American Chemistry Council | SEHSC Silicones Environmental, Health, and Safety Center

Recommendations for Aerosol Applications of Silicone-Based Materials

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This document provides information and recommendations relevant to formulating aerosol products containing silicone-based materials and explains the impact of aerodynamic particle size in aerosol product applications containing these silicone-based materials (ISO, 1995). Silicone-based materials may be safely used in industrial spray applications where exposure to aerosols can be minimized through appropriate industrial hygiene practices including engineering controls and use of personal protective equipment. The considerations and recommendations set forth in this document should be followed for aerosol applications, such as consumer spray applications, in which industrial hygiene practices are not available. It is recommended that if a silicone-based material or emulsion is being developed for an aerosol application, the developer should pay particular attention to the aerodynamic particle size distribution (MMAD) that will be generated and consider the potential for enhanced toxicity resulting from the presence of other components in the aerosol formulation.

General Recommendations

When considering a consumer aerosol application using any silicone-based material, regardless of the method of aerosol generation, the aerodynamic particle size distribution (expressed as the Mass Median Aerodynamic Diameter; MMAD) should be 30 μm or greater with no more than 1% of the particle mass having an aerodynamic diameter of 10 μm or less. By following this recommendation, virtually all aerosol particles will be deposited in the nasopharyngeal region with substantially less deposited in the tracheobronchial (conducting airways) or alveolar (gas exchange) regions. If an aerosol application results in a particle size distribution with more than 1% of the aerosol mass with a MMAD of 10 μm, or less, further evaluation of the inhalation toxicity potential (*e.g.* acute inhalation toxicity test) should be considered.

Potential Effects

The physical properties of an oil or fat aerosol may lead to a number of potentially serious health effects following inhalation exposure. Chemical pneumonitis, lipoid pneumonia, and petroleum distillate pneumonitis are all terms that describe pulmonary (deep lung) tissue damage, edema, fibrosis, or other inflammatory changes in the lungs. These changes can be induced by inhalation of an oil or fat aerosol such as a silicone-based material into the alveolar region of the lung. Regional release of endogenous lipid (fatty) or oil within the lung, as occurs in certain disease

700 2nd Street, NE, Washington, DC 20002

states, also can produce a pneumonitis reaction. Ostensibly, this damage is not due to a specific mechanism of chemical toxicity but rather is driven by a physical disturbance of the alveolar lining and subsequent attempts by inflammatory cells within the lung to resolve the lesion.

Considerations

Physical characteristics, such as surface tension/activity and spreadability, contribute to the similarity between silicone-based materials and other oils or fats, and the potential for pulmonary effects for aerosols of MMAD <30 μm. Silicone-based materials have a wide variety of uses including applications for consumer use. It is recommended that if a silicone-based material is being developed for an aerosol application, the developer should pay particular attention to the aerodynamic particle size distribution (MMAD) that will be generated and also consider the potential for respiratory effects resulting from the presence of other components in the aerosol formulation.

APPENDIX

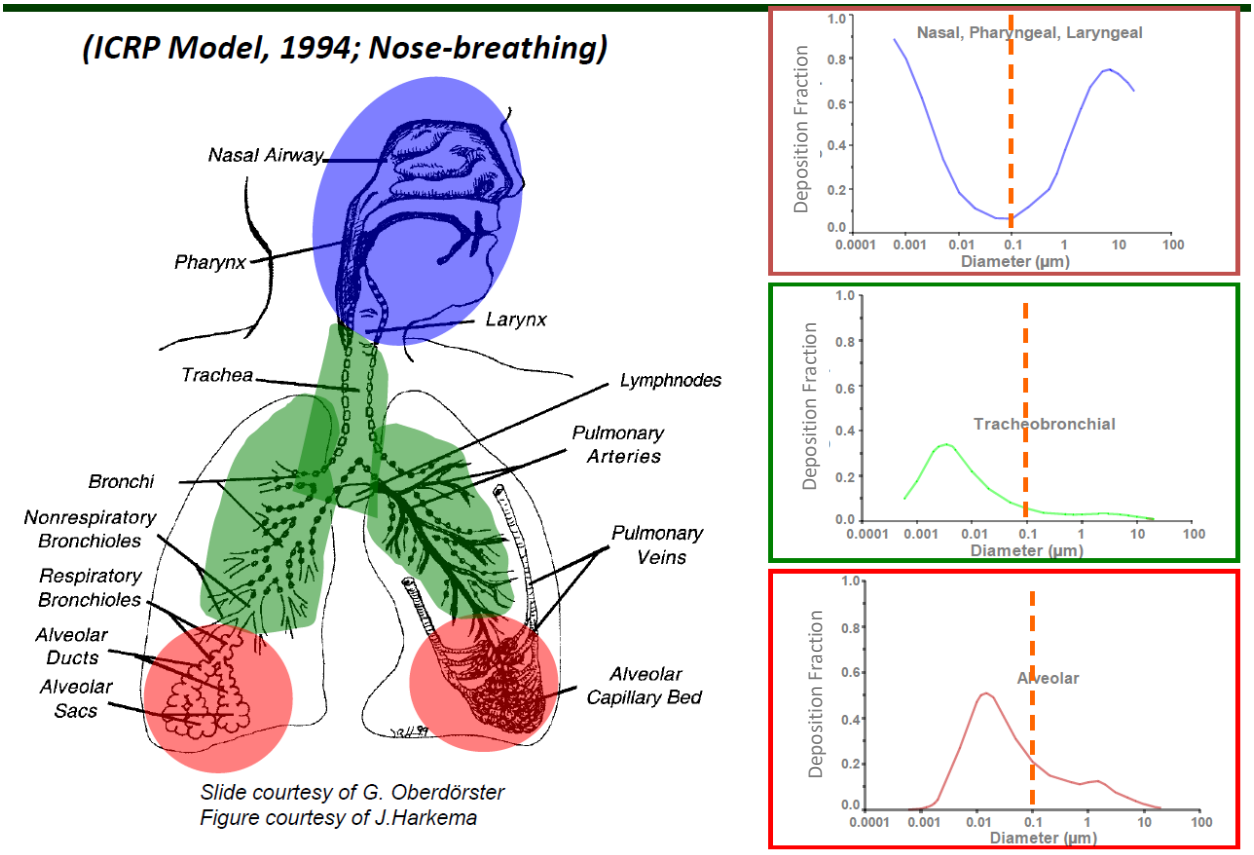
What Are Aerosols?

