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Domestic Preparedness Program: Phase 2 Sarin Vapor Challenge and Corn-Oil Protection Factor (PF) Testing of Commercial Air-Purifying Negative Pressure Respirators

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PREFACE

The work described in this report was authorized under the Expert Assistance Program for the U.S. Army Edgewood Chemical Biological Center (ECBC) Homeland Defense Business Unit. The work started in March 2001 and was completed in August 2001.

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DOMESTIC PREPAREDNESS PROGRAM: PHASE 2 SARIN VAPOR CHALLENGE AND CORN-OIL PROTECTION FACTOR (PF) TESTING OF COMMERCIAL AIR-PURIFYING NEGATIVE PRESSURE RESPIRATORS

1. INTRODUCTION

In 1996, Congress passed Public Law 104-201 (Defense Against Weapons of Mass Destruction Act of 1996), directing the Department of Defense (DoD) to assist other federal, state, and local agencies in enhancing preparedness for terrorist attacks using weapons of mass destruction. The DoD responded by forming the Domestic Preparedness Program that same year. One of the objectives of the Domestic Preparedness Program is to enhance federal, state and local emergency and hazardous material (HAZMAT) response to nuclear, biological and chemical (NBC) terrorism incidents. As part of an effective response, emergency and HAZMAT personnel who are responding to an incident will use personal protective equipment (PPE) to protect them from exposure to chemical agents or biological agents. The specific PPE that would be used by these federal, state and local emergency and HAZMAT personnel would depend upon the situation encountered and what PPE is held in inventory. In some cases, commercial respirator systems with canisters/cartridges may be used to enter a contaminated or potentially contaminated area.

This program tasked the Edgewood Chemical Biological Center (ECBC) of Soldier and Biological Chemical Command (SBCCOM) to perform chemical agent testing of commercial respirator systems and canisters/cartridges. A cartridge is distinguished from a canister by virtue of the quantity of adsorbent, i.e., a canister contains more than 150 mL of adsorbent and a cartridge contains less.

For this phase of the program five different NIOSH-approved airpurifying negative pressure respirators were selected. A negative pressure respirator (tight-fitting) is a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator. A tightfitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

A glossary of terms used is included as the Appendix of this report.

2.

OBJECTIVES AND RESPIRATORS' DESCRIPTIONS

The objectives of this project were threefold: 1) to determine the protective potential of some commercial air-purifying full facepiece negative pressure respirators against GB vapor; 2) to determine the adsorption efficiency of the canister/cartridge to GB vapor; and 3) to determine the protection factor (PF) for the respirators.

The respirators selected to be tested in this phase of the project are as

follows:

- Avon AVFM12 Mask with NBC Protection Canister
- Avon AVSF10/2 Mask with NBC Protection Canister
- Draeger Kareta M65 Mask with NBC Canister
- Micronel M-95 Respirator with NBC Filter Cartridges
- 3M FR/M40-20 Full Facepiece Respirator with FRC2A1 Gas Filter

3. CHEMICAL AGENT TESTING

3.1 <u>Chemical Agent Testing Equipment.</u>

3.1.1 <u>Vapor Generator</u>.

GB vapors were generated by using a syringe pump that injected liquid GB into a heated tee in the air dilution line. The rate of injection was such that the concentration was controlled to that specified in the test plan. The GB vaporized in the heated tee, was carried by the dilution air into the mixing chamber, thence into the exposure chamber. An Ambient Air Analyzer, (MIRAN) model 1A was used to monitor the concentration in the test chamber during the test.

3.1.2 <u>Negative Pressure Respirator (NPR) Test Chamber</u>.

The test chamber for the NPRs was a Plexiglas box approximately 2 feet cubed with a removable front panel and four legs on the bottom about 4 inches long, which allowed air to flow under the chamber when it was located inside a fume hood. A test fixture, called SMARTMAN (SiMulant Agent Resistant Test MANikin), which is a human head form, medium size, with a movable facepiece and an inflatable peripheral seal, was attached to the floor of the chamber. The mouth orifice of the head form was connected by a large tube to a breather pump; there were also two sampling tubes in the nose, one in the eye, and one in the forehead. All these tubes pass down through the interior of the head form, down through the floor of the chamber, and connect to remote detectors and the breather pump or other monitoring devices, such as pressure gauges. Since agent-air mixture passes through the test chamber during the test, the outlet ports on top of the chamber are covered by military M12A1 filters to scrub agent from the air passing through. Other ports in the chamber walls are used for introducing the agent challenge into the chamber, to attach pressure gauges for monitoring pressure, to introduce oil aerosol for preliminary leak testing of an installed respirator, or to monitor the agent concentration inside the chamber.

