

HEALTH RISK ANALYSIS OF FIRST DEFENSE® PEPPER SPRAY USING AN ACUTE WHOLE-BODY INHALATION EXPOSURE

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INTRODUCTION

First Defense® aerosols contain food grade ingredients formulated to provide a safe and reliable means of incapacitation. First Defense is a water-miscible, non-flammable pepper spray designed to fill a void in the force continuum. The ability to enhance officer safety while minimizing the risk of injury to a suspect has long been a goal within the law enforcement and correctional communities. In order for a tool to be effective, it must have the ability to deter individuals from unwanted action or provide a means to aid in incapacitation or apprehension. Pepper spray accomplishes this task by eliciting an undesirable response when the active ingredient, oleoresin capsicum, comes in contact with the eye, nose, and mucous membranes. This response is in the form of a burning sensation upon contact, causing inflammation and tearing of the eyes, which leads to involuntary closure. Should the spray become inhaled, it causes swelling to the mucous membranes and a sensation of shortness of breath. This effect, combined with involuntary closure of the eyes, is a very useful tool within the force continuum.

Previous studies have been done on First Defense to determine the aerodynamic particle size of the spray when actuated. The findings have been incorporated and are useful when quantifying exposure levels. As a further method to ensure the safety of First Defense, a whole-body inhalation exposure was performed on two species of rodents. This route of exposure was chosen, as it would most likely mimic the application of the spray to humans. An initial study was conducted on Sprague-Dawley rats in order to determine any short-term toxicity of the product and to provide valuable information in accessing the health risk of First Defense. A follow-on study was conducted on CD-1 mice in an attempt to duplicate the findings in an alternate species, further validating the data and method.

BACKGROUND

The use of chemical agents on individuals has been practiced throughout this century in various arenas. The use of tear gas by the military in foreign conflicts first proved the effectiveness of this method to deal with combatants. Throughout this period, law enforcement agencies faced the challenge of dealing with civil disturbances in the U.S. The lack of manpower and tools to adequately deal with these types of conflicts, without resorting to the use of lethal force, prompted the need for an alternate method. Incorporating the use of tear gas and the tactics used by military to dispense the agent, effectively controlling large crowds and aggressive or threatening individuals, provided the much-needed solution for law enforcement.

Throughout the use of chemical agents, the need to find a safer and more effective product has been explored. The introduction of oleoresin capsicum, a natural extract of chili peppers, has been embraced as a more effective means to deal with individuals with a high tolerance for pain or individuals under the influence of drugs or alcohol. The placement of pepper spray within the force continuum deleted the void between verbal commands and soft contact, where resistance is not anticipated, and the use of blunt force (fist or baton). The implications of this addition are several fold.

First and foremost, the ability of an officer to remove themselves from a situation in which blunt force is involved benefits both the officer and the suspect. The weapon of choice nine out of ten times of suspects is the hands and feet (REFERENCE). Without an alternative method or tool, the officer is forced to use at least the level of force dictated by the suspect, if not more. However, by using pepper spray, the officer can preclude the need for violence or blunt force and effectively "take the fight out of the fighter." By reducing the level of



force needed to resolve an issue, the risk of injury to both parties is greatly reduced. A benefit, often overlooked, is the use of these products as a visual deterrent when used with verbal commands. The ability to draw the pepper spray and threaten the use of it, may often be sufficient to resolve an issue without the use of force.

Even though pepper sprays were used as early as 1977 in the United States, it wasn't until about 1992 that they gained widespread use. The use of pepper sprays to incapacitate individuals, either from a defensive standpoint or as a deterrent from unwanted action, has become a useful tool to traditional law enforcement. However, the rush to find a safer and more reliable replacement to the traditional defense sprays, CS and CN, has led to a flood of pepper sprays on the market. This haste has allowed products to become available that may be even more harmful than what they were intended to replace. With no regulatory agency overseeing and setting guidelines in the production of these sprays, the responsibility of providing a safe product to the consumer rests solely with the manufacturer.

