Industry Accepted Enzyme Applications in Institutional and Consumer Cleaning Products

This document summarizes the approved applications of enzymes when used in institutional and consumer cleaning products.

The enzyme industry has a long tradition of working actively with customers on health and safety issues, including allergen and irritancy concerns. As part of the continuing effort to advise customers on the safest and most effective use of enzymes in institutional and consumer related applications, the Consumer Specialty Products Association (CSPA) would like to provide general guidance regarding industry accepted range of applications in the marketplace today.

Enzymes are proteins that upon inhalation can act as allergens just like other naturally occurring proteins such as pollen or house dust mites. Inhalation of enzyme dust or aerosols may therefore induce sensitization. At high concentrations proteolytic enzymes can also irritate skin and eye tissue, but the enzyme can be readily removed by rinsing with water as enzymes are water soluble. Responsible enzyme suppliers have instituted comprehensive product stewardship programs for the use of enzymes in industrial processes.

Tools and techniques for assuring the safe use of enzymes have been applied by the detergent industry for decades and have shown that enzymes can be handled safely in the factory where a proper risk assessment and safety management program has been applied (Ref. 1).

The potential exposure and risk for consumers and institutional-users is much lower (orders of magnitude lower) than in a manufacturing environment. By following label directions, these enzyme-based cleaning products can be safely used by consumers and institutional-users (Ref 2). The acceptable exposure limit for enzymes used in consumer products has been suggested as part of the European REACH legislation in a peer reviewed publication (Ref. 3). According to this publication it is – depending on the condition of use – safe for consumers to be exposed to up to 15 ng/m³ of enzyme protein.

Solid enzyme products included in cleaning products must have a size exceeding 0.15 mm in diameter and be encapsulated with a protective coating that minimizes the inhalable enzyme exposure. If no detailed exposure assessment has been performed on the cleaning product the maximum concentration of proteolytic enzymes must not exceed 0.2%, active enzyme protein, due to the skin irritation potential. For all other enzymes the maximum concentration limit is 0.5% active enzyme protein per enzyme class.

The majority of known institutional- and consumer-use cleaning products containing enzymes have been evaluated in accordance with this recommended limit for the following applications:

- Household Laundry
- I&I laundry
- Manual Laundry
- Automatic Household Dishwashing
- I&I Dishwashing
- Hand Dishwashing
- Drain and drain line cleaners
- Grease Trap Clearing
- Industrial Waste Water system treatment
- Septic system treatment
- Portable Toilet treatment
- Small Sewage Holding Tank treatment
- Medical device cleaning (If ultrasonic equipment is used in the cleaning process it is mandatory that the equipment is kept closed during use and allowed to stand 5 minutes before opening after stopping operation)

Other institutional and consumer-use cleaning products will require safety evaluation for the specific product before commercial availability. This covers products for:

- Spray pretreatment of laundry, and any spray application in general (Ref. 4)
- Hard Surface Cleaning (e.g. floor cleaning)

Please remember, it is the final cleaning product manufacturer/marketer's legal responsibility to introduce a safe product to the market. Although there are currently no regulatory requirements for assessing the exposure to sensitizers in consumer applications in the US and Canada, it is recommended that formulators and distributors conduct quantitative risk assessments for their enzyme containing product formulations and application systems to ensure that the exposure to consumers and institutional-users is within acceptable limits. Responsible enzyme

suppliers can be consulted for guidance on performing such assessments as well as referrals to third party agencies.

When enzymes are formulated and used within established industry and company guidelines, the industry stands firmly by the efficacy and consumer safety of enzyme technology.

References

- 1. GUIDELINES FOR THE SAFE HANDLING OF ENZYMES IN DETERGENT MANUFACTURING, AISE 2002.
- US SDA. Risk assessment guidance for enzyme-containing products. Soap and Detergent Association, Washington, (2005). <u>http://www.cleaning101.com/files/SDA_Enzyme_Risk_Guidance_October_200</u> <u>5.pdf</u>
- 3. Basketter, D.A.; Broekhuizen C; Fieldsend M; Kirkwood S; Mascarenhas R; Maurer K; Pedersen C; Rodriguez C; Schiff H-E. (2010) Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH, Toxicology 268(3), 165-170.
- John A. Weeks, Robert A. Harper, Ronald A. Simon, and Joel D. Burdick (2011) Assessment of sensitization risk of a laundry pre-spotter containing protease, *CUTANEOUS AND OCULAR TOXICOLOGY*; DEC, 2011; 30; 4; p272-p279

For further information regarding the safe use of enzymes and related guidelines please see the reference material listed below.

- Basketter, D.A.; English, J.S.; Wakelin, S.H. and White, I.R. (2008) Enzymes, detergents and skin: facts and fantasies. British journal of dermatology 158, 1177-1181
- HERA. Human and environmental risk assessment on ingredients of household cleaning products Subtilisins (Proteases). Edition 2.0. 2007. <u>http://www.heraproject.com/RiskAssessment.cfm</u>
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- Sarlo, K; Kirchner, DB; Troyano, E; Smith, LA; Carr, GJ; Rodriguez, C. (2010) Assessing the risk of type 1 allergy to enzymes present in laundry and cleaning products: Evidence_from the clinical data, TOXICOLOGY; MAY 27, 2010; 271; 3; p87-p93