grenades are used by the military for ground-to-ground and ground-to-air signaling. It is imperative that soldiers are trained in a similar manner in which they fight, therefore, these training exercises often result in soldiers and training instructors being repeatedly exposed to materials used to simulate battlefield scenarios. Current Army policy regarding colored smokes (old formulation) states that, during training, troops must carry a protective mask, mask when passing through or operating in a dense smoke cloud (visibility < 50 meters), mask when operating or passing through a smoke haze (visibility > 50 meters) if exposure duration exceeds 4 hours, and mask anytime exposure to smoke produces breathing difficulty. In addition, production personnel who are exposed to the dyes/mixtures, or propellant and fuse system materials must wear coveralls, butyl rubber gloves, head and shoe coverings, and a NIOSH-approved full face or hood type supplied air respirator (AEHA, 1992, 1993a, 1993b). A health risk assessment was performed on the combustion products of the old red smoke grenade formulation to determine the risk associated with living near military training facilities that conduct colored smoke exercises. The risk assessment concluded that residents who live as close as 100 meters directly downwind from training areas are safe from breathing air emissions from the old red-colored M18 (AEHA, 1992, 1993a, 1993b). As the Army transitions to colored smoke formulations believed to pose less of a health risk, the toxicity of the combustion products must be evaluated so that exposure guidance can be updated.

Research, development, testing, and training with explosives and pyrotechnics potentially less hazardous to human health and the environment is vital to the readiness

of the U.S. Army. The AEQT OEP is dedicated to finding replacements for substances causing environmental and/or occupational risks to health. Toxicity assessments such as this proposed study are necessary for safeguarding the health of Soldiers, civilians, and the environment and, if begun early in the research, development, testing, and evaluation process, can save significant time and effort by identifying unacceptable replacement compounds (ASTM, 2008).

V. MATERIALS AND METHODS

Test Article: Both phases of this study will be conducted on the emission products from the new sugar-based red smoke formulation in a M18 style grenade. A list of the neat ingredients in the red smoke formulation along with their recommended parts by weight is provided below. A description of the test atmosphere analysis is provided in section V.1.1.4. The M18 smoke grenade is approximately 5.75 inches long, 2.50 inches in diameter and weighs 19 ounces. The smoke mixture itself weighs approximately 11.5 ounces and is pressed into a total of 4 pellets inside the canister.

M18 Red Smoke Formulation

Ingredient	**Recommended Parts By Weight**
Dye, Solvent Red 169	36.5
Magnesium Carbonate	16.5
Potassium Chlorate	20.5
Sugar, Type 1, Style C	19
Sugar, Type 1, Style B	6.5
Polyvinyl Acetate	1

V.1. Experimental Design and General Procedures:

The acute and subacute inhalation toxicity of a pyrotechnically disseminated red smoke formulation will be determined using a two-phased laboratory study in rats. The acute toxicity (LC_{50}) will first be conducted in male and female rats. Based upon the results of the LC_{50}, a 10-exposure subacute inhalation toxicity study will then be performed to determine the potential effects of repeated daily exposure to the red smoke formulation.

Group	**Male Rats**	**Female Rats**	**Male Recovery**	**Female Recovery**	**Pain Category**
Acute (LC_{50})					
2000 mg/m^3	5	5			5C/5E
TBD (if needed)	5	5			5C/5E
TBD (if needed)	5	5			5C/5E
	TOTAL = 15	**TOTAL = 15**			**TOTAL = 15C/15E**

Subacute					
Air Control	6	6	6	6	24D
Low	6	6			12D
Intermediate	6	6			12D
High	6	6	6	6	12D/12E
	TOTAL = 24	**TOTAL = 24**			**TOTAL = 60D/12E**
	GRAND TOTAL = 39	**GRAND TOTAL = 39**	**GRAND TOTAL = 12**	**GRAND TOTAL = 12**	**GRAND TOTAL = 15C / 60D / 27E**

If animals do not show any signs of distress, the pain category will be downgraded. Pain categories were determined as follows:

B: Held, but not used on study.
C: No pain or distress. It is expected that half of the acute study rats will not experience pain or distress.
D: Alleviated pain/distress with moribund euthanasia or drug treatment (e.g., anesthesia). Rats placed in this category were done so due to the method of blood collection (cardiac puncture).
E: More than momentary pain/distress that cannot be alleviated. Rats placed in this category have the potential to experience toxic effects from exposure.

V.1.1. Acute Study:

In an attempt to determine the acute toxicity associated with single, high-concentration exposures to red smoke, 5 male and 5 female rats will be exposed for 30 minutes to atmospheric concentrations of the test material targeted to 2000 mg/m^3. The design of the acute study is based primarily on the limit test provision outlined in the EPA Health Effects Test Guidelines for an Acute Inhalation Study (USEPA, 1998). By guideline, if the test material produces any lethality at the limit concentration targeted to 2000 mg/m^3, additional exposures at lower concentrations may need to be considered. Two additional groups of 5 male and 5 female rats each are included in the animal numbers requested for this protocol but will not be ordered unless necessary for the LC_{50} determination. Additional modifications to the acute inhalation test guidelines were made to reflect the unique issues associated with conducting an inhalation study with pyrotechnically-disseminated smokes and to accurately reflect a typical military exposure regime.

V.1.1.1. Administration of Test Substance and Exposure Mode:

Rats will be exposed nose-only to atmospheres of the test substance. The nose-only (head-only) exposure mode is typically used for test atmospheres that contain particulates/aerosols in an attempt to minimize deposition of the test substance onto the fur of the animals and, therefore, minimize inadvertent dermal and oral exposure to the animals. For the nose-only exposures, rats will be individually restrained during

exposure in perforated, stainless steel cylinders with conical nosepieces. These types of cylinders are typically used for nose-only inhalation exposures and are widely accepted equipment for inhalation toxicity test systems (Phalen, 1984 & 1997). Rats will be positioned in the exposure cylinders such that their noses will be at the conical end of the cylinder. In order to secure the rat in this position, a plastic disc with a hole in the center will be inserted over the tail and positioned within the cylinder close to the base of the rat's tail to prevent the animal from backing out of the rear of the cylinder. Care will be taken to properly insert each rat into its exposure cylinder, such that there is a balance between allowing the rat space to move while ensuring that it is positioned properly for adequate exposure. Each exposure cylinder will be inserted into one of the ports in the faceplate of the exposure chamber such that only the head/nose of each rat extends into the exposure chamber. Exposure cylinders will be appropriately cleaned after each animal/use.

V.1.1.2. Exposure Duration:

Rats for the acute phase will be exposed to a single 30-minute exposure of red smoke atmosphere. The starting time of the exposure will be defined as the time when the chamber has reached the desired concentration (see section V.1.1.3 below for confirmation of atmosphere generation and the concentration of red smoke) and the rats have been placed into the faceplate. The ending time of each exposure will be defined as the time when the rats are removed from the faceplate. At the end of each exposure, the rats will be removed from the exposure cylinders and returned to their home cages in the animal room. Rats will be restrained in the exposure cylinders for no more than approximately 90 minutes which includes the time required to place the rats in the cylinders, expose them, and remove the rats from the cylinders.

