



SAFETY ANALYSIS OF REPULS® SOLUTION

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INTRODUCTION

Crotega was founded to develop a product that safeguards the personal safety of building occupants who may find themselves under attack. Buildings with high concentrations of people such as schools, movie theaters, businesses and government offices can be vulnerable to attack from an individual or individuals who are intent on causing injury, death and property destruction. The primary objective of the Crotega SentiZone™ System design was to deter, disrupt, and delay intruders without causing harm to the innocents in a targeted building.

The SentiZone System accomplishes this by spraying a solution onto the active threat, allowing building management and law enforcement the opportunity to maintain or regain control of the building. Crotega's proprietary solution, hereafter referred to as REPULS®, causes significant discomfort to the eyes, skin and respiratory system.

During development testing by Crotega, REPULS in the SentiZone System was shown to be effective in deterring an intruder while ensuring no permanent injuries to other building occupants.

OBJECTIVE

This document outlines the measures that have been implemented to protect innocent bystanders who might be exposed unintentionally upon activation of the SentiZone System.

The goal of the SentiZone System is to meet the following criteria:

- The capacity to impair or stop intruders to the extent that will allow building management and law enforcement to retain control of the building
- No serious or permanent harm to innocent bystanders
- Any effects on humans are temporary and easily, quickly remedied
- Allow the facility to return to normal operation within a reasonable time after deployment
- No interference with the actions of in-house responders and first responders

ANALYSIS

Evaluation of REPULS® Solution

As part of the development process, Crotega researched whether published safety standards exist that could apply to the SentiZone™ System. It was found that there are no existing safety standards or regulations that fully apply, so the search was narrowed to determine which elements of existing standards could be applied.

Several standards under the auspices of the National Fire Protection Association (NFPA), American Society of Mechanical Engineers (ASME) and Title 40 of the US Code of Regulations were useful in the design of the system, particularly since there is commonality between fire sprinklers and the SentiZone System. Other standards were integrated into the System as deemed appropriate.

Development Testing: The REPULS solution was evaluated feed according to protocols established by a similar product, one which had been extensively tested for its use in animal and human food. During development of the SentiZone System, Crotega's testing protocol consisted of volunteers entering the test room, being sprayed with the solution for a specified time, then carrying out specific tasks. After the test, the subjects were allowed to rinse their eyes and skin with water to remove the solution.

The results show that REPULS was effective and that the effects of the solution dissipated immediately upon rinsing with water. It should be noted that two of the volunteers had current asthma diagnoses. They reported acute reactions (coughing and lung discomfort) that are common upon exposure to asthma triggers but were able to recover quickly when removed to fresh air. One of the asthmatic subjects used an inhaler after the test; the other did not. No effects beyond the immediate reactions were reported by any of the test subjects.

Toxicological Testing: The manufacturer performed a battery of toxicity and irritation tests on the solution. The concentration of the active ingredient in the solution was four times that of REPULS. The testing protocols used were in accordance with Title 40 of the Code of Federal Regulations. A summary of the results of the testing is below:

1. ACUTE ORAL TOXICITY. LD50¹ of the solution is greater than 5000 mg/kg of body weight
2. DERMAL SENSITIZATION. The solution is not considered a contact sensitizer
3. ACUTE INHALATION TOXICITY. The LC50² of a single exposure of four hours is greater than 2.04 mg/L
4. PRIMARY EYE IRRITATION. The solution in concentrated form is considered a severe irritant to the eye
5. PRIMARY SKIN IRRITATION. The solution is considered slightly irritating to the skin (skin irritation index of 0.8)

Acute Oral Toxicity and Acute Inhalation Toxicity results do not indicate whether a substance is toxic. For Acute Oral Toxicity testing, the consensus of the scientific community is that LD50 values over 1000 mg/kg indicate low toxicity risks. As a comparison, sodium chloride (table salt) has an LD50 of 3000 mg/kg, indicating that it is more toxic than the solution³.

For Acute Inhalation Toxicity testing, the National Institute of Occupational Safety and Health (NIOSH) has a Recommended Exposure Limit (REL) with a Time Weighted Average (TWA) of 30 mg/cubic meter exposure for a 10-hour workday and a 40-hour work week⁴. The solution has an LC50 of greater than 2040 mg/cubic meter exposure for four hours. It is noteworthy that the Occupational Safety and Health Administration does not have a Proposed Exposure Limit (PEL) for the active ingredient in REPULS. Since REPULS exposure will likely be less than one hour, it is unlikely that toxic effects will occur as confirmed in the section below.