3.1.3 <u>Cartridge/Canister Test Chamber.</u>

The test chamber for the canister comprises two parts, the base plate and the cover. Both parts are machined from stainless steel. The assembled chamber is a closed cylinder. The base plate has a raised portion and a somewhat wider rim; when the cover is in place the bottom of the cover rests on the rim while the raised portion of the base plate seals against the inside of the cover by means of O-rings. In the center of the base are an orifice and an adapter machined to accommodate a NATO thread of a canister. Another orifice is offset from the center and is machined with pipe threads; agent challenge is introduced into the chamber by this means. The chamber, when closed, accommodates a canister up to the size of a C2A1. The center orifice is connected by a line outside the chamber to a vacuum source of a breather pump in order to pull the agent challenge through the chamber. A rotameter and a scrubber filter are placed in this line; there is also a connection between the rotameter and the test chamber for a detector used to monitor GB agent breakthrough.

3.1.4 <u>Breather Pump</u>.

The Military Breather Pump E1R1 (Jaeco Fluid Systems, Inc, Exton, PA) was used to simulate breathing through the respirator. This is a reciprocating pump that produces a sinusoidal breathing pattern by means of a reduction planetary gear system that incorporates a Scotch Yoke. With each piston stroke the flow rate starts at zero liters per minute, rises to a peak flow midway through the stroke and falls back to zero at the end of the stroke. During the initial stroke air is pulled from the test chamber through the respirator (including the canister); on the return stroke this air is exhausted through the exhalation valve of the respirator. The two pump strokes, forward and reverse, produce a complete sine wave pattern. The peak flow produced by this pump is approximately pi times the minute volume. The minute volume (liters pumped in 1 min) and the number of strokes per minute (breaths) can be adjusted on this pump.

3.2 <u>Chemical Agent Testing Methods</u>.

3.2.1 <u>Respirator Systems.</u>

The respirator system, including an attached canister or cartridge, was mounted on the SMARTMAN by tightening the straps of the harness. The peripheral seal was inflated (3-5 psig) to form a seal against the inside of the face blank of the respirator. Before an agent test was started, an aerosol leakage test was performed, using the TDA-99M Aerosol Leak Tester. The detector section of the tester was connected to one of the SMARTMAN sampling ports inside the respirator, and the aerosol was directed against the respirator through a wand. The breather pump was turned on during the leak test. If no leak was detected, then the chamber was closed and the aerosol was injected into the test chamber. If an aerosol leak was detected, the leak path was found and corrected. If there was no leak, the agent test was performed. For the GB test, a MINICAMS® detector was connected to two ports in the eye and nose areas, to monitor for the presence of GB inside the respirator. The GB challenge, generated as described above (Section 3.1.1), was passed from the mixing chamber into the NPR test chamber. The conditions used for testing are listed in Table 1.

Table 1 - Conditions for Testing Respirator Systems				
Rate of air flow through exposure chamber	50 L/min			
Concentration of challenge GB	200 mg/m^3			
Breakthrough concentration limit	0.0001 mg/m^3			
Total test time if breakthrough is not observed	60 min or 6 hr			
Precondition of cartridge/canister	25°C/50% RH/6 hr			
Temperature of test chamber	25±3°C			
Flow rate of breather pump	25 L/min			
Pump strokes per minute	25			
Volume per breath	1 L			

3.2.2 <u>Cartridges/Canisters</u>.

The cartridges/canisters were tested separately to establish their performance against a GB vapor challenge. Twenty-two canisters (of each type) were tested. This number represents 90% reliability at 90% confidence level when no failures occur amongst the 22 items tested. The canisters were preconditioned at 50% relative humidity (RH) and 25 C for 6 hr before agent testing. The purpose of the preconditioning was to establish a uniform level of moisture on the adsorbent similar to what might be encountered in use, and that would not adversely affect the adsorption of GB. Testing the canisters alone would also allow one to infer if a system failure occurs that the reason is either the respirator or the canister. Each canister was tested for 60 min, which is the maximum time the system is expected to be used. The test conditions are listed in Table 2.