V.1.1.3. Atmosphere Generation:

Chamber atmospheres will be generated by pyrotechnic dissemination of the test material inside an empty inhalation chamber with solid rubber stoppers placed in the faceplate to contain the smoke atmosphere. This inhalation experiment is somewhat unique in that the pyrotechnic dissemination of the test material in the chamber will serve as the generation system rather than metering a test substance at a constant rate into the chamber. Test atmospheres exiting the exposure chamber will be directed through a pre-filter and high-capacity HEPA filter prior to discharge into the exhaust system. The concentration of red smoke will be monitored gravimetrically after grenade initiation to determine when the target concentration has been achieved and the rats can be placed in the faceplate.

Measurements will be obtained during method development to ensure a uniform distribution of the test substance within the exposure chamber. The methods for performing the chamber distribution analysis are described in TOX SOP 058 (USAPHC, 2013b).

Three chambers will be utilized for acute phase of this experiment. One chamber will

serve as the initiation chamber that will house the M18 red smoke grenade. Two additional chambers are connected to the initiation chamber with 2 inch PVC pipe and serve to contain the overpressure generated from the smoke grenade and supply the initiation chamber with oxygen for the smoke grenade to burn. The PVC pipes come out of 2 side ports in the initiation chamber and are connected to the top turrets of the other 2 chambers. These additional 2 chambers are also connected from the bottom to the exhaust with PVC pipe to contain any additional overpressure should it exceed the capacity of the 3 chambers. All exposure chambers are constructed of stainless steel and glass/Lexan with a nominal internal volume of approximately 1 m^3. The chambers are modeled after the NYU style inhalation exposure chambers. The NYU design refers to an inhalation exposure chamber with a cubical mid-section, square-pyramidal inlets and outlets, and a tangential feed at the top of the chamber inlet to promote uniform distribution of the test atmosphere (Drew, 1978). Each of the 3 connected exposure chambers is equipped with Lexan nose-only faceplates so that any of the 3 may be used for the acute exposure. The chamber to be used for the exposure will be determined during method development. No animals will be placed in a chamber until the grenade has completed its burn in the initiation chamber and temperature/oxygen measurements are taken in the exposure chamber to ensure oxygen is $\geq$ 19% and the temperature is within the targeted range of 23 ± 3ºC.

V.1.1.4 Analyses of the Test Atmosphere:

The atmospheric concentration of the red smoke particulate will be determined at least twice during the half-hour acute exposure. Known volumes of chamber atmosphere will be drawn from the exposure chamber through a filter cassette containing a pre-weighed glass fiber filter. Filters are weighed again after the sampling period is completed. All filters will be weighed on a Cahn microbalance. The atmospheric concentration of red smoke particulate will be calculated from the difference in the pre- and post-sampling filter weights divided by the volume of chamber atmosphere sampled. Samples to determine particle size distribution (mass median aerodynamic diameter and percent particles less than 1, 3, and 10 µm diameter) of the red smoke particulate will be collected at least once for the acute study. Particle size samples will be collected with a Sierra® Series 210 8-Stage Cascade Impactor fitted with a cyclone preseparator and an Anderson Series 110 Constant Flow Air Sampler (USAPHC, 2015b).

Combustion gases (e.g., CO_2, CO, NO_x) will be analyzed at least once during the acute study. The appropriate method for analysis will be determined by either Aberdeen Test Center or LS personnel. The method and results for the analysis will be appropriately documented in the study records. In addition, analysis of the particulate contained on the filters may also be performed on selected filters collected during the acute study. The appropriate method for analysis will be determined by LS personnel. The method and results for the analysis will be appropriately documented in the study records.

Since the exposure chamber will essentially be a static system, chamber airflow will

not be measured during this study. Oxygen content will be measured prior to placing the acute animals in the exposure chamber and during the exposure to ensure they have adequate oxygen (i.e., $\geq$ 19%). Oxygen readings will be collected at least twice during each exposure. Chamber temperature and relative humidity will be targeted to 23 ± 3ºC and 50 ± 20%, respectively. Temperature and humidity will be monitored continuously and recorded at least 2 times during the acute exposure.

V.1.1.5. Observations:

A thorough physical examination of each rat will be performed by study personnel at least once per day, ideally at a similar time, during the 14-day observation period (weekends excluded). The examination process will consist of each rat being removed from its home cage, individually handled, and carefully observed. Observations will include, but not be limited to, evaluation of skin and fur, eyes and mucous membranes, respiratory and circulatory effects, autonomic effects such as salivation, central nervous system effects, including tremors and convulsions, changes in the level of activity, gait and posture, reactivity to handling or sensory stimuli, altered strength, and stereotypes or abnormal behavior (e.g., self-mutilation, walking backwards) (USAPHC, 2014g). All data related to the observation of rats will be detailed and thoroughly documented in the study records by study personnel.

V.1.1.6. Body Weight and Food Consumption:

Animals will be weighed prior to the exposure, at least weekly thereafter, and at termination. In addition, any animals displaying toxic signs will be weighed if necessary to determine health status. Food consumption will not be monitored during the acute study.

V.1.1.7. Gross Necropsy, Tissue Collection and Preservation:

At the time of termination, animals will be euthanized as described in section V.4.6. Animals will then be necropsied and examined macroscopically for any structural abnormalities or pathological changes. Tissues may be removed, weighed and processed as described in sections V.1.2.8.2 and V.1.2.8.3, at the discretion of the PI/SD.

V.1.2. Subacute Study:

Four groups of 12 rats each (6 rats/sex/group) will be exposed to control (0 mg/m^3), low, intermediate, and high concentrations of red smoke. Target concentrations for the low, intermediate, and high levels will be determined after evaluating the results of the acute phase. The high concentration will be targeted to not exceed 2000 mg/m^3. Animals will be randomly assigned to exposure groups stratified by weight sextile. Rats will be exposed nose-only for 30-minutes per day, 5 days/week, for a total of 10 exposure days (weekends excluded). The start date will be staggered over a period of several days to facilitate the scheduling of necropsies. In addition, the control and high dose levels will each have an additional recovery group utilizing 6 rats/sex/group. Both recovery groups

will be exposed to the target concentrations for a total of 10 exposure days, but will be held for a one-month observation period following the exposures. The design of the subacute study is based on a military-unique exposure scenario rather than an EPA Health Effects Test Guideline. Modifications were again made to reflect the unique issues associated with conducting an inhalation study with pyrotechnically-disseminated smokes and to accurately reflect a typical military exposure regime.

V.1.2.1. Administration of Test Substance and Exposure Mode:

Rats will be exposed nose-only to atmospheres of the test substance for the subacute study. A complete explanation of the nose-only exposure mode is provided in V.1.1.1. above.

V.1.2.2. Concentration Level Selection:

Results from the acute study will be used to finalize design concentrations for the subacute study. Exposure levels for the subacute study will be designed such that the low level should not produce adverse toxicological effects, the intermediate level should produce some degree of toxicity, and the high level will produce toxic effects without symptoms of pulmonary overload.

V.1.2.3. Exposure Duration:

Rats for the subacute phase will be exposed to a 30 minutes per day, 5 days/week, for a total of 10 exposure days. The initiation/completion of the exposure period for the subacute study will be staggered over several days in order to accommodate limitations in the necropsy scheduling process. The starting time of the exposure will be defined as the time when the chamber has reached the desired concentration and the rats have been placed into the faceplate. The ending time of each exposure will be defined as the time when the rats are removed from the faceplate. At the end of each exposure, the rats will be removed from the exposure cylinders and returned to their home cages in the animal room.

