

AERODYNAMIC PARTICLE SIZE ANALYSIS OF FIRST DEFENSE® PEPPER SPRAY

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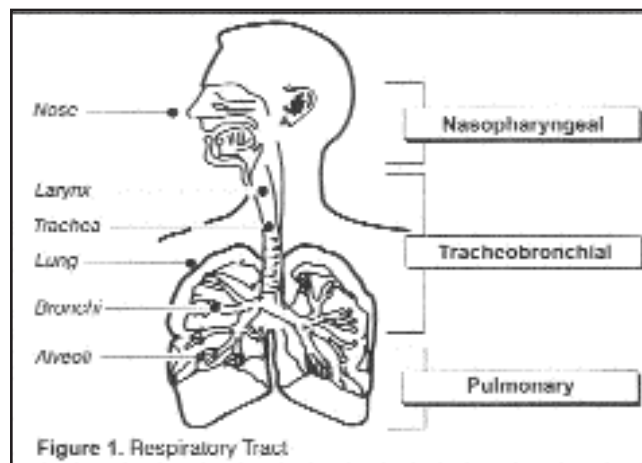
INTRODUCTION

In an effort to further evaluate the safety of First Defense aerosol products, an aerodynamic particle size analysis was conducted on the MK-4. Based upon the aerodynamic size of the particles, a theoretical respiratory deposition can be determined. It should be noted that the mechanism of delivery utilized produces a stream of ballistic droplets. It is not dispensed in the form of a mist or fog, which generally produces significantly smaller particles.

BACKGROUND

Pepper sprays have been used in various capacities throughout the United States over the past fifteen years. In that time, numerous products have been produced and sold in a variety of shapes and sizes. Unfortunately, very few manufacturers have conducted adequate safety evaluations of their products. Recently, however, increased concern from legitimate manufacturers and regulatory agencies have forced a review of the products on the market. The initial focus has centered around formulations and potentially harmful ingredients, with additional concerns on flammability and environmentally safe propellants. The latest issue is the delivery system, and the resulting aerodynamic particle size of the aerosol produced.

Particle size is generally considered the critical factor that determines the region of deposition within the respiratory tract (3). For the purpose of understanding the mechanism of deposition, the respiratory tract will be compartmentalized into three regions: the nasopharyngeal, tracheobronchial, and the pulmonary (Figure 1). As air is inhaled, it travels through these regions following a complex pathway that includes nasal hair and mucous-lined surfaces. This combination, along with the changing velocities in the branching pathways, help to filter inhaled particles.



The nasopharyngeal region consists of the oral and nasal cavity down to the larynx. This region removes the larger inhaled particles, 5 to 30 μ (microns), by impaction and filtration. The tracheobronchial region, as the name implies, includes the trachea and extends to the terminal bronchioles. Particles ranging from 1 to 5 μ generally are deposited in this region by sedimentation due to the lower airflow and gravitational forces. The remaining particles, 1 μ and smaller, settle in the pulmonary region by diffusion. This region consists of the respiratory bronchioles and alveoli, where gas exchange takes place.

The aerodynamic particle size is crucial to minimizing the possibility of undesirable and even harmful effects from an exposure to pepper spray. The active ingredient in pepper sprays is oleoresin capsicum (OC), an oily resin plant extract. The spray is intended to cause a burning sensation in the eyes, nose and mouth. Contact with OC particles incapacitates subjects by causing an almost immediate burning of the skin, and a burning, tearing and swelling of the eyes. This exposure to the OC can cause severe blepharospasm (twitching or spasmodic contraction) of the eyes and even involuntary closing of the eyes (1).



When the agent is inhaled, the respiratory tract is inflamed, resulting in a swelling of the mucous membranes lining the breathing passages, and temporarily restricting breathing to short, shallow breaths (6). Inhalation causes coughing and shortness of breath. This, in turn, causes a gagging reflex and gasping for breath. This has been reported to be a response to bronchoconstriction, a constriction of the airway (2, 5). Repeated exposure can cause tachyphylaxis, a decreasing response following consecutive administration (2). Furthermore, if a significant amount of the aerosolized product reaches the pulmonary or alveolar region, where air exchange takes place, it may greatly interfere with essential respiration. This is a primary concern for aerosols generating a mist or a fog where the aerodynamic particle size is much smaller, thus potentially allowing an excess amount of active ingredient to travel to the alveolar region.

