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Consumer Risk Assessment for Products Containing Enzyme Preparations

Guidance is provided on the consumer risk assessment framework used to help ensure the safety of products containing enzyme preparations. This process is used to identify the risk profile of an enzyme containing product and to evaluate the likelihood of exposure that may occur during consumer handling or use. Once the risks are characterized, effective risk management strategies can be implemented to minimize exposure to the user of enzyme-containing products. The key steps and additional reference information are diagrammed below.¹

Hazard Identification

Hazard identification is the characterization of the physical, chemical, and biological effects of a material. The primary hazard associated with enzymes is development of respiratory allergies from repeat inhalation exposures.

Dose Response (Benchmark Exposures)

The dose response for enzyme allergy is not well understood. Thus, benchmarks are used to support risk assessments. Benchmark values are based on studies in which exposure levels are associated with a demonstrated effect or the lack of an effect, in the people exposed. A commonly accepted derived minimal exposure limit for consumer applications is 15 ng/m³.²

Exposure Assessment

Exposure assessment evaluates the amount of enzyme the user may be exposed to during intended use, foreseeable misuse, and accidents. This value is then compared to the benchmark exposure to make risk characterization. The assessment also helps to define factors that may influence exposure.



Risk characterization is the examination of the relationship between human exposure (calculated or measured) and the hazard identification of a substance, to assess the likely incidence and severity of any effect. The risk characterization process for enzymes relies on comparing potential exposure to benchmark values associated with development of allergen-specific antibodies.

Risk Management

The objectives of the risk management process are two-fold: 1) To establish safe use of products within an acceptable risk level and, 2) To effectively communicate the risks, or lack there of, to appropriate audiences. Risk control measures to minimize enzyme exposures include: product design, reduction of enzyme concentration, and implementation of alternate applications.

References:

1- SDA (ACI) published "Risk Assessment Guidance for Enzyme Containing Products" in 2005. http://www.aciscience.org/docs/SDA_Enzyme_Risk_Guidance_October_2005.pdf

2 -Basketter DA, Broekhuizen C, Fieldsend M, Kirkwood S, Mascarenhas R, Maurer K, Pedersen C, Rodriguez C, Schiff HE: Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH. Toxicology 268 (2010) 165–170. 2009 Dec 21. https://www.ncbi.nlm.nih.gov/pubmed/20026217