V.1.2.4. Atmosphere Generation:

The atmosphere generation method used for the subacute study will be the same as that described in section V.1.1.3 for the acute study. A total of four chambers will be utilized for this phase of this experiment with one chamber for all air control exposures and 3 additional chambers for all smoke exposures. One smoke chamber will serve as the initiation chamber that will house the M18 red smoke grenade. Two additional chambers are connected to the initiation chamber with 2 inch PVC pipe and serve to contain the overpressure generated from the smoke grenade and supply the initiation chamber with oxygen for the smoke grenade to burn. The PVC pipes come out of 2 side ports in the initiation chamber and are connected to the top turrets of the other 2 chambers. These additional 2 chambers are also connected from the bottom to the exhaust with PVC pipe to contain any additional overpressure should it exceed the

capacity of the 3 chambers. All exposure chambers are constructed of stainless steel and glass/Lexan with a nominal internal volume of approximately 1 m^3. The chambers are modeled after the NYU style inhalation exposure chambers. The NYU design refers to an inhalation exposure chamber with a cubical mid-section, square-pyramidal inlets and outlets, and a tangential feed at the top of the chamber inlet to promote uniform distribution of the test atmosphere (Drew, 1978). Each of the 3 connected exposure chambers is equipped with Lexan nose-only faceplates so that any of the 3 may be used for the different exposure levels of the subacute experiment. The chamber to be used for each exposure level will be determined during method development. No animals will be placed in a chamber until the grenade has completed its burn in the initiation chamber and temperature/oxygen measurements are within targeted ranges in the exposure chamber.

V.1.2.5 Analyses of the Test Atmosphere:

A complete description of the test atmosphere analysis is provided in section V.1.1.4 for the acute study and the types of analyses will remain the same for the subacute phase. Gravimetric analysis of the test atmosphere will be performed at least twice during each subacute exposure for each exposure concentration. Particle size and combustion gas samples will be collected at least 2 times from each of the test atmosphere concentrations over the 2-week study period. Oxygen, temperature, and humidity readings will also be recorded at least 2 times per exposure for each exposure concentration.

V.1.2.6. Observations:

A thorough physical examination of each rat will be performed by study personnel prior to each exposure. The examination process will consist of each rat being removed from its home cage, individually handled, and carefully observed. Observations will include, but not be limited to, evaluation of skin and fur, eyes and mucous membranes, respiratory and circulatory effects, autonomic effects such as salivation, central nervous system effects, including tremors and convulsions, changes in the level of activity, gait and posture, reactivity to handling or sensory stimuli, altered strength, and stereotypes or abnormal behavior (e.g., self-mutilation, walking backwards) (USAPHC, 2014g). Observations will also be performed daily on all animals once all exposures are completed. Observations taken during the exposures will be somewhat limited due to the density of the test atmosphere in the exposure chambers. Daily observations will also be performed on the recovery animals during the 4-week recovery period. All data related to the observation of rats will be detailed and thoroughly documented in the study records by study personnel.

V.1.2.7. Body Weight and Food Consumption:

All rats will be weighed at least once per week. Weights will be collected during the acclimation period and on specified days during the exposure period. In addition, any animals displaying toxic signs may be weighed if necessary to determine health

status. Food consumption will be monitored weekly during the subacute study.

V.1.2.8. Terminal Observations:

V.1.2.8.1. Clinical Chemistry and Hematology Assessments:

Fasted blood samples will be taken from all animals at termination (as described in section V.4.4.3.1.) and subjected to hematology and clinical chemistry analyses. The following hematology parameters will be evaluated: hematocrit, hemoglobin concentration, erythrocyte count, total and differential leukocyte count, platelet count, and clotting time. Serum will be evaluated for the following chemistries: BUN, CREA, GLU, TP, ALB, ALT, ALK P, AMYL, AST, GLOB, CHOL, TBIL, CA, PHOS, LDH, and electrolytes. Details concerning clinical chemistry and hematology analyses are outlined in TOX SOP 011 and TOX SOP 013, respectively (USAPHC, 2015a & 2013a).

V.1.2.8.2. Gross Necropsy, Organ Weight, and Tissue Preservation:

At the time of reported pre-term death or euthanasia, all animals will be necropsied by trained study personnel and examined macroscopically for any structural abnormalities or pathological changes. Wet weights of the organs listed below from all animals will be determined as soon as possible after dissection to avoid drying. Testes and epididymides from each male animal and ovaries and uterus from each female animal will be placed in Davidson's fixative (2-Propanol, acetic acid, formaldehyde, water) overnight (no longer than 24 hours) and then transferred to 70% ethanol. All other organs will be placed in 10% buffered formalin for at least 24 hours for fixation. All gross pathology changes will be recorded on TOX DOC 4.0. This tissue list may be altered at the discretion of the study staff based on observed toxicity and gross pathology findings.

- Uterus (with oviducts and cervix)
- Ovaries
- Testes
- Epididymides
- Brain
- Liver
- Kidneys
- Heart
- Spleen
- Thymus
- Adrenal glands
- Lungs

In addition to the organs listed above, samples of peripheral nerve, muscle, spinal cord, eye(s) plus optic nerve, gastrointestinal tract, urinary bladder, trachea (with thyroid and parathyroid attached), pharynx, larynx, nose, salivary glands, pancreas,

seminal vesicles, prostate, representative lymph node(s), mammary gland, thigh musculature, exorbital lacrimal gland, femur, skin, bone marrow, pituitary, vagina, and all gross lesions may be collected and placed in 10% buffered formalin for at least 24 hours for fixation. Trained study personnel and the procedures they perform will be documented at the time of necropsy.

V.1.2.8.3. Histopathology:

Full histopathology of the organs listed in section V.1.2.8.2. will be performed for all high-dose and control animals. Organs demonstrating treatment-related changes may also be examined in animals in the lower dose groups. Additionally, all gross lesions will be subjected to histopathological evaluation. At a minimum, full histopathology will be performed on the respiratory tract of all recovery animals.

V.1.3. Study Time Frame:

Estimated initiation date for the study is February 2015 but will depend on receipt of test material. Estimated completion date for the study is April 2015.

V.2. Sample Size Evaluation, Data Analysis Plan, and Archiving of Data:

Sample sizes were selected in accordance with applicable USEPA and OECD Health Effects Testing Guidelines as well as previous inhalation toxicity studies performed on smokes by this Institute (USEPA, 1998, OECD, 1981, & USAPHC, 2014g). These samples sizes have been widely used and have been demonstrated to provide adequate statistical power in these methods. Data from the acute study will be evaluated by the study director for an LC_{50} determination and will not require a formal statistical evaluation.

For variables that are measured only at the end of the subacute phase (clinical pathology and organ weights), the exposure levels will be compared using a one-factor ANOVA. Organ to brain and organ to body weight ratios will be calculated and analyzed similarly to the other parameters measured at the end of the study. If the dose group effect is significant, an appropriate post hoc test will be used to compare pairs of dose groups and dose groups to the control group. Data will be tested for normality and variance equality and adjusted if necessary.

For absolute organ weights, comparison of the dose groups will be made using an ANCOVA, with body weight at the end of the study being the covariate used. Even though the dose groups will be assigned at Day 0 to keep the average weight for each dose group similar, the weights can change during the study dependent on the dose group. The ANCOVA will adjust for any differences in body weights among the dose groups at the end of the study, because heavier animals would tend to have heavier organs. If the dose group effect is significant, an appropriate post hoc test will be used to compare pairs of dose groups and dose groups to the control group.

