



Optim1 Safety Profile Overview

Introduction

Chemical disinfectants are widely used in infection control, and as such our reliance on them is increasing. Preventive strategies are necessary due to antibiotic resistance and mounting threats from emerging and re-emerging pathogens. An imperative aspect to preventing the spread of these harmful microorganisms is through disinfection of contaminated surfaces. Although an essential step in infection control, it is a common belief that due to their toxicity to microorganisms, disinfectants are also toxic to human health resulting in user apprehension and compliance deficit. For those seeking a safer disinfectant alternative, a compromise between germicidal efficacy and safety is often required. However a new generation of Accelerated Hydrogen Peroxide® (AHP®) based disinfectants has accomplished this balance between safety and efficacy like no other.

Background

Cleaning and disinfecting products have emerged as a significant risk for users and occupants. Research has indicated the potential of disinfectant products to contribute to respiratory hazards including the onset of asthma or exacerbation of existing asthma. In fact work-related asthma accounts for approximately 16% of total reported asthma cases in the USⁱ. Additionally, disinfectants have been associated with acute illness reports among workers, primarily affecting the eyes and skin. A 2010 report by the Centers for Disease and Control and Prevention (CDC) highlighted that the most common active ingredients responsible for illness were Quaternary Ammonium Compounds, Glutaraldehyde, and Sodium Hypochloriteⁱⁱ. These occupational human health hazards not only have negative physical implications, but also negative economical impacts both directly and indirectly. Furthermore, disinfectants that

are perceived as toxic are less likely to be used correctly, reducing user compliance and increasing the risk of pathogen transmission.

Selection of the Ideal Disinfectant

According to Rutala and Weber, the safety profile of a disinfectant should be one of the key criteria that should be used when evaluating disinfectant productsⁱⁱⁱ. As per the recommendation set forth by Rutala and Weber, disinfectant products should be nontoxic and should not cause any harm to users, patients and visitors. Facilities where disinfection is required should choose disinfectants with the lowest toxicity and flammability rating, as well as choose products that require the least personal protective equipment to provide protection from exposure to adverse health effects^{iv}.

However, Rutala and Weber have also identified the importance of selecting a disinfectant that achieves broad-spectrum germicidal efficacy in rapid and realistic contact times, to ensure pathogens of concern are eradicated. The struggle is often finding a disinfectant product that meets both of these key criteria.

Evaluating Disinfectant Safety Profiles

A good indication of a disinfectant's safety profile is by its associated Safety Data Sheet (SDS), which is a summary document that provides information about the hazards of a product and advice about safety precautions. As of June 2016, the United States adopted the Globally Harmonized System (GHS), a "system for harmonizing hazard classification criteria and chemical hazard communication elements worldwide. The purpose of the classification under the GHS is to provide harmonized information to users of chemicals with the goal of



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enhancing protection of human health and the environment”^V.

Optim1 Overview

Optim1 Ready to Use (RTU) Liquid and Wipes is a new generation of Accelerated Hydrogen Peroxide[®] (AHP[®]) based surface disinfectants specifically formulated for the dental market. Compared to Optim 33TB, this new and improved disinfectant has dramatically improved its fungicidal contact time from 10 minutes to 1 minute, as well as its tuberculocidal contact time from 5 minutes to 1 minute. Amazingly, these improved contact times were successfully achieved all while remaining nontoxic and non-irritating. To put that into context, significant performance improvements of legacy disinfectant formulations are almost always accompanied by increased hazards and risk. In other words, safety is directly compromised. The safety profile of Optim1 was designed to ensure ease of use and increase user compliance, which is an essential element to ensuring a successful environmental hygiene program. All the ingredients used in Optim1 are listed on the EPA Inerts list which are ingredients approved for use in disinfectant products. Optim1 utilizes the globally patented AHP[®] technology as its active ingredient which readily degrades into water and oxygen, leaving no active or toxic residues behind on the surface.

