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A literature review of disinfectants: effects when used by CF divers in cleaning rebreather sets

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Defence R&D Canada – Toronto
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Abstract

As a result of the health concerns expressed by the combat divers, the consultant in Diving and Hyperbaric Medicine at CFEME Toronto requested a toxicological review of the disinfectant *Virkon S* to determine its suitability for continued use as a cleaning/disinfectant of re-breather sets for the Canadian Forces (CF) diving community. An initial assessment of the components of Virkon S revealed the product had not been approved nor was it intended for human topical disinfection. As a result, a literature review was performed on *Virkon S*, but as well the review was expanded to include other disinfectants used by civilian and military divers around the world. The aim was to assess the health hazards of using disinfectants to clean re-breathers, as well as, assess the capability of disinfectants to kill the full spectrum of biological contaminants (bacterial, viral, and fungal) to which divers might be exposed.

Nine disinfectants were found to be used by divers nationally and internationally (*Virkon S., Sanizide, Confidence, Advance TBE, BI-Arrest, Buddy Clean, Trigene II, Listerine, Cavicide*) and all were evaluated against the same criteria. In order to be recommended for use two mandatory criteria had to be complied with; the product had to exhibit an absence of components that would cause undue risk to human health during use that could not be prevented by reasonable protective measures, and proof must be available to indicate the disinfectant was effective. Products should be able to kill the full spectrum of viruses, bacteria and fungi that divers could be exposed while using a re-breather. Two further considerations were applied in reviewing all disinfectants, compatibility with system components and ease of use.

Based upon the above criteria the review of these nine disinfectants revealed that only two products, *Virkon S* and *TriGene II*, met all of the criteria considered essential for use by CF divers using rebreather equipment. Although both products have met all of the minimum criteria, *Virkon S* is recommended as the continued disinfectant of choice for the CF as it has been shown to be able to provide a more rapid and more complete microbial kill than *TriGene II*. It is thus considered a better disinfectant.

Résumé

Par suite des inquiétudes d'ordre médical manifestées par les plongeurs de combat, le conseiller en matière de médecine hyperbare et de plongée du Centre de médecine environnementale des Forces canadiennes (CMEFC) à Toronto a demandé une vérification toxicologique du désinfectant *Virkon S,* afin que l'on détermine s'il convient de continuer d'utiliser ce produit pour nettoyer/désinfecter les appareils à circuit fermé des plongeurs des Forces canadiennes (FC). Un premier examen des constituants du *Virkon S* a révélé que ce produit n'avait pas été approuvé pour des fins de désinfection topique chez des humains et qu'il n'avait pas été conçu à cette fin non plus. À la lumière de cette découverte, on a entrepris un examen de la littérature sur *Virkon S,* ainsi que sur d'autres désinfectants utilisés par les plongeurs civils et militaires dans le monde. Le but de cet examen était d'évaluer les risques pour la santé que pose l'utilisation de désinfectants pour nettoyer les appareils à circuit fermé et d'évaluer la capacité de ces produits de tuer tous les contaminants biologiques (bactériens, viraux et fongiques) auxquels les plongeurs peuvent être exposés.

L'examen a révélé que neuf désinfectants sont utilisés par les plongeurs au Canada et ailleurs dans le monde (*Virkon S., Sanizide, Confidence, Advance TBE, BI-Arrest, Buddy Clean, Trigene II, Listerine, Cavicide*); ces produits ont tous été évalués en fonction des mêmes critères. Pour que l'utilisation d'un produit donné soit recommandée, deux critères obligatoires devaient être remplis : le produit devait être exempt de constituants qui, lors de l'utilisation du produit, pouvaient présenter un risque inacceptable pour la santé humaine (risque qui ne pouvait être prévenu par des moyens de protection raisonnables), et il devait y avoir des preuves attestant l'efficacité du produit. Les désinfectants devaient aussi tuer tous les virus, bactéries et champignons auxquels les plongeurs peuvent être exposés lorsqu'ils utilisent un appareil à circuit fermé. Deux autres critères ont été utilisés dans l'évaluation des désinfectants, soit leur compatibilité avec les composants de l'appareil et leur facilité d'utilisation.

L'évaluation des neuf désinfectants en fonction des critères indiqués précédemment a révélé que seuls deux produits, *Virkon S* et *TriGene II,* remplissent tous les critères considérés comme essentiels en vue d'une utilisation par les plongeurs des FC se servant d'appareils à circuit fermé. Même si les deux produits ont rempli tous les critères minimaux, on recommande aux FC de continuer d'utiliser le désinfectant *Virkon S,* car ce produit a une activité microbicide plus efficace et plus rapide que le *TriGene II.* Nous considérons donc le *Virkon S* comme un meilleur désinfectant.