Exposure levels will also be compared with respect to absolute body weights, as well as weekly changes in body weight and net weight changes using a repeated measures model. Exposure levels will also be compared with respect to net food consumption for the study using a one-factor ANOVA. If the ANOVA is significant, an appropriate post hoc test will be used to compare pairs of dose groups. Data will be tested for normality and variance equality and adjusted if necessary.

Other observational data including gross necropsy observations and histopathology data may be converted to categorical data and analyzed using a Chi-square or Fisher's exact test.

An appropriate statistical software package, such as SPSS® and/or SAS® will be used to perform all analyses and statistical significance will be defined as $p \leq 0.05$ for all tests.

This study will be conducted in a manner consistent with the principles of 40 CFR Part 792 TSCA GLP Regulation (CFR, 1989). The investigators and technicians will adhere to the Guide for Care and Use of Laboratory Animals (NRC, 2011).

Records will be kept in standard USAPHC laboratory notebooks and/or three ring binders. Daily records will be kept on survival and clinical signs collected on the animals during the study. Procedures for preparation of any euthanasia solution, drug administration, animal blood collection, observation logs, morbidity/mortality logs, etc., will be stored with the study records. All post mortem procedures not listed in this protocol will be documented in the study records and kept with the study raw data. These records will be made available to oversight organizations such as the USEPA, Quality Systems Office, and the IACUC. The protocol, protocol amendments, raw data, statistical analysis, tabular calculations, and graphic analysis of the data will be saved with the study records. Additionally, memoranda to the study file, study logs, signature logs, final reports, and final report amendments will be archived at USAIPH. Some ancillary records such as maintenance and calibration logs, environmental monitoring logs, animal room husbandry and health rounds sheets, training files, etc. may be stored in the archives but not stored with the study files.

V.3. Laboratory Animals Required and Justification

V.3.1. Non-animal Alternatives Considered:

The objectives of this study are to determine the acute and subacute toxicity of pyrotechnically-disseminated red smoke. There are no appropriate animal substitutes (e.g., computer models, tissue/cell cultures) that simulate the pharmacokinetics and pharmacodynamics of *in vivo* animal exposure. No non-animal alternative would provide the necessary toxicological information provided by this study. Therefore, it is necessary to perform this study in an animal model.

V.3.2. Animal Model and Species Justification:

Applicable EPA and OECD test guidelines state that the rat is the preferred species (USEPA, 1998 & OECD, 1981). Sprague-Dawley rats are the strain of rat that have been historically used for toxicity studies by USAIPH PTOX and are the recommended species due to an historical and extensive database.

V.3.3. Laboratory Animals

V.3.3.1. Genus species: *Rattus norvegicus*

V.3.3.2. Strain / Stock / Breed: Sprague-Dawley (Crl: CD)

V.3.3.3. Source / Vendor: Charles River Laboratories, Wilmington, MA (USDA 14-R-0144)

V.3.3.4. Age: Acute Study: 7-9 weeks old on arrival
Subacute Study: 6-8 weeks old on arrival

V.3.3.5. Weight: Appropriate for age

V.3.3.6. Sex: Male and female (nulliparous and non-pregnant)

V.3.3.7. Special Considerations: None

V.3.4. Number of Animals Required (by Species): 108

V.3.5. Refinement, Reduction, Replacement (3 Rs):

V.3.5.1. Refinement:

Standard rat enrichment will be implemented in accordance with the version VMD SOP 004 current at the time of study initiation (USAPHC, 2014c). All animals on this study will be handled on a frequent basis and provided a form of environmental enrichment (e.g., nylabones, rodent retreats) throughout the study period. Animals will be considered for early removal from this study as described in section V.4.5. Animals will be anesthetized prior to painful procedures as described in section V.4.1.2.1. In addition, for the subacute study, an approximately 30-minute acclimation for the rats to the exposure cylinders will be performed at least one day prior to their initial exposure.

V.3.5.2. Reduction:

The limit test provision will be employed to initially evaluate the acute toxicity rather than the traditional evaluation using several concentrations.

V.3.5.3. Replacement:

No non-animal alternatives are known to exist that will provide the required data. At this time, there are no non-animal alternatives that can fully replicate the complex processes that occur within an intact mammalian organism.

V.4. Technical Methods:

V.4.1. Pain / Distress Assessment:

V.4.1.1. APHIS Form 7023 Information:

V.4.1.1.1. Number of Animals

V.4.1.1.1.1. Column B: 0

V.4.1.1.1.2. Column C: 15

V.4.1.1.1.3. Column D: 60

V.4.1.1.1.4. Column E: 27

V.4.1.2. Pain Relief / Prevention

V.4.1.2.1. Anesthesia / Analgesia / Tranquilization:

Animals will be anesthetized with CO_2 prior to blood collection. Animals will be brought to the necropsy room preferably in their home cage or in a transport cage. The appropriately-sized stainless steel lid will be placed on the cage. The CO_2 tank will be turned on, then the regulator opened to approximately 1/2 turn, and the flow meter set to 4-5 LPM. Animals will remain in the cage until they are recumbent with a shallow breathing pattern. Once recumbent, a toe or space between the toes will be pinched to assess appropriate depth of anesthesia. If no response to the toe pinch, animals will be removed and blood collected (as described in V.4.4.3.1.). Upon completion of blood collection animals will be returned to the home/transport cage and euthanized IAW the version of VMD SOP 002 current at the time of study initiation (USAPHC, 2014b).

V.4.1.2.2. Pre- and Post-Procedural Provisions:

A physical examination will be made at least once each day during all phases of the study. Observations will be detailed and carefully recorded in the study records. Details related to observations and/or physical examinations of rats are described in Sections V.1.1.5. and V.1.2.6.

V.4.1.2.3. Paralytics: N/A

V.4.1.3. Literature Search for Alternatives to Painful or Distressful Procedures:

V.4.1.3.1. Source(s) Searched: NTIS, PubMed, Web of Science

V.4.1.3.2. Date of Search: 30 June 2014

V.4.1.3.3. Period of Search: 1900-2014

V.4.1.3.4. Key Words of Search: ("colored smoke*" or "m-18 smoke grenade" or "m18 smoke grenade" or "m 18 smoke grenade" or "red smoke" or "red dye") and (toxic or

toxicity) and ("lethal concentration 50" or "median lethal concentration" or mlc or lc50 or lc-50 or "lc 50" or "lethal dose 50" or "median lethal dose" or mld or ld50 or ld-50 or "ld 50" or inhal* or lung or pulmo* or pneumo* or aerosol* or respir* or inhal* or alveol* or bronchi*) and (pain or distress or refine or reduce or replace or artificial or vitro or culture or tissue or cell or organ or insect or arachnid or invertebrate or fish or mollusk or cephalopod or simulate or digital or interactive or mannequin or manikin or model)

V.4.1.3.5. Results of Search: The literature search did not identify any references pertaining to alternatives to the painful procedures described in this protocol. Although certain *in vitro* toxicity screens are known to exist, a live mammalian model is required to provide the necessary toxicity information at this time. In addition, other methods of blood collection are known to exist (e.g., saphenous vein, tail vein) but would not provide a sufficient volume to perform the clinical chemistry and hematology analyses.