STUDY DESIGN

This study was performed to assess the aerodynamic particle size when aerosolized under exaggerated clinical use conditions. The test article was discharged into a 22-liter collection chamber maintained under slightly negative pressure. A total of 14 live MK-4 units were consecutively discharged into a collection chamber. The total discharge time was 5 minutes and 25 seconds. The stream impacted the end cap of the chamber at a distance of 18 inches. The aerosol was drawn from the chamber through an exhaust system consisting of a pre-filter, a HEPA filter, a charcoal filter and a water scrubbing tower. The chamber was equilibrated prior to the initiation of the sampling by completely discharging one MK-4 into the chamber.

The aerosol was sampled using a cascade impactor which was attached to a dry gas meter and a vacuum pump. The filters within the cascade impactor were weighed prior to initiation of the sampling and upon completion. A controlled amount of aerosol was drawn from the chamber at a rate of 7 liters per minute for 5 minutes to ensure an adequate sample.

RESULTS

A total of 1,182 grams of the test article was discharged into the 22-liter collection chamber. This produces an aerosol concentration of 0.057 mg/L resulting in an estimated aerosolization rate of 0.0001%. Of the percent aerosolized, the mass median aerodynamic particle size and geometric standard deviation was calculated to be $6.0\mu \pm 4.2\mu$ (microns). The aerodynamic particle size range would theoretically result in a 70% nasopharyngeal deposition, a 20% tracheobronchial deposition, and a 10% alveolar deposition (3, 4).

Based upon the experimental results for the MK-4, values were calculated for recommended one.

	MK-3	MK-4	MK-5	MK-6
Net Weight:	41.7 grams	85.0 grams	41.7 grams	19.3 grams
Avg. 1-Second Burst:	8	19	8	4
mg/Burst:	5213	4474	5213	4825
mg Aerosolized:	0.5213	0.4474	0.5213	0.4825
Nasopharyngeal:	0.3649 mg	0.3132 mg	0.3649 mg	0.3378 mg
Tracheobronchial:	0.1043 mg	0.0895 mg	0.1043 mg	0.0965 mg
Pulmonary:	0.0521 mg	0.0442 mg	0.0521 mg	0.0482 mg

Milligrams per burst were calculated by dividing the content weight by the average number of bursts for each container. This number was multiplied by the aerosolization rate of 0.0001% determined in the analysis, in order to calculate the milligrams aerosolized in each one-second burst. Based upon a particle size of $6.0\mu \pm 4.2\mu$, the theoretical deposition for each region of the respiratory tract was calculated.

DISCUSSION

This study was designed under exaggerated clinical conditions in order to provide valuable information on the safety of these products. For example, the material was impacted from a minimal distance of 18 inches onto a flat surface. This close distance and flat surface produces an elevated aerosolization rate compared to what would be expected in true field exposures. In addition, the aerosol generated was maintained in an enclosed container, allowing the aerosol concentration to remain unaffected by movement or natural influences such as a breeze. Other considerations and factors that would influence the exposure would be impaction in the close proximity of the nasal and/or oral cavities, and respiration at the time of impact.

CONCLUSION

Based upon an average 70 kg human, the MK-3 and MK-5 produce a 0.00074 mg/kg pulmonary dose, while the MK-4 and MK-6 produce 0.00064 mg/kg and 0.00069 mg/kg pulmonary dose, respectively. All three values would be considered low under ideal clinical exposures. However, it should be noted that individuals with respiratory conditions such as emphysema, asthma, or bronchitis may be more sensitive to any foreign agent.

The delivery systems used in the products mentioned above produces a stream of ballistic droplets. This mechanism proves to be very advantageous from both a tactical, i.e., accuracy and distance, and a safety viewpoint. Because the agent is dispensed in this form, very little of the product becomes aerosolized, minimizing the potential for pulmonary exposure. This is the distinct advantage over aerosols generating similar particles in a mist or fog.

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