Executive summary

As a result of the health concerns expressed by the combat divers the consultant in Diving and Hyperbaric Medicine at CFEME Toronto requested a toxicological review of the disinfectant *Virkon S* to determine its suitability for continued use as a cleaning/disinfectant of re-breather sets for the Canadian Forces (CF) diving community. An initial assessment of the components of Virkon S revealed the product had not been approved nor was it intended for human topical disinfection. As a result, a literature review was performed on *Virkon S*, but as well the review was expanded to include other disinfectants used by civilian and military divers around the world. The aim was to assess the health hazards of using disinfectants to clean re-breathers, as well as, assess the capability of disinfectants to kill the full spectrum of biological contaminants (bacterial, viral, and fungal) to which divers might be exposed.

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Sommaire

Par suite des inquiétudes d'ordre médical manifestées par les plongeurs de combat, le conseiller en matière de médecine hyperbare et de plongée du Centre de médecine environnementale des Forces canadiennes (CMEFC) à Toronto a demandé une vérification toxicologique du désinfectant *Virkon S,* afin que l'on détermine s'il convient de continuer d'utiliser ce produit pour nettoyer/désinfecter les appareils à circuit fermé des plongeurs des Forces canadiennes (FC). Un premier examen des constituants du *Virkon S* a révélé que ce produit n'avait pas été approuvé pour des fins de désinfection topique chez des humains et qu'il n'avait pas été conçu à cette fin non plus. À la lumière de cette découverte, on a entrepris un examen de la littérature sur *Virkon S,* ainsi que sur d'autres désinfectants utilisés par les plongeurs civils et militaires dans le monde. Le but de cet examen était d'évaluer les risques pour la santé que pose l'utilisation de désinfectants pour nettoyer les appareils à circuit fermé et d'évaluer la capacité de ces produits de tuer tous les contaminants biologiques (bactériens, viraux et fongiques) auxquels les plongeurs peuvent être exposés.

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Introduction

Background

In 1994, clearance divers using Canadian Underwater Mine-countermeasures Apparatus (CUMA)/Canadian Clearance Diving Apparatus (CCDA) at the Experimental Diving Unit – CFEME Toronto experienced recurrent respiratory infections. The working hypothesis to explain this problem was the practice of sharing the rebreather sets, leading to the spread of viruses and bacteria between divers. Savlon solution (Chlorhexidine Gluconate - Cetrimide based) was the product used to clean the diving equipment after each dive. In an attempt to alleviate the respiratory symptoms experienced by the divers, an alternative cleaning agent was sought. The Diving Medicine Consultant at CFEME suggested Virkon S as a suitable replacement for Savlon. Virkon S appeared to solve the immediate problem and has since gained acceptance throughout the CF diving community.

The CFSME Army Dive Center recently expressed concerns regarding the use of Virkon S. It was purported to contain Glutaraldhehyde, which is a known health hazard inducing asthma [1] and other allergic reactions [2]. An initial review of the components of Virkon S revealed that it does not contain Glutaraldhehyde and is Health Canada approved for disinfection on external work surfaces, but has not been approved nor was it intended for human topical disinfection [3]. With this knowledge, the Consultant in Diving and Hyperbaric Medicine at CFEME Toronto expressed concerns over the use of Virkon S in the diving community, knowing that divers could potentially inhale the product after the equipment was cleaned.

Aim

Guided by the health concerns expressed by the CFEME Toronto Diving Medicine consultant, the aim of this literature review was twofold. To investigate the disinfectant Virkon S, as well as, other disinfectants used by civilian and military divers around the world to assess the health hazards of the product. Specifically, the health risks posed from any residue present within the counterlung after cleaning. Second, to assess the capability of disinfectants to kill the full spectrum of biological contaminants (bacterial, viral, and fungal) to which divers might be exposed.

Requirements/Criteria

In order to provide a thorough review, the following criteria were considered over and above those initially requested when evaluating a disinfectant for cleaning the CF CUMA/CCDA:

A mandatory requirement for a disinfectant is the **absence of components that will cause undue risk to human health** during use that **cannot be prevented by reasonable protective measures**. This would include potential exposures during the preparation of the solution, cleaning of the apparatus, as well as, exposure that may result from residue present while using the CUMA/CCDA;

A second mandatory requirement is that the disinfectant must be effective, and **should be able to kill the full spectrum of viruses, bacteria and fungi that divers could be exposed while using the CUMA/CCDA**. To determine the adequacy of the bactericidal properties data must be available that identifies the efficacy (killing capability) of the product against specific organisms;

Another major consideration in the assessment of a disinfectant is its **compatibility with system components** (does not degrade the equipment); and,

Consideration will also be given for ease of use and simplicity.

Methodology

The *disinfectant review* was limited to those products that were either officially or unofficially used by divers both nationally or internationally (US and UK) and therefore, this review should not be considered an exhaustive review of all available disinfectant products. Sources of information were obtained from Material Safety Data Sheets (MSDS), product information (chemicals and specific components) from the manufacturer, health and safety Web sites, and published literature on a products capacity to kill bacteria, viruses and fungi, as well as, the potential health risks presented from use (both chemical and biological exposure).

Results

Table 1: Disinfectant used by Canadian Forces Divers [4]

As indicated in the tables below the search identified nine different disinfectants.

Product	***Manufacturer or distributor***	***Notes***
Virkon S Peroxygen	Vetoquinol Canada Inc. Joliette, QC	Product also distributed by Syndel International Inc., Vancouver, BC and is manufactured by Antec Int, UK.