V.4.1.4. Unalleviated Painful or Distressful Procedure Justification:

The nature of these studies precludes the use of totally painless procedures. An attempt to alleviate pain or distress by the administration of anesthetics, analgesics, or drugs may alter the manifestation of the toxic responses. Typical pain relievers such as opiates and non-steroidal anti-inflammatories as well as anesthetics have the ability to mask certain toxic signs that may be observed due to the administration of the test compound, especially those signs resulting from pain or distress. In addition, certain side effects such as alterations in blood chemistry and hematology may arise from the use of these drugs and could be misinterpreted by the investigator as clinical signs caused by the test material. The observation of the onset, duration and/or reversibility of toxic signs is critical to mechanistic interpretation, especially since the acute study is being used to set dosages for a longer-term study. “Toxic signs” are defined in the version VMD SOP 016 current at the time of study initiation (USAPHC, 2014f). Animals determined to be moribund with no possibility for recovery will be euthanized as described in section V.4.6. However, unalleviated pain and mortality is expected to occur in the determination of a median lethal concentration.

V.4.2. Prolonged Restraint and Restraint Methods:

Rats will be contained in nose-only exposure cylinders during the 30-minute exposure period. Rats will be contained in the exposure cylinders during both the time it takes to insert the rats into the cylinder prior to the exposure (approximately 30 minutes) and the time it takes to remove the rats from the cylinders following the exposure (approximately 30 minutes). The total time that the rats will be in the exposure cylinders is estimated to be approximately 90 minutes. This type of exposure cylinder and restraint regimen is a commonly accepted method of restraint for rats exposed nose-only during an inhalation exposure (Phalen, 1984 & 1997). A 30-minute period of acclimation for the rats to the restrainers will be performed at least one day prior to their initial exposure for the subacute study.

V.4.3. Surgery: N/A

V.4.3.1. Pre-surgical Provisions: N/A

V.4.3.2. Procedure: N/A

V.4.3.3. Post-surgical Provisions: N/A

V.4.3.4. Location: N/A

V.4.3.5. Surgeon: N/A

V.4.3.6. Multiple Survival Operative Procedures

V.4.3.6.1. Procedures: N/A

V.4.3.6.2 Scientific Justification: N/A

V.4.4. Animal Manipulations

V.4.4.1. Injections: N/A

V.4.4.2. Use of Non-Pharmaceutical-Grade Chemicals: The compounds being tested are not available in a pharmaceutical-grade composition. They are under investigation as described in the objectives section (III) of this protocol.

V.4.4.3. Biosamples:

V.4.4.3.1. Blood Collection and Analysis:

Blood will be collected from all animals at termination of the subacute study. All blood collection will be conducted under CO_2 gas anesthesia (as described in section V.4.1.2.1) just prior to euthanasia. Once the anesthetic has taken effect (ensured by a toe pinch) the rat will be placed in dorsal recumbency. The rat can then be immobilized by either holding the base of the tail or by holding the forelimbs apart and upward with the thumb and index finger. There should be no response by the rat to entry of the needle into its skin. If there is any response, the rat is not at a deep enough level of anesthesia for this method of blood collection and the procedure will stop until the rat is anesthetized to a deeper plane of anesthesia. An appropriate size needle (18-25 gauge, 1-1.5 inch needle, depending on the size of the rat) will be fitted onto a 3-10 mL syringe and inserted anteriorly under the xiphoid region of the rat at an approximately 45º angle and advanced firmly through the diaphragm and into the heart. Slight negative pressure will be placed on the syringe plunger and the required amount of blood withdrawn from the rat. The goal of the blood draw is to obtain as large a sample as possible, and is generally 4-6 mL. Following collection of the blood sample, the needle will be slowly withdrawn from the rat. To minimize blood hemolysis, the needle should be removed from the syringe before discharging the blood sample into microtubes. Blood collection will be promptly followed by euthanasia as described in section V.4.6.

For hematology samples, approximately 1-2 mL of blood will be transferred to an EDTA microtube and immediately inverted gently several times. For clinical chemistry samples, approximately 1-2 mL of blood will be transferred to a serum-gel microtube

and allowed to stand at room temperature for at least 20 minutes to allow sufficient clotting prior to centrifugation. The remainder of the blood from each animal (approx. 1-2 mL) will be transferred to a sodium citrate microtube for analysis of prothrombin time. Details concerning clinical chemistry and hematology parameters are outlined in TOX SOP 011 and TOX SOP 013, respectively (USAPHC, 2015a & 2013a).

V.4.4.4. Adjuvants: N/A

V.4.4.5. Monoclonal Antibody (MAb) Production: N/A

V.4.4.6. Animal Identification:

Animals will be identified by cage cards according to the version of VMD SOP 014 current at the time of study initiation (USAPHC, 2014e). An identification number (e.g., the last 3 digits of the animal number) will also be marked on the tail of each rat with a water-insoluble marker in order to ensure proper identification of rats when removed from their cages.

V.4.4.7. Behavioral Studies: N/A

V.4.4.8. Other Procedures: N/A

V.4.4.9. Tissue Sharing:

Tissues from animals euthanized on this study may be made available to other personnel with approved protocols if coordinated through the PI/SD and the AV. Tissue sharing will be allowed only if doing so does not affect the quality and validity of the study or change the euthanasia methods.

V.4.5. Study Endpoint:

The study endpoint of the acute study is intervention euthanasia of moribund animals, study-related mortality, or euthanasia following an observation period not to exceed 14 days. The study endpoint of the subacute study is intervention euthanasia of moribund animals, study-related mortality or euthanasia on the day following the final exposure or recovery period.

Although some form of euthanasia is the projected study endpoint, the possibility still exists that a compound-related death may occur during an unobserved period (i.e., overnight). The novelty of the compound being tested prevents the assurance that a compound-related death may not occur. Additionally, the time at which signs of toxicity appear, their duration, and the time to death are important, especially if there is a tendency for deaths or morbidity to be delayed or if the signs of toxicity are reversible or recovery is possible. This is particularly important in the acute study when the type, onset and duration of toxic signs are still unknown. As such, potentially moribund animals will be monitored, in consultation with the AV, during the acute and subacute studies for possible reversal and recovery of toxic signs.

Animals will be assessed for morbidity based on a weight of evidence of the following signs: impaired ambulation which prevents animals from reaching food/water; excessive weight loss or emaciation (≥ 20% body weight loss compared to controls); lack of physical or mental alertness; prolonged labored breathing (e.g., lasting longer than 8 hours and accompanied by extreme lethargy); unabated seizure activity (e.g., lasting longer than 1 hour); inability to urinate or defecate for greater than 24 hours; or a prolonged inability to remain upright (e.g., lasting more than 2 hours). The AV may be consulted, if needed, to evaluate potentially moribund animals, unless the PI/SD plans to immediately euthanize the animal. Intervention euthanasia will be conducted by trained study staff on animals determined to be moribund by the PI/SD or AV.

V.4.6. Euthanasia:

Euthanasia will be accomplished by asphyxiation from CO_2 exposure IAW the version of VMD SOP 002 current at the time of study initiation (USAPHC, 2014b). Death of all rats euthanized by CO_2 will be ensured by bilateral thoracotomy or immediate necropsy with perforation of the diaphragm. Thoracotomy will be accomplished by inserting a sharp blade into the chest cavity behind a rib and moving the blade the length of the ribcage on both sides. Alternatively, for animals being immediately necropsied, the abdomen will be opened and a puncture made through the diaphragm via the abdominal cavity.