¹ LD50 = Lethal Dosage of 50%, the amount of test substance that causes death in 50% of the test animals in an Acute Toxicity Test

² LC50 = Lethal Concentration of 50%, the concentration of vapor or gas that will cause death in 50% of the test animals during a specified time period

³ Lethal Dose Table, Toxins, UC Regents, LHS Living by Chemistry, 2004

⁴ NIOSH Pocket Guide to Chemical Hazards, 2007

Toxicological Risk Assessment: Test data on the original solution was collected and provided to a qualified toxicologist along with the current formulation. The following are excerpts from the conclusions of the Risk Assessment:

1. ACUTE ORAL TOXICITY. "A single exposure to unprotected individuals from the REPULS® solution does not pose significant risk from incidental oral exposure."
2. ACUTE INHALATION TOXICITY. "Inhalation of REPULS spray droplets is likely to cause coughing, lung irritation and nasal discharge. Water droplets may cause less inhalation exposure. Insufficient data exists to evaluate the potential for more severe adverse reactions for individuals with asthma or other respiratory illnesses."

It should be noted that the toxicologist did not have access to the test data where asthmatic individuals participated in Crotega testing, and that NIOSH does not make exceptions in their requirements for exposure of sensitive populations to the active ingredient in REPULS.

3. PRIMARY SKIN IRRITATION. "Irritation effects on exposed skin is a reasonable expectation for individuals exposed to the spray. These effects are expected to be temporary and unlikely to pose a significant health hazard."

The effects of skin contact will be even less severe with REPULS, however, than a concentrated form of the active ingredient which has a pH of 2.94-3.96⁵. The pH of the REPULS solution is 5.6–5.8.

4. DERMAL SENSITIZATION. "A dermal sensitization study demonstrated that [the active ingredient] in REPULS, through dermal exposure, does not cause sensitization reactions."
5. LONG TERM HEALTH EFFECTS. "Exposures to [the active ingredient in] REPULS defense spray will almost certainly be relatively short, perhaps less than one hour, and occur as one-time events and not involve repeated exposures. As such, the risk(s) of health effects induced from repeated or long-term exposure are not an issue. The available testing for [the active ingredient] indicates that single exposures pose a low concern for mutagenic, reproductive or teratogenic effects."

Primary Eye Irritation Follow-up Studies: Based on the results of previous Primary Eye Irritation studies and the Risk Assessments by the toxicologist, Crotega reformulated the REPULS solution and performed three additional Primary Eye Irritation studies, each with a different concentration of the active ingredient, varying from 17% to 30%. The results indicated that at 17% and 24%, the material is "moderately irritating" with all the test subjects having no symptoms by the seventh day of the study.

Additional Test Results: Since some potential customers are subject to food contamination regulations, Crotega had REPULS tested at a laboratory that specializes in agriculture to determine if there were any pesticide residues present. REPULS was tested for 133 pesticides and none were detected.

⁵ Aqion, pH of Organic Acids and Salts, 11/14/2015

SUMMARY

The SentiZone™ System using REPULS® solution meets all the established objectives. During research and development, Crotega rejected other materials due to their potential for harm and mid- to long-term effects. One was pepper spray, a widely accepted material for self-defense devices, which can have lingering effects on the eyes⁶, lasting for months and requires significant time to dissipate from buildings. Pepper spray is insoluble in water and thus requiring solvents or emulsifiers for removal.

Innocent bystanders exposed to REPULS can be treated immediately using eye wash stations and showers, eliminating much of the discomfort from contact with the material. Existing eye irritation testing protocols do not account for the fact that REPULS causes involuntary closure of eyelids, minimizing the amount of material contacting the eye. All the volunteers who tested the system reported that once the liquid was sprayed on their face, they could not open their eyes and they experienced immediate relief upon washing with water.

The testing on the reformulated version of REPULS confirms that irritation to the eyes is temporary and recovery will occur over time. The testing performed by Crotega and toxicological evaluations confirm that REPULS will not pose unreasonable risks of injuries to innocent bystanders.

ABOUT CROTEGA

Crotega employs technology to bring about a safer world. We empower law enforcement, individuals, and building owners to take control with advanced solutions that neutralize active threats while reducing the risks to the user. We aim to make public safety more humane, offer peace of mind, and ultimately, save lives. Learn more at crotega.com.

ABOUT THE AUTHOR

Gary Jones is president of BGA Consulting, LLC, a firm that specializes in consumer product safety and compliance. He has over 40 years of experience working in the children's product industry to ensure safety, reliability and quality. He is an ASQ Certified Reliability Engineer and an ASQ Certified Quality Engineer.

⁶ "Effects of Oleoresin Capsicum Pepper Spray on Human Corneal Morphology and Sensitivity", Vesaluoma, et al, July 2000