Note: With the exception of the Search And Rescue teams, CF divers solely use Virkon S. [4]

Table 2: Disinfectants recommended by the Naval Experimental Diving Unit (Panama, US) [5-7]

Product	***Manufacturer or Distributor***	***Notes***
Sanizide Plus Quaternary Ammonium Compound (QAC)	*Safetech of America* Buffalo, NY, US	Navy Experimental Dive Unit (NEDU, US Navy) tested the four products with gas chromatograph and mass spectrometry and found all to be safe for hyperbaric use [5].
Confidence Plus QAC	Ecolab Ltd St-Paul , Minnesota, US	NEDU currently use Confidence Plus [8].
Advance TBE QAC	Infection Control Technology Woods Cross, UT, US	*Quaternary Ammonium compounds contain NH_4, ammonium. [9]*
Bi-Arrest 2 Phenolic based	Infection Control Technology	

Note: Above products reviewed by NEDU, but no references cited. [10]

Table 3: Disinfectant used by some civilian divers in Europe

Product	*Manufacturer or Distributor*	*Notes*
Buddy lean Halogenated Tertiary Amine	Ambient Pressure Diving Ltd Cornwall, UK	HTA is a name given to chlorides (halogenated) and different amines.
Trigene Halogenated Tertiary Amine (HTA)	MediChem International Ltd. Kent, UK	Sachets are approved for use on HM Submarines in UK in accordance BR 1326 (A) under NATO stock number 6850-99-439-7179. Is suggested for the cleaning of breathing apparatus equipment [11]. Avisafe by Vetafarm, Australia is another HTA.

Table 4: Product used by different diving organizations [4, 12-15]

Product	*Manufacturer or Distributor*	*Notes*
Listerine Antiseptic Essential oil antiseptic	Pfizer Canada Inc Consumer Health Care Division, Toronto, ON	Listerine is known as an antiseptic mouthwash and many civilian rebreather divers use Listerine to clean their counterlung. Listerine has been suggested as an interim alternative replacement to clean divers equipment until disinfectant review is completed. [4]
Cavicide® Quaternary Amine with Alcohol [9]	Metrex Research Corporation Division of Sybron Canada Ltd Mississauga, On EPA Reg. No. 46781-6	Currently used by divers in Bermuda [16]

Disinfectant review

The disinfectants products used by the various diving organizations listed above have been reviewed according to the criteria stipulated in Para 4. The following tables identify each product, the composition if available, potential health risks, disinfectant effectiveness to kill a variety of bacteria, viruses and fungi (efficacy), and the impact of use on equipment.

Table 5: VIRKON S®

Sulfamic Acid 3-7% (powder)
Potassium Persulfate 10-30% (powder)

Health Hazards	*Microorganism killing ability (Efficacy)*	*Effects on equipment*
Powder form: Inhalation may cause coughing, choking or wheezing. Moderately irritating to eyes and skin. Chronic exposure effects have not been established. A 100% powder solution considered a moderate irritant. [17, 18]. No associated risk of occupational asthma as a result of exposure to Virkon components [19]. No abnormalities or histopathology reported on acute inhalation in rats [20]. Chronic exposure effects have not been established [3]. Liquid solution: 1% Virkon solution is considered a non-irritant to skin and eyes [21]. No vapour phase to Virkon: chemistry of Virkon defines that no vapour can be given off [22]. Approved by Health Canada as a surface sanitizer, DIN 02125021 [3].	Virus: 1% Virkon completely destroys Hepatitis B with complete loss of infectivity immediately after contact [23-25]. Effective against enveloped and non-enveloped viruses [26], and completely inactivates Measles, Yellow Fever, West Nile, Rift Valley Fever and Polio viruses in 10 min [27]. Bacteria: Kills Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia Coli and Bacillus subtilis in 22 seconds with 1% Virkon [28]. 1% Virkon also kills Enterococcus feacalis, and Mycobacterium tuberculosis in 10 minutes [29]. 1% Virkon is bactericidal on 30 strains of Gram-Negative aerobic bacteria, 20 strains of Gram-Positive aerobic bacteria, 20 strains of anaerobic bacteria in 5 min or less[25]. Herpes Simplex Virus inactivated with 1% Virkon (time unkown) [30]. Fungi: Virkon 1% is fungicidal on 20 strains of fungi in 5 minutes or less [25]. Kills Candida Albicans with 1% Virkon in 10 min [29].	If used correctly Virkon will not damage equipment, if immersion is limited to no more than 10 minutes. Long-term immersion will lead to corrosion or damage to metal. [31, 32]

Table 6: CONFIDENCE PLUS

Alkyl-dimethyl-benzyl-ammonium chloride (Benzaconium chloride)
Nonylphenol polyethylene glycol ether

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: Corrosive to the skin and eyes upon direct or prolonged contact. Ingestion can cause immediate burning pain in the mouth, throat and abdomen, severe swelling of the larynx, skeletal paralysis affecting ability to breathe, circulatory shock and/or convulsions [33]. Vapour form: Solvent vapours or mists can cause irritation of mucus membranes [33]. *MSDS not yet approved in Canada.*	Virus – bacteria – fungi: Quaternary ammonium compounds are considered unacceptable as bactericidals as they do not destroy the full spectrum of agents (Bacillus subtillis and Klebsiella pneumoniae) and should be considered a sanitizer, not a disinfectant [34, 35]. They are not effective against non-enveloped viruses, fungi and bacterial spores [26].	QAC compounds cling to organic material, including soaps, so the area to be disinfected must be clean and rinsed free of soap Extremely hard water also deactivates [26].