Table 2 - Conditions for T	esting Cartridges/Canisters
GB challenge concentration	200 mg/m ³
Flow rate, NPR canisters	25 L/min
Breakthrough concentration	0.0001 mg/m^3
Test time if breakthrough is not observed	1 hr
Precondition of cartridge/canister	
Temperature of test chamber	25°C/50% RH/6 hr
Relative humidity of test air	25±3°C
iterative number y of lest air	50±5%

Table 2 - Conditions for Testing Cartridges/Canisters

3.3 <u>Chemical Agent Test Results and Discussions.</u>

3.3.1 Full Respirator on Head Form.

The negative pressure respirators were tested for a period of 1 hr, with the exception that one of each was tested for 6 hr. The results are tabulated in Table 3. The concentration of GB inside the respirator at the nose sampling port is given in ng/L at the end of 1 or 6 hr.

Respirator	ng/L	ng/L
	1 hr	6 hr
Avon AVFM12	0.0	
Avon AVFM12	0.75	
Avon AVFM12	0.93	4.65
Avon AVSF 10/2	0.0	
Avon AVSF10/2	0.0	
Avon AVSF10/2	0.0	1.0
Draeger Kareta M65	0.3	
Draeger Kareta M65	0.5	
Draeger Kareta M65	0.75	5.8
Micronel M-95	0.0	
Micronel M-95	0.0	
Micronel M-95	0.0	0.0
3M FR/M40-20	0.0	-
3M FR/M40-20	0.0	
3M FR/M40-20	0.0	0.0

Table 3 - Concentration of GB Inside Respirator (acceptable concentration is <0.1 ng/L)

3.3.2 <u>Cartridges/Canisters</u>.

Cartridges/canisters for the negative pressure respirators were tested for GB under the conditions stated above. None of the cartridges/canisters showed penetration of GB.

3.3.3 <u>Discussion</u>.

Because none of the cartridge/canister tests showed any GB penetration, it is unlikely that any of the GB detected inside the respirators during the system tests penetrated the cartridges/canisters. Each system had an aerosol leak test performed before the agent test to assure that any agent detected inside the respirator did not enter by the sealed surfaces or the exhalation valves. Three of the five NPRs allowed no permeation within the first hour and two of the five allowed no permeation in 6 hr.

4. **PROTECTION FACTOR TESTING**

4.1 <u>Corn-Oil Testing Equipment.</u>

A challenge aerosol concentration of approximately 20-40 mg/m³, polydispersed corn-oil aerosol having a mass median aerodynamic diameter (MMAD) of 0.4-0.6 microns (the Army Standard) was generated in a 10-ft \times 10-ft \times 32-ft test chamber. The test chamber challenge aerosol was generated by atomizing liquid corn-oil at room temperature using a Laskin nozzle. The Laskin nozzle produced a coarse aerosol cloud, which was directed into an impaction plate to remove the larger particles and yield an aerosol in the desired size range. The concentrated aerosol from the generator was diluted with filtered ambient air to control the challenge aerosol concentration in the exposure chamber.

A 6-decade, 45 degree off-axis light-scattering laser photometer, sampling at a flow rate of 1-2 L/min, was used to quantify concentration of the challenge and the in-mask corn-oil aerosols. For a given particle size, the quantity of scattered light is proportional to the aerosol concentration. The photometer converted the quantity of scattered light to a voltage, which was then digitized and recorded by a microcomputer.

The respirator sampling port was connected from the masks oro-nasal cavity to the photometer with flexible silicone tubing to measure the amount of aerosol penetrating the mask. A Tygon® sampling tube line was connected from the exposure chamber sampling port to the photometer to determine the challenge aerosol concentration.

4.2 <u>Protection Factor Testing Method.</u>

4.2.1 <u>Test Procedure</u>.

Each respirator was donned by military volunteers and challenged, on separate dates, with the corn-oil aerosol. The number of volunteers for each test ranged from 6 to 24, and 12 respirators were used of each model. Prior to testing, each test volunteer was given an orientation in which the PF test was explained by ECBC personnel and a volunteer agreement was signed by each test volunteer. The minimum number of trials necessary is 22 to give a statistical validity or 90% reliability at a 90% confidence level. Additional trials may have been performed simply to provide a larger sample.

