

EXPOSURE MEASUREMENTS OF ENZYMES FOR RISK ASSESSMENT OF HOUSEHOLD CLEANING SPRAY PRODUCTS

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The enzyme and the detergent industry have a long tradition of working actively on health and safety issues, including allergy and irritancy concerns. A continuing effort to advise on the safest and most effective use of enzymes in industrial, institutional and consumer related applications has long been conducted.

Enzymes can act as respiratory sensitizers (1) and at high concentrations proteolytic enzymes can also irritate skin and eyes. Hence, when including enzymes into household cleaning spray products, an assessment of the level of airborne enzyme exposure must be conducted. Enzyme containing spray products for household cleaning must meet various REACH requirements and suppliers of enzyme products as well as downstream users have obligations related to these requirements. A product specific exposure scenario must be generated documenting that the enzyme exposure during use will be below the acceptable exposure limit. According to (2) the acceptable exposure limit for consumers and for the vast majority of professionals will be 15 ng/m³.

Enzymes exposure (expressed as concentration of airborne enzyme protein) of consumers and professionals derived from use of household cleaning spray products must be evaluated to demonstrate safety prior to marketing. The level of exposure generated by a spray product is dependent on several parameters, e.g. formulation, enzyme concentration in product, temperature, nozzle design, habits and practices of the user and, the target surface and the distance from the spray to the target which will determine the impact velocity.

The interaction of these parameters has been shown to play an important role influencing the levels of airborne enzyme during spray applications. Hence, a more concentrated product in regard to enzyme inclusion in combination with an appropriate delivery method and formulation may generate exposure well below the acceptable exposure limit, whereas a less concentrated product with an inappropriate delivery method may generate exposure several times above the acceptable exposure limit. Also, 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. guidance (3) and the SDA guidance (4) for additional details on how to conduct an exposure assessment for enzyme containing consumer products.

Procedure

The experimental setup is described in the Weeks et al (5) and in appendix 3 of the *Risk assessment guidance for enzyme-containing products* (5) by SDA, and it is illustrated in figure 1 and 2.

This protocol describes how to assess enzyme exposure for a laundry pre-spotter spray product applied to fabric under normal use conditions. For other spray applications, the protocol will need to be modified as described above for the actual conditions of use, also considering habits and practices to determine the actual number of sprays and length of use employed by a typical user – which may differ from the use instructions. The test surfaces will also need to be modified to simulate the specific applications for each product under test. Due to the very low DMEL value, the analytical method for determination of enzyme protein accumulated on the airmonitoring filter must be sufficiently sensitive.

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. Make sure that the temperature of the spray product and study conditions equals the temperature for normal use of the product, as the extent of exposure will depend on the temperature of the product. Normal temperature of use should be consolidated via market research prior to the exposure study.

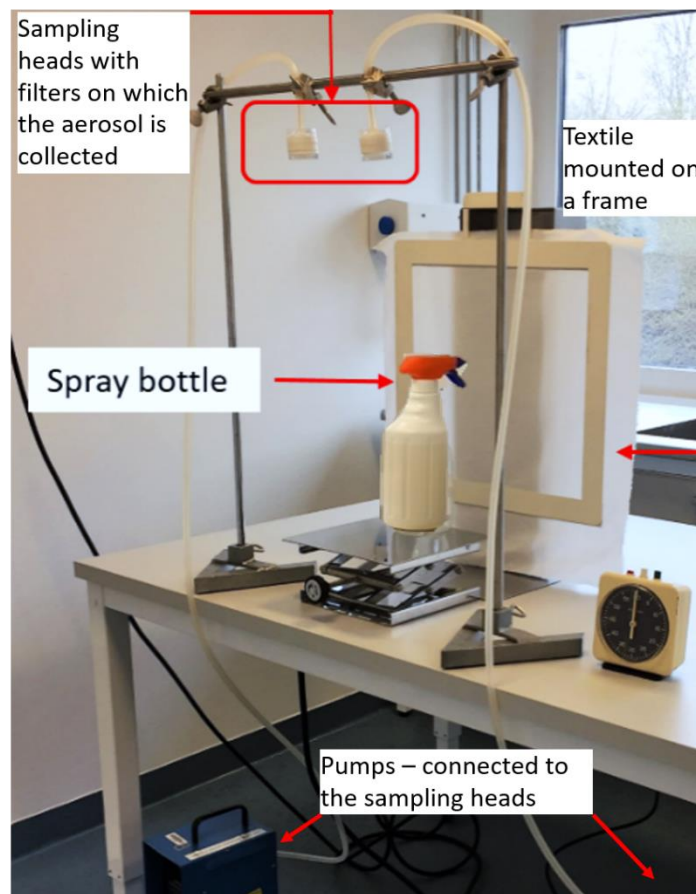


Figure 1. The set-up for spray exposure studies. Air-sampling equipment is used to collect airborne enzymes during the application of the spray on a surface corresponding to the specific use. After air sampling, the filters are analysed for enzyme protein collected during air sampling.

Procedure for an experiment evaluating a fabric pre-spotter application:

1. Pumps are 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 pumps 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.

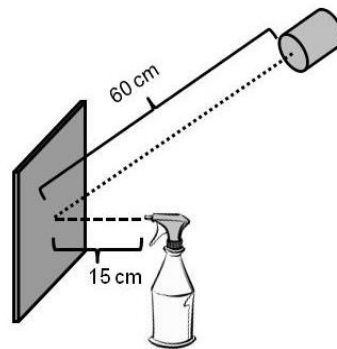


Figure 2. Schematic presentation of the distances between the spray bottle, textile target and the air filter.

Results:

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

Average exposure is compared to the DMEL for consumers: 15 ng/m³

If average exposure is < DMEL, the enzyme containing spray product will be approved

If average exposure is > DMEL, improvements of the enzyme containing spray product will have to be made before it can be approved – based on data from a new exposure assessment.

Improvements could be:

- Adjust enzyme concentration
- Increase viscosity
- Replace spray nozzle

Each exposure assessment covers the exact product assessed: Content, spray bottle and spray device. If any changes are made to any of these parameters, new exposure assessment must follow.

References

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.
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