V.5. Husbandry & Veterinary Care:

V.5.1. Husbandry Considerations:

Animal rooms will be maintained IAW the version of VMD SOP 008 current at the time of study initiation (USAPHC, 2014d). Animals will be provided ad lib rodent chow that is certified free of contaminants (except during exposure and periods of overnight fasting prior to necropsy). Water will be provided ad lib by the automated watering system, by reservoirs that feed into the racks, or by water bottles. Light cycle will be 12 hours on and 12 hours off. Room temperature will be set at 68-79ºF and humidity at 30-70%. Cage sanitation will be checked at least once daily by animal care staff. The animals will be housed in plastic, solid-bottom shoebox cages (size appropriate to the body weight of the rat). Rats will be individually housed during both phases of the study to minimize ingestion of the test material that typically results from pair-housed animals preening each other. All rats will undergo a minimum of a 5-day acclimation period during which time they may be pair-housed (sexes separate). Body weight and observation data may also be collected on rats by study personnel during the acclimation period in an attempt to more accurately monitor the health status of the rats in preparation for their use on study. However, animals will not be weighed or handled by study personnel within the first 24 hours after their arrival to the facility.

V.5.1.1. Study Room:

Inhalation exposures will be conducted at the AIPH TOX animal facility, Bldg E-2101, IACUC-approved room 10. Housing room will be as assigned, preferably Bldg. E-2101

or Bldg. E-2100. All live animal work will occur in either the housing room, necropsy suite (E-2100) or the exposure room (room 10, E2101).

V.5.1.2. Special Husbandry Provisions:

Food consumption for all subacute study animals will be monitored based on the weight of the food hopper. Therefore, feed should not be added to feeders and feeders should not be replaced without consulting the PI/SD. Food enrichment may not be used due to food consumption monitoring. When animals are being fasted, PI/SD or study staff (or Vet Med staff when directed to do so) will remove the food hopper no earlier than 1600 the day prior to necropsy. Fasting of rats will not exceed 18 hours before necropsy.

V.5.1.3. Exceptions:

Restraint cylinder acclimation, as well as body weight measurements, will be conducted during the animals' acclimation period, but not during the first 24 hours following their arrival in this facility. These procedures will be performed by the study staff. Rats will be individually housed with the exception of acclimation periods. As stated in V.5.1., individual housing is necessary to minimize ingestion of the test material that typically results from pair-housed animals preening each other. Attempts to remove residual test material from the animal's fur (e.g., wiping or vacuuming) to allow for pair-housing would simply smear, rather than remove, it from the animal. The test substance contains a high concentration of dye that is not easily removed and attempts to do so would increase the potential dermal exposure and possibly induce additional stress associated with the exposure. Test substances will be evaluated on an "as received" basis and are non-pharmaceutical grade.

V.5.2. Veterinary Medical Care

V.5.2.1. Routine Veterinary Medical Care:

Animals will routinely be observed no less than once daily by assigned veterinary medical personnel for husbandry conditions, humane care, and general health status. IAW current IACUC policy, in the event an animal becomes ill or injured, veterinary or toxicology personnel will contact the AV or his/her designated backup who will determine the appropriate course of action. Animals will be observed daily by study personnel as described in sections V.1.1.5 and V.1.2.6. Animals appearing ill or displaying toxic signs will be assessed for morbidity and early removal from the study as described in section V.4.5. Animals will routinely be observed no less than once daily by assigned veterinary medical personnel for husbandry conditions, humane care, and general health status. In the event an animal becomes ill or injured, veterinary or toxicology personnel will contact the Attending Veterinarian or his/her designated backup who will determine the appropriate course of action. V.5.2.2. Emergency Veterinary Medical Care:

In the event an animal requires after-hours emergency veterinary care, a veterinarian is available 24 hours a day, 7 days a week. In the case of an emergency health problem, if the PI or co-PI is unavailable and the present investigator staff and veterinary staff

cannot reach consensus on treatment of a study animal, the AV has the authority to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary. However, all decisions involving the treatment of a study animal in which a consensus cannot be reached will only be made after the veterinarian or designated backup veterinarian has actually observed and examined the animal in question. To facilitate communication, the PI and study staff will provide the Veterinary Medicine Office a current emergency contact roster. In an emergency, the animal care staff will phone the numbers (office, home, and mobile) listed for the PI and co-PI. If the PI or co-PI cannot be reached by phone within 15 minutes, then they are considered unavailable.

V.5.3. Environmental Enrichment

V.5.3.1. Enrichment Strategy:

All animals will be individually housed except during acclimation periods. All animals will have an enrichment device (e.g., nylabone, rodent retreat) in their cage. All animals on this study will receive the same type of enrichment throughout the study. There will be an environmental enrichment plan posted on the door of the animal room to communicate the enrichment plan to everyone working on the study. This enrichment plan will be in accordance with the version of VMD SOP 004 current at the time of study initiation (USAPHC, 2014c), unless otherwise noted in this section.

V.5.3.2. Enrichment Restrictions:

Food enrichment may not be used due to food consumption monitoring during the subacute study. Rodent retreats may be removed for observation of animals, but will be replaced following observation periods of no more than eight hours. All animals will be individually housed following exposure initiation as described in V.5.1.3. above.

VI. STUDY PERSONNEL QUALIFICATIONS AND TRAINING:

Personnel on Protocol	Activity to be Performed on Protocol	Formal Training	Qualifications and Experience
Lee Crouse	Handling/observations	Rodent handling techniques (11/21/96); Rat handling (7/19/07)	M.S.,Environmental Science 19+ Yrs Animal Research Experience
	Test Article Exposures	OJT ('96-present)	
	CO_2 anesthesia/blood collection	OJT (1996-present)	
	Intra-cardiac blood collection	Rat bleeding techniques: cardiac under isoflurane (12/17/08); rat blood collection (7/19/07); Terminal cardiac blood draw	
	CO_2 euthanasia	Rat euthanasia via CO_2 (08/14)	
Matthew	Handling/observations	Rodent and Small Animal Handling Workshop (MRICD, 12/07/04); Rodent Handling Workshop (MRICD, 02/17/04); Rodent Surgical Techniques (hands-on workshop) (CHPPM, 02/17/05);	M.S., Biology 14+ Yrs Animal

Bazar	Test article exposures	OJT ('05-present)	Research Experience
Theresa Hanna	Handling/observations	Animal handling: rat (3/12/92); rat techniques: handling/observations (11/3/08); Rodent small animal handling workshop (2/25/98; 4/2/04; 11/22/05)	ALAT 24+ Yrs Animal Research Experience
Allison Jackovitz	Handling/observations	Small animal handling workshop (6/4/09); Rat handling, injections, oral gavage, vaginal lavage, CO2 euthanasia (06/2012)	B.S., Biology, 4+ years Animal Research Experience
Alicia Shiflett	Handling/observations	Rat techniques: handling/observations (11/3/08); Rat handling, oral gavage, vaginal lavage (6/12/12);	Associates Degree, Histology/ Science 4+ Yrs Animal Research Experience
Emily Lent	Handling/observations	Rat handling (7/19/07)	Ph.D., Natural Resources and Environmental Studies; M.S., Wildlife Biology 15+ Yrs Animal Research Experience
Adolph Januszkiewicz	Handling/observations	WRAIR Rodent Workshop; Mouse, Rat (Feb 06); ACUP (Aug 09); Aseptic Class (Mar 07)	Ph.D., Pharmacology and Toxicology 35+ Yrs Animal Research Experience
	Test article exposures	OJT 1980 - present	
Charles Crouse	Test article exposures (no animal handling)	OJT 1970-present AAALAC online learning courses (6/2014)	41+ Yrs Inhalation Toxicology Experience

VII. BIOHAZARD/SAFETY: Risks associated with this protocol include bites/scratches/needle sticks, transmission of zoonotic diseases, the development of animal allergies and potential exposure to smoke grenade emissions. To minimize risk, appropriate handling techniques will be used and appropriate PPE will be worn for all animal handling work. This includes (but may not be limited to) facemask, gloves, disposable lab coat, and an N95 mask when loading/unloading animals into chambers containing particulate atmospheres. Personnel will wash their hands upon completion of animal work. Applicable current TOX and VMD SOPs at the time of study initiation and PHC regulations (USAPHC, 2014a & USACHPPM, 2007) will be followed. These documents specify hazardous waste disposal, bite/scratch procedures, and zoonotic disease prevention. A sharps container will be present at all times when using sharps and needles will not be recapped after entering animal tissue. Precautions have been taken to contain the overpressure generated from igniting the M18 smoke grenades inside the exposure chamber including the use of a 3-chamber design for the exposures and overpressure valves while the grenade is burning. The minimum number of study

personnel will be present in the exposure room when the grenades are ignited and burning.