Table 7: SANIZIDE PLUS

Alkyl-dimethyl-benzyl-ammonium chloride (Benzaconium chloride)
Alkyl-dimethyl-ethyl-benzyl-ammonium chloride

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: May cause irritation to upper respiratory tract by constant inhalation of product. Moderate eye irritation with contact, gastrointestinal irritation, nausea, vomiting and diarrhea on ingestion. Prolonged skin contact can cause irritation and prolonged contact with eyes associated with burning and redness. No known chronic effects. Carcinogenicity not established [36].	Virus – bacteria – fungi: Quaternary ammonium compounds are considered unacceptable as they do not destroy the full spectrum of agents (Bacillus subtillis and Klebsiella pneumoniae) and should be considered a sanitizer and not a disinfectant [34, 35]. They are not effective against non-enveloped viruses, fungi and bacterial spores [26].	QAC compounds cling to organic material, including soaps, so the area to be disinfected must be clean and rinsed free of soap Extremely hard water also deactivates [26].

Table 8: ADVANCE TBE

n-alkyl-dimethyl-benzyl ammonium chloride (Benzalkonium chloride)
n-alkyl-dymethyl ethylbenzyl-ammonium chloride

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: Contact with eyes causes irritation. Prolonged or repeated contact with skin may cause irritation. Dust, vapours or mists may irritate respiratory passages [37].	Virus – bacteria – fungi: Quaternary ammonium compounds are considered unacceptable as they do not destroy the full spectrum of agents (Bacillus subtillis and Klebsiella pneumoniae) and should be considered a sanitizer and not a disinfectant [34, 35]. They are not effective against non-enveloped viruses, fungi and bacterial spores [26].	QAC compounds cling to organic material, including soaps, so the area to be disinfected must be clean and rinsed free of soap Extremely hard water also deactivates [26].

Table 9: BI-ARREST 2

c-phenylphenol 6.73%
o-benzy-p-chlorphenol 5.76%
Isopropanol 7.00%

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: Skin and eye irritant, corrosive. High concentrations resulted in decreased survivability and bladder tumors in rats [38]. EPA registered: 67813-1	Virus –bacteria-fungi: Test performed by Clinical research Associates with and with out blood: did not kill Tuberculosis, M Bovis and Polio [39] and is considered ineffective against hydrophilic/non-enveloped viruses (Polio virus, Hepatitis A and B) [40].	Phenolic compounds are more difficult to rinse from equipment than other disinfectants [9]. Therefore, increased risk of tranferance to users.

Table 10: BUDDY CLEAN

Note: As supplied by the manufacturer , A.P. Valves datasheet

Halogenated Tertiary Amine
Biquanide Hydrochloride
NP9 Surface Active Agent
Stabilisers Chelating Agents
Demineralised Water

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: Mild degreaser to sensitive skin, may cause irritation to eyes, mouth, throat and digestive tract. Chronic exposure effects have not been established [41]. Data Sheet taken from manufacturer web site is not considered an approved MSDS	No research found on Pubmed or from the manufacturer on efficacy of product.	Unknown.

Table 11: TriGene

Polymeric (Hexamethylene) Biguanide Hydrochloride 2%
Alkyl-dimethyl-benzyl-ammonium chloride (Benzaconium chloride) 15%
Dodecylamine 5%
Sulfamic acid 5%
Nonoxynol <10%

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: Non-toxic on inhalation, may degrease skin. Low risk to eye, inhalation and ingestion. No known health hazards [42].	Virus: inhibits Adenovirus human type 5, Enterovirus Polio 1, Hepatitis B and Orthopox virus (time not provided) [43]. Bacteria: Kill Enterococcus feacium and hirae, Escherichia coli, Klebsiella pneumoniae, Listeria monocytogenes, Pseudomonias aeruginosa, Salmonella (4 types) and Staphylococcus aureus with a concentration of 1:50 [43]. Mycobacteria (6 types) are also killed with 1:50 [43]. Spores such as Anthrax, Bacillus subtilis, Clostridium sporogenes are killed in 1:10 solution [43]. Fungi: 16 different type of fungi can be killed with 1:50 solution [43].	Does not harm sensitive surfaces when used as directed [44].