All volunteers had anthropometric measurements taken of their facial features, and then they were given a respirator and asked to wear their normal clothing (Battle Dress Uniform (BDU)). The test volunteers were then led into the aerosol exposure chamber, 8 at a time, by ECBC personnel, hooked up to their photometer stations, and asked to perform a standard Army PF Test devised to stress the face seal of the respirator, namely the following ten exercises for 1 min each:

- 1. Normal Breathing
- 2. Deep Breathing
- 3. Turn Head Side to Side
- 4. Move Head Up and Down
- 5. Recite the Rainbow Passage (Reading a paragraph aloud to stress talking)
- 6. Sight the Rifle
- 7. Reach for the Floor and Ceiling
- 8. On Hands and Knees, Turn Head Side to Side
- 9. Facial Expressions
- 10. Normal Breathing

The test equipment operator monitored and communicated with the test volunteers on when to start an exercise, finish an exercise, and exit the aerosol chamber, and monitored their performance. All exercises were completed by the test volunteers without the intervention of test personnel. The raw data was collected by a computerbased system and stored for later analysis.

4.2.2 Data Analysis.

Mask performance was quantified in terms of a protection factor (PF). The PF was calculated by determining the ratio of the challenge aerosol concentration to the in-mask aerosol concentration as quantified by integrating the peak voltage output from the photometer over the time interval (nominally one minute). A PF was calculated for individual exercises (PF_i). The individual PFs were then used to calculate an overall PF for a subject (PF_o) as follows:

$$PF_o = n \left(\sum_{i=1}^n \frac{1}{PF_i} \right)^{-1}$$

where n is the number of exercises. The overall PF provides a time-integrated measure of the protection afforded. It is somewhat analogous to calculating the total resistance of resistors in parallel in an electronic circuit. The PF_0 is affected most by the smallest PFs. Under the conditions of this test and the sensitivity of the photometer, the maximum PF that can be reported is 100,000. The PFs were calculated by a computer.

4.3 Protection Factor Test Results and Discussion.

Because these were commercially available respirators there were no Army requirements established for these respirators. Therefore, we took the conservative approach and reported the data in pass and fail percentages for each respirator configuration at selected PF levels. These PF tests were performed to provide useful information to federal, state and local emergency and hazardous materials (HAZMAT) teams operating in a chemical agent environment. The pass percentages included in the summary tables are based on the PF levels used by the U.S. Army. The test data are summarized below in Tables 4 - 8. The first column lists each range of PF computed. The second column is the number of test trials falling within each calculated PF range. The third column presents the cumulative-percentage of test trials that resulted in a PF below the lower limit of the range and the fourth column presents the percentage of trials that exceed the lower limit of the range shown. The final PF range shown may be over 100,000, but the current data acquisition system cannot measure PF over 100,000, so it truncates the data and puts all the remaining subjects in the final range.

Table 4 shows that the Avon FM-12 Mask with NBC Protection Canister

had:

- Pass percentage of 87.1% at the 50000 PF level.
- Pass percentage of 100% at the 20000 PF level.

PF	Frequency	Cumulative %	Pass %	
0	0	.00%	100.00%	
10	0	.00%	100.00%	
50	0	.00%	100.00%	
100	0	.00%	100.00%	
500	0	.00%	100.00%	
1000	0	.00%	100.00%	
1667	0	.00%	100.00%	
2000	0	.00%	100.00%	
5000	0	.00%	100.00%	
6667	0	.00%	100.00%	
10000	0	.00%	100.00%	
20000	0	.00%	100.00%	
50000	4	12.90%	87.10%	
100000	27	100.00%	.00%	

Table 4 - Avon FM-12 Mask with NBC Protection Canister Results

Table 5 shows that the Avon AVSF10/2 Mask with NBC Protection d:

Canister had:

- Pass percentage of 75% at the 50000 PF level.
- Pass percentage of 93.75% at the 10000 PF level.
- Pass percentage of 93.75% at the 6667 PF level.
- Pass percentage of 96.88% at the 1667 PF level.
- Pass percentage of 100% at the 1000 PF level.

