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Nontoxic And Nonfuming Sporicide: Science At Its Best

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Conventional wisdom states that a sporicidal disinfectant must also be toxic and corrosive to be effective. This makes the sterilization of clean rooms, bench tops, table tops, and instruments an arduous, unpleasant, and difficult task, not to mention risky. The use of most disinfectants requires the use of respirators and other cumbersome protective equipment. The Material Safety Data Sheets (MSDS) for these conventional products make statements that are scary at best and worrisome at worst. These statements run the gamut from "irreversible eye damage" to "serious damage of the upper respiratory tract" to "unconsciousness and possible death". We take every precaution to minimize employee exposure to these harsh chemicals but there is still the risk of accidental exposure either from employee misuse or an accidental spill. Environmental concerns are also high with most of these products. As an industry, we have come to accept these risks because the alternative of producing contaminated product is simply unacceptable.

Fortunately, we live in the age of advanced cellular research and new technology. It has long been known that ionic silver has great antimicrobial properties, and a number of FDA approvals for products based on this technology have been granted. However, it has not been known how to harness these properties such that they become sporicidal, bactericidal, and tuberculocidal while maintaining a non-toxic, non-corrosive, and non-fuming profile. STERIPLEX HC is a new sterilant/disinfectant product that has recently received US EPA registrations as a Broad-Spectrum Sporicidal Sterilant and disinfectant. This product takes silver ion technology and turns it "nuclear" for pathogens while remaining completely non-toxic to humans and non-corrosive to materials and equipment. STERIPLEX HC has been demonstrated to kill spores such as B. subtilis, C. sporogenes, C. difficile, and B. anthracis in seconds, compared to several minutes or even hours by other products. STERIPLEX HC kills most microbes within 15 to 30 seconds. This product is an extremely fast and effective antimicrobial, but even more amazing is that it carries a Hazardous Materials Identification System (HMIS) health rating of "0", meaning "minimal". With the exception of safety glasses, there is no need for cumbersome respirators, gloves, or other protective equipment while using STERIPLEX HC. There is no inhalation risk as this product is non-fuming. Environmental concerns are also wiped away with STERIPLEX HC because the product decomposes naturally with no environmental impact. STERIPLEX HC can even be poured down the drain at full strength, and it does not emit poisonous chemicals into the air or water.

Several studies have been conducted on STERIPLEX HC by third party independent labs including Nelson Labs, Eurofins, and Pacific BioLabs. These studies have consistently shown that STERIPLEX HC is fast, efficient, and non-toxic. One particular efficacy study conducted at Brigham Young University by Dr. Richard A. Robison demonstrated that STERIPLEX HC was able to achieve a >5.85 log reduction on C. sporogenes within 15 seconds (this number represented a complete kill so the actual log reduction may be greater). This was compared side-by-side with a gluteraldehyde product that only achieved a 3.15 log reduction after 20 minutes. This same study also showed a 6.01 log reduction with STERIPLEX HC on B. subtilis spores after just 60 seconds. The same gluteraldehyde product only achieved a log reduction of 4.67 after 190 minutes on the same spores. Other efficacy studies have shown similar results. Several toxicity studies have also been conducted and STERIPLEX HC has consistently been shown to be completely non-toxic by oral administration, ingestion, and dermal absorption. In an oral LD50 toxicity study conducted at Pacific BioLabs, STERIPLEX HC (known as Peradox HC at the time) was shown to live up to its claims of being non-toxic. Lab rats were dosed at 5000 mg/kg, which is 250% the normal initial dose of 2000 mg/kg. The rats not only survived that extremely high dose but they also experienced no abnormal effects and even exhibited normal weight gain and respiratory function. STERIPLEX HC, a sporicide, was shown to be completely non-toxic.

With STERIPLEX products, the pharmaceutical and medical device industry is no longer limited by the conventional wisdom that an effective sporicidal must be corrosive, toxic, and fuming. STERIPLEX eliminates those concerns while increasing efficacy and kill speed over conventional products currently on the market. No longer do we need to accept the risks of toxicity to accomplish our sterility objectives. STERIPLEX is poised to change the industry.

Tim Sandle, Ph.D, M.A., BSc (Hons), CBiol, MSBiol., MIScT – Dr. Sandle is the Head of Microbiology at the UK Bio Products Laboratory. Dr. Sandle is a chartered biologist and holds a first class honors degree in Applied Biology; a Masters degree in education; and obtained his doctorate from Keele University. His role involves overseeing a range of microbiological tests, batch review, microbiological investigation and policy development. In addition, he is an honorary consultant with the School of Pharmacy and Pharmaceutical Sciences, University of Manchester and is a tutor for the university's pharmaceutical microbiology M.Sc course. Dr. Sandle serves on several national and international committees relating to pharmaceutical microbiology and cleanroom contamination control (including the ISO cleanroom standards). He is currently chairman of the PharMIG LAL action group and serves on the NBS cleaning and disinfection committee. He has written over eighty book chapters, peer reviewed papers and technical articles relating to microbiology. He is currently the editor of the Pharmaceutical Microbiology Interest Group Journal and runs an on-line microbiology forum (www.pharmig.blogspot.com). Dr. Sandle is an experienced auditor and frequently acts as a consultant to the pharmaceutical and healthcare sectors.