VIII. ENCLOSURES:

A. References

IX. ASSURANCES:

IX.1. As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

A. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.

B. Duplication of Effort: I have made every effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

C. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

D. Biohazard/Safety: I have taken into consideration and made the proper coordination regarding all applicable rules and regulations concerning radiation protection, biosafety, recombinant issues, and so forth, in the preparation of this protocol.

E. Training: I verify that the personnel performing the animal procedures / manipulations / observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures / manipulations.

F. Responsibility: I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R", namely, "Responsibility," which the DOD has embraced for implementing animal use alternatives where feasible and conducting humane and lawful research.

G. Scientific Review: This proposed animal use protocol has received appropriate peer scientific review and is consistent with good scientific research practice.

H. Painful Procedures: (*Applicable if the research being conducted has the potential to cause more than momentary or slight pain or distress even if an anesthetic or analgesic is used to relieve the pain and/or distress.*)

I am conducting biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals. This potential pain and/or distress WILL / WILL NOT (circle one or both, if applicable) be relieved with the use of anesthetics, analgesics and/or tranquilizers. I have considered alternatives to such procedures; however, I have determined that alternative procedures are not available to accomplish the objectives of this proposed experiment.

I. Unexpected Adverse Events: I acknowledge the responsibility for reporting unexpected adverse events IAW the most current version of IACUC Policy Memorandum No. 8. "Policy on Unexpected Adverse Event Reporting".

Lee Crouse		26 Jan 2015
(PRINT) Principal Investigator	(Signature)	(Date)

IX.2. As the Primary Co-Investigator on this protocol, I provide the following assurances:

A. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.

B. Authority: I understand that, as the Primary Co-Investigator, I am authorized and responsible for performing all procedures and manipulations as assigned to the SD/PI in the SD/PI's absence. This includes euthanasia of distressed animals.

C. Training: I verify that I am technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

D. Responsibility: I acknowledge the inherent moral and administrative obligations associated with the performance of this animal use protocol, and I assure that I will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to conduct this study in the spirit of the fourth "R", namely "Responsibility," which the DOD has embraced for implementing animal use alternatives where feasible, and conducting humane and lawful research.

E. Painful Procedures: I am conducting biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals. This potential pain and/or distress WILL or WILL NOT (circle one or both, if applicable) be relieved with the use of anesthetics, analgesics and/or tranquilizers. I have considered alternatives to such procedures; however, I have determined that alternative procedures are not available to accomplish the objectives of this proposed experiment.

F. Unexpected Adverse Events: I acknowledge the responsibility for reporting unexpected adverse events IAW the most current version of IACUC Policy Memorandum No. 8. "Policy on Unexpected Adverse Event Reporting".

Matthew A. Bazar

(PRINT) First name, MI, Last name of Primary Co-Investigator

Matthew A. Bazar 26 Jan 2015

(Signature) (Date)

IX.3. As a Co-Investigator on this protocol, I provide the following assurances:

A. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC prior to its implementation.

B. Authority: I understand that, as a Co-Investigator, I am authorized, responsible for, and willing to perform all procedures and manipulations as assigned to me by the SD/PI.

C. Training: I verify that I am technically competent and have been or will be properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the assigned procedures/manipulations performed by me.

D. Responsibility: I acknowledge the inherent moral and administrative obligations associated with the performance of this animal use protocol, and I assure that I will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to participate in this study in the spirit of the fourth "R", namely "Responsibility," which the DOD has embraced for implementing animal use alternatives where feasible, and conducting humane and lawful research.

E. Painful Procedures: I am participating in biomedical experiments, which may potentially cause more than momentary or slight pain or distress to animals. I will follow the direction of the SD/PI relative to potential pain and/or distress and relief by use of anesthetics, analgesics, and/or tranquilizers.

F. Unexpected Adverse Events: I acknowledge the responsibility for reporting unexpected adverse events IAW the most current version of IACUC Policy Memorandum No. 8. "Policy on Unexpected Adverse Event Reporting".

(PRINT)	(SIGNATURE)	(DATE)
Charles L Crouse	Charles L Crouse	1-26-15
First name, MI, Last name of Co-Investigator		
Theresa L Hanna (Terry)	Theresa Hanna	1/26/15
First name, MI, Last name of Co-Investigator		
First name, MI, Last name of Co-Investigator		
First name, MI, Last name of Co-Investigator		

APPENDIX A

REFERENCES

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PROTOCOL REVIEW, SUPPORT, APPROVAL SHEET

PROTOCOL NUMBER: - 35 - 15-01-01 (SUB-JONO / TEST TYPE / IACUC NUMBER)	TITLE: Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke

1. SCIENTIFIC MERIT (PEER REVIEW)			
1a. Printed Name (First, MI, Last) Emily N. Reinke	1b. Title Biologist	1c. Signature REINKE.EMILY.NICOLE.1447560628	1d. Date (yyyy/mm/dd) 20141113
2. DIRECTOR			
2a. Printed Name (First, MI, Last) Mark S. Johnson	2b. Title Portfolio Director, Toxicology	2c. Signature Click to Approve	2d. Date (yyyy/mm/dd)
3. PROGRAM MANAGER			
3a. Printed Name (First, MI, Last) Arthur J. O'Neill	3b. Title Program Manager, Toxicity Evaluation	3c. Signature Click to Approve	3d. Date (yyyy/mm/dd)
4. ATTENDING VETERINARIAN			
4a. Printed Name (First, MI, Last) Mary E. Sprangel	4b. Title MAJ, VC Attending Veterinarian	4c. Signature SPRANGEL.MARY.E.1023776878	4d. Date (yyyy/mm/dd) 20141211
5. ANALYTICAL CHEMISTRY (If Applicable)			
5a. Printed Name (First, MI, Last) Jose M. Pizarro	5b. Title MAJ, Chief Molecular Biology Section	5c. Signature Click to Approve	5d. Date (yyyy/mm/dd)
6. SAFETY MANAGER			
6a. Printed Name (First, MI, Last) Roy A. Valiant	6b. Title Safety Manager	6c. Signature Click to Approve	6d. Date (yyyy/mm/dd)
7. STATISTICIAN (If Applicable)			
7a. Printed Name (First, MI, Last) Shane Hall	7b. Title Statistician	7c. Signature HALL.SHANE.1384276136	7d. Date (yyyy/mm/dd) 20141113