PF	Frequency	Cumulative %	Pass %
0	0	.00%	100.00%
10	0	.00%	100.00%
50	0	.00%	100.00%
100	0	.00%	100.00%
500	0	.00%	100.00%
1000	0	.00%	100.00%
1667	1	3.13%	96.88%
2000	0	3.13%	96.88%
5000	0	3.13%	96.88%
6667	1	6.25%	93.75%
10000	0	6.25%	93.75%
20000	1	9.38%	90.63%
50000	5	25.00%	75.00%
100000	24	100.00%	.00%

Table 5 - Avon AVSF10/2 Mask with NBC Protection Canister Results

Table 6 shows that the 3M FR/M40-20 Full Facepiece Respirator with FRC2A1 Gas Filter had:

- Pass percentage of 96.23% at the 50000 PF level.
- Pass percentage of 100% at the 10000 PF level.

PF	Frequency	Cumulative %	Pass %
0	0	.00%	100.00%
10	0	.00%	100.00%
50	0	.00%	100.00%
100	0	.00%	100.00%
500	0	.00%	100.00%
1000	0	.00%	100.00%
1667	0	.00%	100.00%
2000	0	.00%	100.00%
5000	0	.00%	100.00%
6667	0	.00%	100.00%
10000	0	.00%	100.00%
20000	2	3.77%	96.23%
50000	0	3.77%	96.23%
100000	51	100.00%	.00%

Table 6 - 3M FR/M40-20 Full Facepiece Respirator with FRC2A1 Gas Filter Results

Table 7 shows that the Micronel M-95 Respirator with NBC Filter Cartridges had:

- Pass percentage of 78.13% at the 50000 PF level.
- Pass percentage of 78.13% at the 10000 PF level.
- Pass percentage of 78.13% at the 6667 PF level.
- Pass percentage of 78.13% at the 1667 PF level.
- Pass percentage of 100% at the 50 PF level.

PF	PF Frequency Cumulative %		Pass %
0	0	.00%	100.00%
10	0	.00%	100.00%
50	0	.00%	100.00%
100	5	15.63%	84.38%
500	0	15.63%	84.38%
1000	2	21.88%	78.13%
1667	0	21.88%	78.13%
2000	0	21.88%	78.13%
5000	0	21.88%	78.13%
6667	0	21.88%	78.13%
10000	0	21.88%	78.13%
20000	0	21.88%	78.13%
50000	0	21.88%	78.13%
100000	25	100.00%	.00%

Table 7 - Micronel M-95 Respirator with NBC Filter Cartridges' Results

Table 8 shows that the Draeger Kareta M65 Mask with NBC Canister had:

- Pass percentage of 8.33% at the 50000 PF level.
- Pass percentage of 16.67% at the 10000 PF level.
- Pass percentage of 25% at the 6667 PF level.
- Pass percentage of 41.67% at the 1667 PF level.
- Pass percentage of 75% at the 50 PF level.

PF	Frequency	Cumulative %	Pass %
0	0	.00%	100.00%
10	2	8.33%	91.67%
50	4	25.00%	75.00%
100	3	37.50%	62.50%
500	3	50.00%	50.00%
1000	2	58.33%	41.67%
1667	0	58.33%	41.67%
2000	0	58.33%	41.67%
5000	3	70.83%	29.17%
6 667	1	75.00%	25.00%
10000	2	83.33%	16.67%
20000	1	87.50%	12.50%
50000	1	91.67%	8.33%
100000	24	100.00%	.00%

Table 8 - Draeger Kareta Mask with NBC Canister M65

5. CONCLUSIONS

A total of 110 cartridges/canisters (22 each of 5 models) were tested against a concentration challenge of 200 mg/m³ of Sarin (GB). The cartridges/canisters were tested for 1 hr. None of the cartridges/canisters showed any penetration of GB.

Fifteen air-purifying negative pressure respirators (3 sizes of each model) mounted on the SMARTMAN head form were tested against a concentration challenge of 200 mg/m³ of GB. Three of the five NPRs allowed no permeation within the first hour and two of the five allowed no permeation in 6 hr.

PF testing was performed wearing the respirators in accordance with the U.S. Army PF testing standard (available upon request) for negative pressure respirators used in a chemical-biological environment. As shown below, Table 9 summarizes the pass percentages at selected PF levels for the 5 NPRs tested.

