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Mini review

Principle considerations for the risk assessment of sprayed consumer products

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ABSTRACT

In recent years, the official regulation of chemicals and chemical products has been intensified. Explicitly for spray products enhanced requirements to assess the consumers'/professionals' exposure to such product type have been introduced.

In this regard the Aerosol-Dispensers-Directive (75/324/EEC) with obligation for marketing aerosol dispensers, and the Cosmetic-Products-Regulation (1223/2009/EC) which obliges the insurance of a safety assessment, have to be mentioned. Both enactments, similar to the REACH regulation (1907/2006/EC), require a robust chemical safety assessment. From such assessment, appropriate risk management measures may be identified to adequately control the risk of these chemicals/products to human health and the environment when used.

Currently, the above-mentioned regulations lack the guidance on which data are needed for preparing a proper hazard analysis and safety assessment of spray products.

Mandatory in the process of inhalation risk and safety assessment is the determination and quantification of the actual exposure to the spray product and more specifically, its ingredients. In this respect the current article, prepared by the European Aerosol Federation (FEA, Brussels) task force "Inhalation Toxicology", intends to introduce toxicological principles and the state of the art in currently available exposure models adapted for typical application scenarios. This review on current methodologies is intended to guide safety assessors to better estimate inhalation exposure by using the most relevant data.

Contents

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1. Introduction

The human respiratory tract is a dynamic system responsible for the gas exchange and the filtering of airborne pathogens and foreign material (Salem and Katz, 2006).

To understand the specific defence mechanisms and filter function of the respiratory tract, some anatomical basics are introduced. The vestibular hairs in the nose, mucociliary clearance, and high-velocity clearance/reflex mechanisms (sneezing and coughing) are first mechanisms of such defence. Additional, non-ciliated airway secretions, blood/lymph clearance, immunological responses, contribute to this protective function.

As illustrated in Fig. 1, particle/droplet deposition throughout the respiratory tract is determined by the inhalation characteristics (duration, frequency, and strength), the size (aerodynamic diameter) of sprayed particles/droplets and their physicochemical properties and specific clearance mechanisms.

Particles/droplets exceeding a diameter of 30 μm are normally filtered in the nasopharyngeal passage and would not reach the lung. In contrast, smaller ones may reach the lower airways. The mucosal lining of the upper respiratory tract can serve as a protective barrier and a trap for such smaller particles/droplets. The mucociliary escalator, which promotes the movement of mucosal fluid up the extrathoracic region (nose, mouth and throat) plays a major role in the clearance process of inhaled material.

The German MAK Commission stated that the particles/droplets with an aerodynamic diameter of >15 μm are deposited almost exclusively in the extrathoracic region, and healthy humans will clear particles >7 μm within 24 h from the tracheobronchial compartment. The threshold of particle/droplet diameters small enough to reach the alveoli is often set to be 5 μm (MAK, 2012). However, in this document particles/droplets with an aerodynamic diameter <10 μm are conservatively considered to be respirable and suspected to reach the deeper lung.

Beside the mentioned deposition of particles/droplets propellants (gases) and solvents (vapours), often used in spray products, could have an additional health impact which has to be taken into account for the overall hazard assessment of inhalable chemicals and products.

2. Aims

This article is intended to introduce important elements for the inhalation safety assessment, to enable safe use of spray products in both occupational and consumer settings, and help improve the understanding of relevant inhalation exposure scenarios in typical application environments. Product-type specific approaches for modelling the inhalation exposure of spray products will be reviewed.

A tiered (step-wise) approach for preparing a robust safety assessment is recommended, why detailed information on the ingredients hazard, the spray characteristics and data on the explicit exposure is needed. Both, local effects in the respiratory tract and the systemic inhalation toxicity have to be taken into account for the acute and repeated exposure.

It is essential to understand the realistic occupational or consumer exposure and application habits, in order to estimate the impact of other possible routes (such as dermal, oral and/or environmental background exposure) on the total systemic exposure and body burden.

3. Principles of the inhalation safety assessment

Four key elements have to be addressed:

3.1. Data collection

Available safety data for all ingredients and their specific regulation have to be evaluated.

3.2. Hazard assessment

The hazard assessment is processed in hazard identification and hazard characterization. Within hazard identification, ingredients are identified which are suspected to cause health concern when inhaled. For hazard characterization, the level of exposure due to the specific content of certain chemicals in the spray product is considered.

With this information, a decision should be made on the need of an explicit exposure assessment. If no hazardous chemicals are used in the spray product, or if they are only present at negligible, low concentrations, a risk characterization without an explicit exposure assessment could be sufficient.

3.3. Exposure assessment

To get knowledge on the realistic inhalation exposure to identified hazardous ingredients data on the room size in which the individual is present during spraying, and details on the spray application, e.g. frequency, duration and direction is needed. With one