PROTOCOL NUMBER: - 35 - 15-01-01 (SUB-JONO / TEST TYPE / IACUC NUMBER)	TITLE: Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically Disseminated M18 Red Smoke		
8. SIO-QAT (GLP COMPLIANCE AND QA SUPPORT)			
8a. Printed Name (First, MI, Last) Michael P. Kefauver	8b. Title QSRC	8c. Signature Click to Approve	8d. Date (yyyy/mm/dd)
9. CHAIRMAN, IACUC			
9a. Printed Name (First, MI, Last) Kristin T. Newkirk	9b. Title Animal Care & Use Specialist, Chairman, IACUC	9c. Signature NEWKIRK.KRISTIN.TORELL.1014786895	9d. Date (yyyy/mm/dd) 20150126
10. INSTITUTIONAL OFFICIAL			
10a. Printed Name (First, MI, Last) John J. Resta	10b. Title Director, IPH	10c. Signature RESTA.JOHN.J.1229129305	10d. Date (yyyy/mm/dd) 20150127
11. STUDY DIRECTOR/PRINCIPAL INVESTIGATOR			
11a. Printed Name (First, MI, Last) Lee C.B. Crouse	11b. Title Biologist, Toxicity Evaluation Program	11c. Signature CROUSE.LEE.1239523265	11d. Date (yyyy/mm/dd) 20150128
12. OTHER ORGANIZATION(S) PROVIDING SUPPORT (AS NEEDED):			
12a. Printed Name (First, MI, Last)	12b. Title	12c. Signature	12d. Date (yyyy/mm/dd)
13. STUDY SPONSOR:			
13a. Printed Name (First, MI, Last)	13b. Title	13c. Signature	13d. Date (yyyy/mm/dd)

USACHPPM PROTOCOL MODIFICATION

For use of this form, see DTOX SOP 085

1. DATE: (YYYY/MM/DD) 2015/06/26	2. PROTOCOL NUMBER: 35-15-01-01	3. MODIFICATION#: 1

4. PROTOCOL TITLE: Acute and Subacute Inhalation Toxicity Study in Rats Exposed to Pyrotechnically-Disseminated M18 Red Smoke

5. STUDY DIRECTOR/PRINCIPAL INVESTIGATOR:	6. WORK PHONE:	7. OFFICE SYMBOL:
Lee Crouse	410-436-5088	MCHB-IP-TEP

SECTION I. PREVIOUSLY APPROVED AND CURRENTLY IN USE PROTOCOL MODIFICATIONS:

1. MODIFICATION NUMBER	2. SHORT DESCRIPTION OF PRIOR APPROVED MODIFICATION(S)	3. NO. & SPECIES OF ANIMAL REQUESTED	4. APPROVED DATE (XX XXX XXXX)

SECTION II. CHANGE IN TOTAL # OF ANIMALS USED AND/OR CHANGE IN USDA PAIN CATEGORY

1a. CHANGE: INCREASE TOTAL APPROVED ANIMALS BY: 1b. N/A ☑

2. ORIGINAL PROTOCOL TOTAL: 102					3. PROTOCOL TOTAL AFTER MODIFICATION: 102				
2a. USDA pain cat:	B:	C: 15	D: 60	E. 27	3a. USDA pain cat:	B:	C: 15	D: 60	E: 27

4. Yes	No	
☑	☐	Modification requires specific changes or additions to the experimental design of the protocol. (Section V.I. of the template.)
☐	☑	Modification requires changes to the technical methods, i.e., procedures, routes of administration, biosample collection, etc. (Section V.4. of the protocol template.) Indicate training of personnel for new methods, procedures being used.
☐	☑	Modification requires additions or changes in personnel performing procedures. (Section VI of the protocol template.) Include training and qualification information and tasks that each individual will be performing. If changing the Study Director/PI, a signed Assurance Statement needs to be submitted with the modifications.

SECTION III. MODIFICATION/JUSTIFICATION

Explain the modification indicated above in the area below. Indicate any changes to the 3R's (Refinement, Reduction, Replacement) resulting from changes in number of animals

PROTOCOL Page, paragraph, section	
Page 6, V.1., Page 7, V.1.1., Page 10, V.1.1.5. & V.1.1.6.	1. MODIFICATION: One acute exposure with 5 male and 5 female rats has already been completed at a limit concentration of 2 mg/L. The protocol allows for up to 2 additional acute exposures (5 male and 5 female rats each) if needed for an LC50 determination. This modification is requesting the use of these 20 rats but not for a traditional LC50 determination (justification provided below). Five male and 5 female animals will be exposed again to a targeted red smoke concentration of 2 mg/L. Three male and 3 female animals will receive a gross necropsy the day after this exposure and 2 male and 2 female animals will receive a gross necropsy after the traditional 14-day observation period. If the lung lesions observed during the first round of acute exposures are again observed in any of the animals used for the second round of acute exposures (regardless of scheduled recovery time prior to necropsy), this modified necropsy schedule will be repeated at a lower targeted red smoke concentration with 10 rats in an attempt to determine a safe level of acute exposure. If no lung lesions are observed as a result of the second round of acute exposures, no additional animals will be required. This modification is not requesting any additional animals beyond those already approved in the original protocol.
	1a. JUSTIFICATION/REASON: This first acute exposure at a limit concentration of 2 mg/L did not produce any mortality; however, moderate/severe lung lesions were observed in all 10 animals during gross necropsy following a 2-week recovery period. These lesions were not observed in any of the repeated-exposure animals (10 exposures total) exposed to red smoke at an average concentration up to and including 1.5 mg/L. Microscopic evaluation of a small sample of the lungs from the acute exposure revealed effects similar to those observed with a respiratory illness such as emphysema. Although the additional animal exposures would not be used for a traditional LC50 determination, the information gained will be used to determine if the effects observed were due to a pre-existing respiratory illness or were caused by exposure to the red smoke. In addition, the different necropsy times proposed for the second round of acute exposures will also determine if the lung lesions observed were the result of a response mechanism by the lungs in an attempt to repair themselves following exposure or were present the day following exposure. The proposed third round of acute exposures, if needed, would be used to determine a safe level of acute exposure for soldiers using these smoke grenades.

PROTOCOL Page, paragraph, section	*Explain the modification indicated above in the area below. Indicate any changes to the 3R's (Refinement, Reduction, Replacement) resulting from changes in number of animals used.*
	2. MODIFICATION:
	2a. JUSTIFICATION/REASON:
	3. MODIFICATION:
	3a. JUSTIFICATION/REASON:
	4. MODIFICATION:
	4a. JUSTIFICATION/REASON:

Continued on next page YES ☐ NO ☑

SECTION IV. SIGNATURES AND DATES

1. STUDY DIRECTOR: (Printed Name) Lee Crouse	Signature	DATE: (yyyy/mm/dd) 2015/07/07
2. PROGRAM MANAGER:: (Printed Name) ARTHUR J. O'NEILL	Signature	DATE: (yyyy/mm/dd) 2015/07/07
3. ATTENDING VETERINARIAN: (Printed Name) LTC Ken Despain	Signature	DATE: (yyyy/mm/dd) 2015/07/07
4. CHPPM SAFETY OFFICER/OCC HEALTH REP: (IF APPLICABLE)	Signature	DATE: (yyyy/mm/dd)
5. CHAIR, IACUC OR QA (If no animal related changes): (Printed Name) Kristin Newkirk	APPROVED / REVIEWED YES ☒ NO ☐ Signature	DATE: (yyyy/mm/dd) 2015/07/07