Table 12: LISTERINE® ANTISEPTIC

Eucalyptol 0.091%
Thymol 0.063%
Menthol 0.042%
Ethyl Alcohol

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: No exposure hazards [45] Health Canada DIN 02130831 [46]	Virus: Exposure to Listerine for 30s is antiviral against herpes simplex type 1, herpes simplex 2 and influenza A [47]. Completely inhibited HIV in 30 sec [48], and is able to kill Methicillin-resistant Staphylococcus aureaus (MRSA) in 30 sec [49] Bacteria: Listerine kills Staphylococcus aureaus completely after 30s. Kills Staphylococcus mitis, Mycobacterium smegmatis and M Bovis in 20 min [50]. Most of 54 bacterial strains die after 30 sec [51] Fungi: kills Candida Albicans in 20 min [50].	Non-corrosive to metals, adhesives, plastics, gloves, etc [9]. Prolonged exposure to alcohol disrupts adhesives, damage seals, and causes certain plastics to swell and harden making them brittle and more prone to breakage [9, 32].

Table 13: CaviCide®

Isopropanol 10-20%
Butyl Cellosolve 1-5%
Hyamine 1622 0.1-1%
Benzethonium Chloride 0.28%

Health Hazards	*Micro-organism killing ability (Efficacy)*	*Effects on equipment*
Liquid form: *Inhalation*: a low to mild irritant, inhalation of vapors at moderate concentration may cause nose, throat and respiratory tract irritations and above exposure guidelines may result in CNS depression. Ingestion of small amounts may cause irritation and large amounts may cause toxic effects similar to alcohol poisoning [16]. *Eyes and skin*: Mild to moderate irritant, vapors irritating to eyes, may cause eye damage on contact. [52]. *Chronic*: No reported evidence of carcinogenicity or reproductive toxicity [52]. EPA Reg. No. 46781-6	Virus: not considered virucidal against hydrophilic viruses [52]. Bacteria: has a broad spectrum antimicrobial activity with a recommended surface contact time of 10 min at 20° C [9]. Demonstrated antimicrobial efficacy (against Staphylococcus, Pseudomonas, Salmonella, and HIV) [53]at the working concentration designated by the manufacturers [54], Tuberculocide, but not active against bacterial spores at the usual use concentration of 1:750 [52]. Fungi: fungicidal	It can be used as a cleaner, as an ultrasonic cleaning solution, and for instrument immersion [9], and is considered non-corrosive [26]. Action is markedly depressed in the presence of anionic detergents and organic material [40]. Extremely hard water also deactivates [26].

Products not meeting requirements

After reviewing the nine disinfectants, seven did not meet the selection requirements stated in Para 4 and had to be disqualified for recommended use.

Buddy Clean: After an extensive search of the literature, heath and safety websites and requests from the supplier, no further information of the product was available beyond the data sheet produced by Ambient Pressure Diving. Although this product is listed as a Halogenated Tertiary Amine and the manufacturer has indicated the product is also called Trigene but with additional anti-corrosion additives, the datasheet is not an approved MSDS and evidence was not available to indicate the effect of the additional additives to the product. Therefore, as the datasheet is not recognized and no supporting documentation could be retrieved identifying the potential health risks or efficacy of the product, Buddy Clean cannot be recommended for use.

Confidence Plus: Although this product was tested and found to be safe for hyperbaric use [5] and Quaternary Ammonium disinfectants have been found to be effective against gram negative and gram positive bacteria and enveloped viruses, these types of disinfectants are considered sanitizers - reducing the number of microbes to a safe level rather than having the capability to kill a broad spectrum of organisms. Quaternary Ammonium Compounds are not able to kill micro-organisms such as Bacillus subtillis spores [35], Klebsiella pneumoniae [34] and Listeria monocytogenes [55], and QAC's are not

effective against non-enveloped viruses[1], fungi, and spores [26]. The product is not able to meet the efficacy criteria (ineffective against Hep A, B, and C) and risks of even further reducing or eliminating the effectiveness are high as QAC's are easily inactivated by anionic detergents, organic matter and hard water [26, 40]. This product cannot be recommended for use.

Sanizide Plus: the ingredient for this product is also Quaternary Ammonium Compounds and therefore, as with Confidence Plus, the product cannot kill the full spectrum of microorganisms that divers may be exposed and thus the product cannot be recommended for use.

Advance TBE: the ingredient for this product is also Quaternary Ammonium Compounds and therefore, as with Confidence Plus, the product cannot kill the full spectrum of microorganisms that divers may be exposed and thus the product cannot be recommended for use.

Bi-Arrest 2: Although this phenolic-based product has been tested and found to be safe for hyperbaric use [5], this disinfectant has been identified by the distributor as a possible carcinogen, having shown to produce tumours in rats [58] as well as, being an irritant to mucous membranes. The product is also considered ineffective against non-enveloped viruses [40], Tuberculosis bacteria, M. Bovis and bacterial spores [39, 59]. As this product does not meet the efficacy criteria (ineffective against Hep A, B, and C), phenolic compounds have been shown to produce cancer in animals and product residue is difficult to rinse from equipment [9], this product cannot be recommended for use.