Table 9 - Summary of Pass Percentages for Negative Pressure Respirators at Selected PF Levels

PF Level	Avon FM -12	Avon AVSF10/2	3M – FR/M 40-20	Micronel M-95	Draeger Kareta M65
1667	100.00%	96.88%	100.00%	78.13%	41.67%
6667	100.00%	93.75%	100.00%	78.13%	25.00%
10000	100.00%	93.75%	100.00%	78.13%	16.67%

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APPENDIX

GLOSSARY

Air-Purifying Respirator

These respirators contain an air-purifying filter, cartridge, or canister that removes specific contaminants by passing ambient air through the air-purifying element. These do not supply oxygen and must be used only when there is sufficient oxygen to sustain life and the air contaminant is below the concentration limits of the cartridge/canister. In addition, these cartridge/canisters usually do not include any method of indicating when their ability to remove air contaminants has been reduced.

Breather Pump

A pump used to simulate human breathing through a filter. The pump is a piston pump designed to begin the stroke at zero flow, rise to a maximum (peak) flow at midstroke, and decrease to zero at the end of the stroke. The resultant flow is sinusoidal, that is, shaped like a sine wave when plotted. The pump stroke can be adjusted to change the volume of air per stroke over a finite range; some pumps are capable of changing the number of strokes per minute.

Canister (Air-Purifying)

A container filled with sorbents, catalysts and filters that removes gases, vapors, and/or particulates from air drawn through the unit. Canisters rely on a variety of mechanisms for contaminant removal such as chemical absorption, adsorption, catalytic action, neutralization, and mechanical filtration.

Cartridge

A container filled with sorbents, catalysts, and filters that removes gases, vapors, and/or particulates from air drawn through the unit. Cartridges are smaller than canisters (<150 ml capacity) but are designed to work on the same principles.

<u>DoD</u>

Department of Defense

ECBC

Edgewood Chemical Biological Center

Exhalation Valve

A device that allows exhaled air to leave a respiratory device and prevents outside air from entering through the valve while inhaling.

Facepiece

The portion of a respirator that covers the wearer's nose and mouth (a full facepiece also covers the eyes). The facepiece should make a gas-tight or dust-tight seal with the face. The facepiece is supported by headbands, and contains inhalation valves, exhalation valves, and connectors for the air-purifying cartridges or filters.

<u>Filter</u>

A fibrous medium used in respirators to remove solid or liquid particulates from the air before it enters the facepiece (this term may be used interchangeably with cartridge).

Fit Factor (FF)

A Fit Factor is a number that is the direct result of a quantitative respirator fit test. It is a measurement made by an instrument during a simulation of workplace activities or scenarios. It is expressed as the challenge aerosol concentration outside the respirator divided by the challenge aerosol concentration that leaks inside the respirator during a Fit Test.

NPR, Negative Pressure Respirator

This is a respirator that fits tightly to the face; it has a negative (lower) air pressure inside the facepiece with respect to ambient air pressure outside the respirator during inhalation.

SBCCOM

Soldier and Biological Chemical Command

Inhalation Valve

A device that allows air to enter the facepiece through the filtering media but prevents exhaled air from leaving the facepiece through the intake openings.

MINICAMS®

Trade name for a chemical agent detector in which the agent is adsorbed from a specified volume of air onto an adsorbent tube which is then desorbed into the injection port of a gas chromatograph for analysis (quantitation). The acronym stands for "Miniature Continuous Air Monitoring System."

Particulate Matter

A suspension of fine solid or liquid particles in air, i.e., dust, fog, fume, smoke, or sprays. Particulate matter suspended in air is commonly known as an aerosol.

Protection Factor

The overall protection afforded by a certain type of respirator as defined by the ratio of the concentration of contaminant outside a facemask or hood to that inside the mask while in a contaminated atmosphere. The protection factor as used in this report is the overall factor calculated from individual fit factors determined on a number of human volunteers for each of several exercises performed while wearing the respirator.

<u>Sarin</u>

An organophosphorus nerve agent, known by the military symbol GB. The chemical name is isopropyl methylphosphonofluoridate. GB reacts with the enzyme cholinesterase, thus interfering with the transmission of nerve impulses.