Aerosols are often described as multiphase systems of solid (fumes or dusts) or liquid (mists) particulates suspended in air or other gases (Rothe, *et al.* 2011). The particles remain suspended because they are small and, therefore, do not fall (or sediment) rapidly under the force (or pull) of gravity. Many chemicals can be inhaled as aerosols. Just as liquid and solid aerosol particles can sediment in air, they can also be deposited in the upper and lower respiratory tract, if inhaled. The aerodynamic diameter of a particle determines the location and efficiency of deposition within the upper and lower respiratory tract (Fig. 1). Any aerosol can be described based on its particle size distribution and penetration of these particles in the various regions of the respiratory tract (Nieboer et al. 2005). The Inhalable Aerosol Fraction is that fraction of aerosol particles that can enter the body through the nose and/or mouth during breathing. This fraction corresponds to particles with aerodynamic diameter (d_{ae}) $\leq$ 100 µm. This aerosol fraction may be relevant to health effects anywhere in the respiratory tract. The Thoracic Aerosol Fraction (d_{ae} < 30 µm) is a sub-fraction of the Inhalable Fraction composed of particles that can penetrate into the tracheo-bronchial/alveolar region of the lung. The Respirable Aerosol Fraction (or alveolar fraction) is the sub-fraction of inhaled particles (d_{ae} < 10 µm) that penetrates into the alveolar (gas exchange) region of the lung.

The regional deposition, clearance, and absorption of aerosols in the respiratory tract depend on many factors including solubility, reactivity, and aerodynamic diameter (MMAD). (Rothe, *et al*., 2011, Bakand, *et al.*, 2005, WHO, 1999). The aerodynamic diameter of an aerosol particle is defined as the diameter of a hypothetical, smooth sphere of unit density (1 g/cm^3) that has the same gravitational settling velocity as the droplet in calm air, regardless of its actual geometric size, shape and density (WHO, 1999, Phalen and Oldem, 2006). The following are just a few references that can be consulted for information on methods for determining the particle size distribution for an aerosol: Vincent, 1995; Hinds, 1982; FEA European Aerosol Federation, 2009; Kulkarni and Willeke, 2011.

Brown *et al.* (2013) have determined the size of respirable particle fractions for both adults and children. They estimated the fraction of inhaled particles penetrating beyond the larynx (0.5-20 µm aerodynamic diameter, based on experimental data) and ciliated airways (based on a mathematical model) for an adult male, adult female, and a 10-year old child during typical daily activities and breathing patterns and found that the aerodynamic diameter needed to be <3 µm for adults and <5 µm for children in order to pass beyond the larynx. Similarly, the US National Institutes of Environmental Health Sciences, citing Johnson and Vincent (2003), has stated, "Particles in the size of range of 10 to 100 µm are unable to make the turns and impact on the nasal hairs, nasal mucosa, or mucus-covered ciliated epithelium in the bronchi and bronchioles. Soluble particles simply dissolve, while insoluble particles are transported up the conducting airways by the ciliated epithelium and swallowed or expectorated." The Cosmetic Ingredient Review Precedent on Aerosols (2012) concludes the same in that "there is broad scientific consensus that the probability of penetration of droplets/particles with d_{ae} >10 µm into the alveolar region is essentially zero."

Figure 1. Impact of aerodynamic particle size on regional deposition in humans



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