Cavicide: This product is registered with the Environmental Protection Agency (EPA Reg # 46781-6) as an effective surface disinfectant against gram negative and positive bacteria, HIV, and is registered as a tuberculocide. However, the product is not considered effective against non-enveloped viruses (Hep A, B, and C) or bacterial spores [52]. As with other Quaternary Amines, disinfectant action is markedly depressed in the presence of organic materials [40] and extremely hard water can deactivate the disinfectant [26]. Although Quaternary Ammonium compounds (QAC) are generally low in toxicity and the component Benzethonium Chloride found in Cavicide is considered a more 'tissue friendly' QA than the Ammonium Chloride components found in other disinfectants of this type [9], prolonged contact can be irritating [26]. As this product does not meet the efficacy criteria (ineffective against

[1]The ability of soaps or other sanitizers to affect viruses depends in part on whether the virus is enveloped, meaning whether it carries a coat of lipid membrane from the cell it infected. Viruses such as HIV and herpes virus are often more sensitive to soaps and sanitizers as the detergent disrupts the membrane. A common characteristic of non-enveloped viruses (hydrophilic) such as the Hepatitis A, B or C virus is their resistance to most physico-chemical treatments 56. Lazo, A., et al., *Inactivation of non-enveloped viruses in reb blood cell concentrates using the Inactine compound Pen10.* 2001, American Society of Hematology: Watertown.. As non-enveloped or hydrophilic viruses are more resistant than enveloped or lipophilic viruses, they better gauge a disinfectants virucidal efficacy 57. Organization for safety and aseptis procedures, *Chemical agents for surface disinfection reference chart.* 1998: Annapolis..

Hep A, B, and C) and the products effectiveness could be further reduced or inactivated by detergents, organic matter and hard water [40], this product cannot be recommended for use.

Listerine Antiseptic: This product is approved by Health Canada as a mouthwash [46] and is currently used by different diving organizations [12-15]. The product has shown to be effective in killing micro-organisms present in the saliva such as Candidas albicans, Mycobacterium smegmatis, M. Bovis, Streptococcus mitis [50], Staphylococcus aureus [49], and is virucidal against Herpes Simplex type-1 and type-2, influenza A [47] and HIV [48]. However, although Listerine has shown to be effective in eliminating bacterial contamination on surfaces such as toothbrushes [50], the product is not effective against non-enveloped viruses [47]. As well, high alcohol based products such as Listerine have been shown with prolonged exposure to be disruptive to adhesives, seals and plastics [9] [32]. Due to its rapid evaporation rate and diminished activity with bio-burden, the product is not recommended for use as an environmental surface disinfectant [40]. Thus, as this product has only been tested for efficacy for organisms that may be found in saliva, there is reduced activity with bio-burden, and alcohol based products although non-corrosive to metals have been shown to damage other system components, Listerine cannot be recommended for use.

Products meeting criteria specifications

Only two of the nine products met all of the criteria indicated in Para 4.

Virkon S: This disinfectant currently used by CF divers does not have a vapour phase [21, 22] which was a concern for the divers, and the product is considered a non-irritant at its working concentration of 1% [17, 18, 60]. Independent testing to evaluate the acute effects of inhalation (4-hrs at 5.5% w/v dilution with de-ionized water) indicated no pathological abnormalities or histopathology to rats [20], and exposure to product components was not found to be associated with a risk of occupational asthma [19] nor were they found to present toxic effects to animals [28]. The product has been extensively tested and proven to be a broad spectrum disinfectant, considered bactericidal, virucidal (both enveloped and non-enveloped), fungicidal and a tuberculocide when used at its intended working concentration of 1% for a minimum soaking time of 10 minutes [23-25, 27-30, 61-72]. The product is not inactivated by detergents or hard water [26], but may leave a residue if recommended decontamination procedures are not followed [31]. If the product is used as prescribed by the manufacturer, Virkon S is not deleterious to the health or equipment of divers and it is effective against microorganisms to which the divers may be exposed. This product is therefore recommended for use.

Trigene: This Halogenated Tertiary Amine (HTA) composed of chlorides, amines and sulfamic acid is an approved surface disinfectant for use on Royal Navy Submarines (NATO Stock # 6850-99-439-7179). If the product is used according to the manufacturers recommended directions, a minimum working solution of 1:50 (diluted from pre-prepared sachet packets), the product is considered a non-irritant

and non-hazardous [42]. The manufacturer does however suggest that prolonged contact and long term inhalation should be avoided as the degreasing component may lead to dryness. Trigene II has been shown effective at a minimum dilution of 1:100 to kill 55 types of bacteria (both gram negative and positive), 27 types of fungi, 4 types of viruses (both enveloped and non-enveloped – Hep B), mycobacteria and spores [43]. The product has also shown not to harm sensitive surfaces when used as directed [44], and unlike simple QAC's the TriGene blend of components are not inactivated when in the presence of organic compounds [73]. If the product is used as prescribed by the manufacturer and dilutions are adjusted to suit disinfection needs (i.e. 1:100 for relatively clean surfaces and 1:50 for soiled/ body fluids), TriGene II can be considered effective against microorganisms to which the divers may be exposed and is not considered deleterious to the health or equipment of divers. This product can therefore be recommended for use.