Because these products differ so much in their formulation, it would not be accurate to test only the active ingredient and try to generalize the results for pepper sprays as a whole. When evaluating these products, all of the ingredients within the formulation are crucial in determining the safety of the product. This approach is extremely necessary, considering the other ingredients make up 90-95% of the total formulation. Other areas of concern with pepper sprays focus around flammability and delivery mechanisms.

STUDY DESIGN

Sprague-Dawley Rats

This study was designed to assess the short-term toxicity of First Defense in Sprague-Dawley rats when administered by a one-minute, whole-body inhalation exposure. The study was designed to provide information under exaggerated clinical use conditions and is a follow-on study to an earlier aerodynamic size analysis.

The study facility was provided with the test article from lot number OC557. An independent analysis verified the contents ingredients as follows: capsaicinoids 0.21%, ethanol 28%, propylene glycol 13%, and water 59% (3). The study consisted of two parts, a range-finding test and a limit test.

Range-Finding Test

The study was initiated with a range-finding test using one male and one female rat at three different exposure levels. The test article was generated into an aerosol with TSI Model 9306 6- Jet Atomizers. The aerosol was blown through a RHS-100L whole-body inhalation chamber and then vented from the chamber and collected with an air treatment system, which consisted of a pre-filter, HEPA filter, a charcoal bed, and a water scrubbing tower. Once the aerosol was generated inside the chamber, the lid was carefully removed and the appropriate animals were gently placed inside. The lid was then carefully placed back on the chamber for the duration of the exposure. Care was taken to minimize the disruption of the test article aerosol.

Each aerosol exposure lasted for a period of one minute. The chamber pressure was measured prior to the inhalation of each exposure and was maintained at a slightly positive pressure. The aerosol concentration was measured by gravimetric techniques in the breathing zone of the chamber just prior to the introduction of the animals. After each exposure, the animals were removed from the chamber, and any residual test article was rinsed from the hair coat. The animals were dried with a towel and returned to their cages. The animals were observed twice daily for seven days, until completion of the study.



Limit Test

Upon completion of the range-finding test, a limit test was conducted on five male and five female Sprague-Dawley rats. The test article was generated into an aerosol and delivered to the chamber in the same manner as in the range-finding test. The chamber air-flow was maintained slightly positive and the aerosol concentration was recorded once prior to initiation and once during the exposure. In addition, chamber temperature and humidity were recorded prior to the study. An aerosol aerodynamic particle size distribution was conducted prior to the exposure using an ITP 7 L/min. cascade impactor.

The animals were placed into the chamber in the same manner as with the range-finding test. After a one-minute exposure, the animals were removed and test article residue was rinsed off, and the animals towel-dried. The animals were placed back into their cages and observed twice daily for 15 days. At the completion of the study, day 15, the animals were euthanized by carbon dioxide inhalation and a gross necropsy was performed.

CD-1 Mice

A follow-on study was conducted on CD-1 mice in order to validate the study design and protocol.

Range-Finding Test

A range-finding test was not conducted on the CD-1 mice. The levels obtained in the previous species will be used to determine the limit test.

Limit Test

The limit test was conducted on the CD-1 mice in the same manner as carried out with the Sprague-Dawley rats. The one exception was the animals were euthanized with necropsy on day 14.

RESULTS

Sprague-Dawley Rats

The three exposure levels tested in the range finding were 2.56 mg/L, 5.04 mg/L, and 8.42 mg/L. No mortalities were produced at any of these levels. Based on these findings, the concentration selected for the limit test was 8.50 mg/L prior to the introduction of the animals. Once the lid was placed back on the chamber, the test article concentration was measured at 5.76 mg/L during the exposure. The aerodynamic particle size of the test article generated in the chamber was $3.5\mu \pm 1.7\mu$ (microns). The chamber temperature and relative humidity was 76.8°F and 63.2%, respectively. The oxygen content within the chamber was maintained at 21% throughout the study.

An attempt was made to observe the animals during the aerosol exposure period. However, due to the density of the test article, the animals could not be seen. The most notable clinical signs once the animals were removed from the chamber included salivation, lacrimation, urine stain, and dark material around the facial area. No mortalities occurred during the limit test, and all animals survived to the completion of the study. On day 15, the animals were euthanized, and a gross necropsy was performed. No significant internal findings were discovered.