Identifying a disinfectant’s safety profile can be a challenge just by looking at the product label alone which is why having access to the product’s SDS is so important. When evaluating a disinfectant’s safety profile, sections 2 and 11 should be reviewed to identify product hazards and toxicological data. In regards to Optim1, the products are not classified under any GHS hazard class meaning there are no physical or health hazards associated with

Optim1. Furthermore, as per section 2 of the SDS, Optim1 RTU and Wipes do not require any signal words, hazard pictograms or hazard statements. This information is determined by the toxicological data from Section 11 of the SDS. GHS has five categories for acute toxicity. GHS uses the danger signal and skull and cross bones symbol for chemicals in categories 1 to 3 and introduces the exclamation point symbol for category 4. Category 5, which is the safest category, does not have any associated hazard pictograms. In the case of Optim1, the formulation received a LC50 (inhalation) rating of > 2.08 mg/L, a LD50 (oral) rating of >5000 mg/kg and a LD50 (dermal) rating of >5050 mg/kg. These ratings indicate that Optim1 is rated as a category 5 across the board and therefore does not require any hazard or precautionary pictograms or statements. The toxicological data from Section 11 also indicates that under FIFRA (The Federal Insecticide, Fungicide, and Rodenticide Act); Optim1 is classified as an EPA category 4 which is considered the safest category. Additionally, section 8 of the SDS indicates that personal protective equipment (PPE) is not required for eye/face, skin or respiratory protection from Optim1, however PPE is always recommend to be used during the cleaning and disinfection process to protect oneself from harmful microorganisms on the surface. Furthermore, Optim1 does not utilize any ingredients that are carcinogenic, mutagenic or have reproductive toxicity, giving users confidence that they won’t be harmed by their disinfectant if used according to the label directions.

Finally, while no longer a requirement under GHS, another indication of disinfectant safety is by its HMIS (Hazardous Materials Identification System) rating. HMIS ratings help identify the risk of the product in terms of health concerns, flammability and physical hazards which



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in turn determine what type of PPE a user needs to wear and if there are any specific needs in terms of handling or storage of the disinfectant. On a SDS the HMIS rating is represented by a numerical rating system generally as "X/X/X" and are rated from 0 (minimal risk) to 4 (severe hazard). The health risk is represented by the first number, followed by flammability and physical hazard. In the case of Optim1, the HMIS rating is 0/0/0 and is therefore considered to have minimal risk and is safe for the user to handle.

Conclusion

As is evident by the stringent toxicological testing EPA registered disinfectants are required to undergo, Optim1 is considered a more responsible disinfectant choice as it has proven to be nontoxic, non-irritating and non-respiratory sensitizing, all while maintaining superior germicidal efficacy. Optim1 meets Rutala and Weber's safety and efficacy criteria for the ideal disinfectant. This gives disinfectant users confidence that their disinfectant will kill pathogens of concern without negatively impacting users. This confidence in Optim1's safety and efficacy profile increases the likelihood that the disinfectant will be used correctly which will increase user compliance creating a cleaner and safer environment for patients and staff.

ⁱ Pyrek, K. (2012). *Occupational Health: Protecting Workers Against Chemical Exposures*. Infection Control Today. <http://www.infectioncontrolday.com/articles/2012/10/occupational-health-protecting-workers-against-chemical-exposures.aspx>

ⁱⁱ CDC, (2010). *Acute Antimicrobial Pesticide-Related Illness Among Workers in Health-Care Facilities – California, Louisiana, Michigan, and Texas, 2002-2007*. May 14, 2010/ 59(18):551-556. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5918a2.htm>

ⁱⁱⁱ Rutala, WA, and Weber, DJ. (2014). *Selection of the ideal disinfectant*. Infect Control Hosp Epidemiol. 2014 Jul;35(7):855-65. doi: 10.1086/676877.

^{iv} Rutala, WA, and Weber, DJ. (2014). *Selection of the ideal disinfectant*. Infect Control Hosp Epidemiol. 2014 Jul;35(7):855-65. doi: 10.1086/676877.

^v SCHC-OSHA Alliance GHS Information Sheet Workgroup (2010). *What is GHS*. http://www.schc.org/assets/docs/ghs_info_sheets/schc_ghs_fs3_what_is_the_ghs.pdf