Overview and discussion

Products not recommended for use

There is insufficient information on the product *Buddy Clean* to recommend its use at this time. Although the manufacturer has indicated this product is also called TriGene with the addition of anti-corrosive components [74], an extensive search (through supplier and health hazard web sites) provided no further information on the product beyond the manufacturer datasheet. As well, as the manufacturer does not officially state (on their website or datasheet) that Buddy Clean is in fact TriGene the information available from the product TriGene was not considered acceptable. Therefore, no efficacy data was available to adequately assess the acceptability of the product.

The products *Sanizide Plus, Confidence Plus and Advance TBE* have been suggested as safe for use under hyperbaric conditions [5], however, Quaternary Ammonium Compounds (QAC's) do not meet the efficacy requirements for open water diving and CUMA/CCDA use as they are ineffective against non-enveloped viruses [26, 35] and QAC's are known to be easily inactivated by detergents, organic matter and hard water [26, 40].

The product *Bi-Arrest 2* was also suggested as safe for hyperbaric conditions [5], however, the Phenolic component in Bi-Arrest 2 is considered a possible carcinogen [75] and consequently, human health may be at risk when dealing with this product. This product is also ineffective against non-enveloped viruses [26] and thus it does not meet the efficacy requirement for CUMA/CCDA use.

The product *Cavicide,* also a Quaternary Amine with additional detergent added contains Benzethonium Chloride and although more 'tissue friendly' than the pure QAC's [9], prolonged contact can be irritating [26]. This product also does not meet the efficacy criteria under which the CUMA/CCDA will be used (ineffective against non-enveloped viruses) and like other QAC's is easily inactivated by detergents, organic matter and hard water [40].

Listerine Antiseptic is used by different diving organizations [12-15], and has been assessed extensively for its ability to kill bacteria and fungi present in saliva [49, 50], to viruses such as Herpes, influenza and HIV [47, 48]. No confirmation can be given that it is effective against killing bacteria, viruses or fungi that may be present in dived waters (fecal coliforms, Hep A, etc.) which are significant concerns of exposure for divers. A significant limitation to using a product that contains high concentrations of alcohol is with prolonged exposure the product is disruptive to adhesives, seals and plastics [9] [32], and thus high concentrations of alcohol-based products are not recommended for environmental surface disinfection [40].

Products recommended for use

Virkon S is considered a very efficient and effective broad spectrum disinfectant, proving its bactericidal, virucidal (against enveloped and non-enveloped viruses), fungicidal and tuberculocidal capabilities through multiple studies [23-25, 27-30, 61-71]. Virkon S is

considered a non-irritant at its working concentration of 1% [17, 18, 60], there are no acute effects to inhalation [20], exposure to product components are not associated with a risk of occupational asthma [19] and exposure has not resulted in toxic effects to animals [28]. The product has no vapour phase and is not inactivated by detergents or hard water [26], and if the product is used as prescribed with the preventive preparation precautions there are no significant health risks.

Although a residue should not be present if correct manufacturers procedures are adhered (thorough flushing of the system with water), further assurances of complete removal of Virkon S can be made by testing the surface with starch iodide paper [31]. The paper turns blue in the presence of Virkon S. In order for Virkon S to be effective against the entire spectrum of biological contaminants (bacterial, viral, fungal and spores), the manufacturer suggests, and external tests have proven, that the standard application of a 10 minutes soak in 1% solution is effective. When an unusual amount of secretions (blood, saliva) or a suspected disease is present, a 2% solution is recommended for 30 minutes to assure effectiveness.

The product *TriGene II* is an approved surface disinfectant for use on Royal Navy Submarines and if used according to manufacturers direction is considered both a non-irritant and non-hazardous [42]. The detergent in TriGene may lead to dryness of mucous membranes and thus the manufacturer has suggested avoidance of prolonged contact. Trigene II is also an effective broad spectrum disinfectant when used at a minimum dilution of 1:100, proving to be bactericidal, virucidal (against enveloped and non-enveloped viruses), fungicidal and tuberculocidal [43] like that of Virkon S. The product does not harm sensitive surfaces when used as directed [44], and is not inactivated when in the presence of organic compounds [73].

The only shortfall that can be seen while performing the review of TriGene II is that although the product met all of the criteria specified in Para 4, no external, peer reviewed literature could be found that assessed the health and safety or equipment effects of this product. This is not to say that that the product is not effective, its efficacy is not in question. However, review of systems effect and health and safety concerns were based on manufacturers information, which were supported by review papers of the major chemical component group (Quaternary Ammonium compounds) of TriGene II.

It should also be noted that although all of the disinfectants reviewed have been classified as surface disinfectants (with the exception of Listerine) and not intended for human contact, the British Society of Gastroenterology reviewed the acceptability of disinfecting instruments used in invasive procedures and found the only disqualifier for disinfectants was either its insufficient efficacy (Quaternary compounds) [32]. No health and safety issues were noted for either Virkon or TriGene II.

