

ACTIVE TOPICAL SKIN PROTECTANTS CONTAINING AMINES, POLYALKENIMINES AND /OR DERIVATIVES

[0001] The invention described herein may be manufactured, used and licensed by or for the U.S. Government. This application claims priority of provisional application No. 60/378,443 filed May 6, 2003.

BACKGROUND OF THE INVENTION

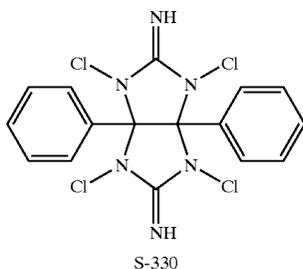
[0002] 1. Field of the Invention

[0003] This invention relates to active topical skin protectants. More specifically, the invention relates to an active barrier cream for protection against all types of harmful chemicals, specifically chemical warfare agents (CWAs). The active barrier cream is applied prior to exposure on the skin of persons at risk of exposure to harmful chemicals to provide a protective barrier for the skin. The active barrier cream chemically or physically reacts with harmful chemicals such as CWAs (vesicants and nerve agents) to neutralize these harmful chemicals while the barrier properties of the cream prevent penetration of harmful chemicals through the cream to the skin.

[0004] 2. Description of Related Art

[0005] The concept of applying a topical protectant to vulnerable skin surfaces before entry into a chemical combat arena has been proposed as a protective measure against percutaneous CWA toxicity since the first use of CWA in World War I. The protectant was applied to vulnerable skin surfaces prior to entry into a chemical combat area. Topical protectants should augment the protection afforded by the protective over garments and/or redefine the circumstances requiring mission oriented protective posture (MOPP) levels. The rapid action of vesicating agents, also known as blistering agents, such as sulfur mustard (HD) and lewisite (L), require a pre-exposure skin protection system or a contamination avoidance approach that may preclude the percutaneous toxicity of these agents. These approaches also reduce the risk of exposure to organophosphorus (OP) chemical agents (nerve agents), which unlike the vesicating agents are lethal in droplet amounts.

[0006] An organic molecule, S-330, that reacts with CWA was incorporated into a product and fielded as the M-5 ointment kit at the end of World War II (Formula 1).



Formula 1.

[0007] However, the unacceptable barrier properties and the undesirable cosmetic properties (specifically foul odor and sticky texture) caused a recall of this product.

[0008] Two non-active topical skin protectant (TSP) formulations were developed at the United States Army Medical Research Institute of Chemical Defense (USAMRICD) and were transferred to advanced development following a Milestone Zero (MS0) Review in October 1990. The timeline of the approval of the TSP continued with MSI in 1993, a Investigational New Drug (IND) filed with the FDA in 1994, MSII in 1995, and culminated with New Drug Application (NDA) approval in February, 2000. Upon approval by the FDA, the TSP was designated Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA). SERPACWA is a 50:50 (wt/wt) mixture of perfluoropolyether oil (Fomblin® Y25 from Ausimont) and poly(tetrafluoroethylene) (Polymist® F5a powder from Ausimont). The formulation described in McCreery U.S. Pat. No. 5,607,979 is directed to a topical skin protectant cream that acts as a barrier to CWA.

[0009] Although SERPACWA extends the protection afforded by MOPP and allows a longer window for decontamination, it does not completely remove the possibility for contamination because the CWA is not neutralized. To avoid contamination of other areas of the battlefield and to preclude the future percutaneous absorption of the CWA, decontamination is still required. Furthermore, although the McCreery formulation provides excellent protection against soman (GD) and sulfur mustard (HD) liquid, its protection against GD and HD vapor is minimal.

[0010] To overcome these deficiencies, there is a need for a new TSP that contains an active component. This active Topical Skin Protectant (active TSP, aTSP) was developed within the following criteria. First, the active TSP should neutralize CWA including but not limited to HD, GD, and VX. Second, the barrier properties of the TSP should be maintained or increased. Third, the protection against GD and HD vapor should increase. And fourth, the cosmetic characteristics (i. e. odor, texture) of the TSP should be maintained.

[0011] This invention meets the above criteria and solves the problems associated with the past TSPs by providing an active topical skin protectant that increases effectiveness of the TSP barrier quality and neutralizes CWA into less harmful products.

[0012] It is therefore, an objective of the present invention to provide an active topical skin protectant that prevents the percutaneous absorption of CWA and converts these toxic materials into less harmful products.

[0013] It is a further objective of the present invention to provide an active topical skin protectant that maintains desirable cosmetic properties making it acceptable to the user. Specifically, the active TSP should not be sticky, should be without offensive odor, and should be nonirritating to the skin.

[0014] It is still a further object of the invention to provide an active topical skin protectant that is practical for field operations. Specifically, the active TSP should have a stable shelf life, not be easily washed off with water, and should not react with insecticides or camouflage paint.

SUMMARY OF THE INVENTION

[0015] A topical skin protectant formulation for neutralizing chemical warfare agents into less toxic products com-