



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products

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Exposure measurements of enzymes for risk assessment of household cleaning spray products

The REACH regulation requires that adequate control of risks be demonstrated for identified uses of substances. Enzymes have respiratory sensitisation potential¹. Risk assessment should be performed by establishing a Risk Characterisation Ratio. The Derived Minimal Effect Level (DMEL) for enzymes was proposed as 60ng/m³ for occupational use and 15ng/m³ for consumers². Exposure to enzymes must be below the DMELs.

Enzymes exposure (expressed as concentration of airborne enzymes) of consumers and professionals derived from use of household cleaning spray products should be evaluated to demonstrate safety prior to marketing. Exposure is dependent on a number of different parameters, e.g. formulation, enzyme concentration in product, habits and practices of the consumer and nozzle device. High viscosity formulations and foam-sprays would be expected to generate lower enzyme exposure than liquid formulations of low viscosity. However, each product and application of use will need an individual safety assessment based on actual exposure data, independent of such considerations. Please see the A.I.S.E. guidance³ and the SDA guidance⁴ for additional details on how to conduct an exposure assessment for enzyme containing consumer products.

This protocol is an example on how to assess enzyme exposure for a laundry pre-spotter spray product under normal use conditions. For other spray applications, the protocol will need to be modified for the conditions of use taking into account habits and practices to determine number of sprays and length of use. Also the test surfaces will need to be modified for the specific uses. Due to the very low DMEL value, the analytical method for determination of enzyme must be sufficiently sensitive.

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¹ AMFEP policy on classification of enzymes as "Respiratory Sensitisation Category 1" in accordance with the EU Regulation on classification, labeling and packaging of substances and mixtures (EC No 1272/2008, "CLP Regulation").

² Basketter et al., 2010. Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH. Toxicology 268: 165-170.

³ A.I.S.E., 2006, Developing consumer products containing enzymes: ensuring consumer safety. Brussels.

⁴ The Soap and Detergent Association, 2005. Risk Assessment Guidance for Enzyme-containing Products. Washington DC.

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Material and method

The experimental setup is described in the Weeks *et al*⁵ and in appendix 3 of the *Risk assessment guidance for enzyme-containing products*⁴ by SDA. The orientation and distances are given in figure 1.

Filters to catch the enzyme containing aerosols should be validated with respect to enzyme extraction. The air velocity through the sampling head should be around 1.25 m/s simulating air velocity during nasal inhalation. Therefore the pump should be able to circulate air to meet this air velocity.

Procedure for an experiment evaluating a fabric pre-spotter application

1. Pump is started
2. After 1 minute: spray 5 times on the framed textile with a frequency of 1 spray per second
3. Rest for 10 seconds, during this time change the framed textile.
4. Repeat the spray cycle 5 times, resulting in a total of 6 cycles
5. Leave the last framed textile and let the pump run
6. Turn off the pump after a total of 10 minutes from the first spray cycle

Each experiment should be replicated 4 times as a minimum. The total number replications are dependent on the ability to demonstrate statistical significance.

Results are presented as an exposure average, calculated on the basis of the performed experiments.

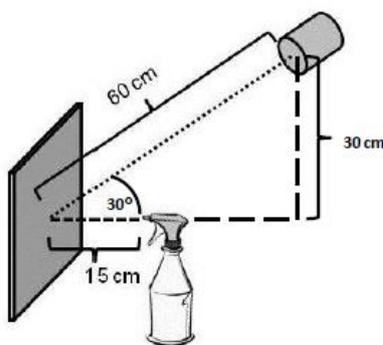


Figure 1. Schematic presentation of the distances between the spray bottle, textile target and the air filter.

⁵ Weeks *et al.* Assessment of sensitization risk of a laundry pre-spotter containing protease. *Cutaneous and Ocular Toxicology*; Dec, 2011; 30; 4; p272-p279