Recommendations

The review of disinfectants that are used by divers nationally and internationally has revealed that only two disinfectants, Virkon S and TriGene II, meet all of the criteria considered essential for use by CF divers using rebreather equipment. Even though both disinfectants met all of the criteria, Virkon S is suggested as the primary choice for a CF disinfectant, as the breadth of testing for disinfectant efficacy is much broader for Virkon S than for TriGene II (70 vs 55 bacterial strains and 25 vs 4 viral strains, respectively) and initial concerns of health risks have been dispelled. Even though both products have met all of the minimum criteria, Virkon S has been shown to be able to provide a more rapid and more complete microbial kill than TriGene II [73], and thus it can be considered a better disinfectant.

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14. ABSTRACT

(U) As a result of the health concerns expressed by the combat divers the consultant in Diving and Hyperbaric Medicine at CFEME Toronto requested a toxicological review of the disinfectant Virkon S to determine its suitability for continued use as a cleaning/disinfectant of re-breather sets for the Canadian Forces (CF) diving community. An initial assessment of the components of Virkon S revealed the product had not been approved nor was it intended for human topical disinfection. As a result, a literature review was performed on Virkon S, but as well the review was expanded to include other disinfectants used by civilian and military divers around the world. The aim was to assess the health hazards of using disinfectants to clean re-breathers, as well as, assess the capability of disinfectants to kill the full spectrum of biological contaminants (bacterial, viral, and fungal) to which divers might be exposed. 9 disinfectants were found to be used by divers nationally and internationally (Virkon S., Sanizide, Confidence, Advance TBE, BI-Arrest, Buddy Clean, Trigene II, Listerine, Cavicide) and all were evaluated against the same criteria. In order to be recommended for use two mandatory criteria had to be complied with; the product had to exhibit an absence of components that would cause undue risk to human health during use that could not be prevented by reasonable protective measures, and proof must be available to indicate the disinfectant was effective. Products should be able to kill the full spectrum of viruses, bacteria and fungi that divers could be exposed while using a re-breather. Two further considerations were applied in reviewing all disinfectants, compatibility with system components and ease of use. Based upon the above criteria the review of these nine disinfectants revealed that only two products, Virkon S and TriGene II, met all of the criteria considered essential for use by CF divers using rebreather equipment. Although both products have met all of the minimum criteria, Virkon S is recommended as the continued disinfectant of choice for the CF as it has been shown to be able to provide a more rapid and more complete microbial kill than TriGene II. It is thus considered a better disinfectant.

(U) Par suite des inquiétudes d'ordre médical manifestées par les plongeurs de combat, le conseiller en matière de médecine hyperbare et de plongée du Centre de médecine environnementale des Forces canadiennes (CMEFC) à Toronto a demandé une vérification toxicologique du désinfectant Virkon S, afin que l'on détermine s'il convient de continuer d'utiliser ce produit pour nettoyer/ désinfecter les appareils à circuit fermé des plongeurs des Forces canadiennes (FC). Un premier examen des constituants du Virkon S a révélé que ce produit n'avait pas été approuvé pour des fins de désinfection topique chez des humains et qu'il n'avait pas été conçu à cette fin non plus. À la lumière de cette découverte, on a entrepris un examen de la littérature sur Virkon S, ainsi que sur d'autres désinfectants utilisés par les plongeurs civils et militaires dans le monde. Le but de cet examen était d'évaluer les risques pour la santé que pose l'utilisation de désinfectants pour nettoyer les appareils à circuit fermé et d'évaluer la capacité de ces produits de tuer tous les contaminants biologiques (bactériens, viraux et fongiques) auxquels les plongeurs peuvent être exposés. L'examen a révélé que neuf désinfectants sont utilisés par les plongeurs au Canada et ailleurs dans le monde (Virkon S., Sanizide, Confidence, Advance TBE, BI?Arrest, Buddy Clean, Trigene II, Listerine, Cavicide); ces produits ont tous été évalués en fonction des mêmes critères. Pour que l'utilisation d'un produit donné soit recommandée, deux critères obligatoires devaient être remplis : le produit devait être exempt de constituants qui, lors de l'utilisation du produit, pouvaient présenter un risque inacceptable pour la santé humaine (risque qui ne pouvait être prévenu par des moyens de protection raisonnables), et il devait y avoir des preuves attestant l'efficacité du produit. Les désinfectants devaient aussi tuer tous les virus, bactéries et champignons auxquels les plongeurs peuvent être exposés lorsqu'ils utilisent un appareil à circuit fermé. Deux autres critères ont été utilisés dans l'évaluation des désinfectants, soit leur compatibilité avec les composants de l'appareil et leur facilité d'utilisation. L'évaluation des neuf désinfectants en fonction des critères indiqués précédemment a révélé que seuls deux produits, Virkon S et TriGene II, remplissent tous les critères considérés comme essentiels en vue d'une utilisation par les plongeurs des FC se servant d'appareils à circuit fermé. Même si les deux produits ont rempli tous les critères minimaux, on recommande aux FC de continuer d'utiliser le désinfectant Virkon S, car ce produit a une activité microbicide plus efficace et plus rapide que le TriGene II. Nous considérons donc le Virkon S comme un meilleur désinfectant.

15. KEYWORDS, DESCRIPTORS or IDENTIFIERS

(U) disinfectants; diving; CUMA/CCDA; rebreather sets; Virkon S; Trigene

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