CD-1 Mice

The aerosol concentration for the limit test was 8.62 mg/L (pre-exposure) and 5.80 mg/L (during exposure). The aerodynamic particle size of the test article generated in the chamber was $3.3\mu \pm 1.8\mu$. The chamber temperature and relative humidity was 66.9°F and 70.4%, respectively. The oxygen content within the chamber was maintained at 21% throughout the study.



No mortality occurred during the study. The only notable clinical observations were ocular discharge in four animals on day 0, and a slight body weight loss in two female mice between day 7 and day 14. All other animals experienced body weight gain or maintenance during the study. There were no gross internal findings observed at necropsy on study day 14.

DISCUSSION

The purpose of these studies was to evaluate any short-term toxicity associated with a one-minute whole-body inhalation exposure. More specifically, the intent was to determine if a level of lethality existed under their exaggerated laboratory setting. Based on the range-finding and limit tests, the one-minute acute inhalation LC50 of First Defense was estimated to be greater than 5.76 mg/L in the rat and 5.80 mg/L in the mice. Using this information and data collected from an earlier particle size analysis (4), conclusions can be drawn as to the health risk of using First Defense.

Particle size is generally considered the critical factor that determines the region of deposition within the respiratory tract (5). It has been previously determined that 1,182 grams of test article discharged into a 22-liter collection chamber produced an aerosol concentration of 0.0057 mg/L (4). Of the percent aerosolized, 0.0001%, the mass median aerodynamic particle size and geometric standard deviation was calculated to be $6.0\mu \pm 4.2\mu$. The aerosol was generated by impacting the stream onto a flat surface within the chamber from a distance of 18 inches. The resulting aerosol was drawn through an air treatment system similar to the one used in the limit test.

The information gathered in these studies provides a useful mechanism in evaluating the health risk of First Defense. In addition to these findings, there are other guidelines in place to ensure the safety of this product. The approach to safety is multi-faceted, encompassing engineering and quality controls. First Defense is a non-flammable formulation consisting of food grade ingredients that are dispensed with a nitrogen propellant, producing a stream of ballistic droplets. The ability to contain the formulation in a stream prevents smaller particles from being generated, which are more readily respirable. Quality control regulates that the amount of active ingredient present in the formulation to be within range of 0.18-0.22 percent. This is verified by an independent laboratory analysis on each lot prior to filling.

Beyond these controls, several conditions exist in these studies that would be extremely difficult to produce in an actual field use of First Defense.

- The aerosol generated in the particle size analysis was impacted from a minimal distance of 18 inches onto a flat surface. This close range and flat surface produces an elevated aerosolization rate compared to what would be generated from an impact greater than the recommended three feet. Furthermore, the contour of the human face would likely deflect much of the spray, quite possibly away from the nasal and oral cavities. Even if little is deflected, the aerosol generated would then have to be respired shortly after impaction so as not to be affected by environmental conditions, such as a breeze.
- The possibility of generating an aerosol concentration of 5.76 mg/L in an outdoor application is almost unachievable. Situations could occur where an individual may be sprayed in an enclosed environment, such as a car or prison cell. However, the amount needed to generate that concentration is highly unlikely with hand-held units. For reference, based on the particle size analysis of First Defense, 14 MK-4 units, or 1,182 grams, were discharged into a collection chamber producing an aerosol concentration of 0.057mg/L. The chamber was approximately the size of a 5-gallon bucket, and yet still only produced a level roughly 1/100 of the level tested in the rat and the mice.



- Lastly, the ability to sustain this concentration for a one-minute continuous exposure would be difficult to produce. It is noted that individuals in physical exertion or duress will have an increased respiratory demand. However, even with increased respiration, the amount that could be respired would be far below the amount generated in a one-minute exposure.

CONCLUSION

Based on the information provided in these studies and the conditions associated with its use, the potential acute health risk of using First Defense, from an inhalation exposure, would appear to be extremely minimal. However, it should be noted that individuals with respiratory conditions such as emphysema, asthma, or bronchitis may be more sensitive to any foreign agent.

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