

AMFEP/24/08

AMFEP POSITION ON INCLUSION OF ENZYMES IN PERSONAL CARE PRODUCTS AND COSMETICS

Enzymes have an excellent safety profile with low probability to cause adverse responses in humans. Enzymes, like other proteins, have the intrinsic potential to act as respiratory sensitizers (Basketter et al. 2012) are therefore classified as such in EU law.

Allergy to enzymes among consumers of enzyme-containing products has not been reported since late 1960s, and it is of utmost importance that this situation remains according to pertinent and safe standards. Isolated reported cases of enzyme allergies among consumers could lead to unwarranted limitations on the use of enzyme technology in other consumer applications.

However, there are several reports on personal care products containing enzymes or hydrolyzed proteins indicating respiratory sensitization from exposure to these products during use. These include one study on one enzyme-containing soap bar used for personal cleansing in one shower cabin (Kelling et al, 1998), enzyme-containing body lotion (Sarlo et al. 2004), and hydrolyzed wheat protein in soap bars used for facial cleansing (Yagami et. al, 2017).

Based on the information presented in these reports, AMFEP firmly believes that a thorough risk assessment process must be conducted by enzyme producers prior to the introduction of enzymes in any personal care and cosmetic product.

Such a risk assessment process needs to take into consideration potential **respiratory exposure during intended use as well as non-intended use as well as updated scientific evidence**. However, as benchmark data for acceptable or unacceptable respiratory exposure is not readily available for enzyme-containing personal care products, it may be necessary to **generate data through a clinical study**.

More information about how to conduct a risk assessment of enzyme-containing consumer products can be found in: AMFEP and ETA guideline on consumer risk assessments for enzyme containing personal care products and cosmetics.

A detailed guideline on the risk assessment process for enzyme-containing consumer products can be found in the ACI/AISE guidance document entitled "Risk Assessment Guidance for Enzyme-Containing Products" (ACI, 2019).

References

1. Basketter, D., Berg, N., Broekhuizen, C., Fieldsend, M., Kirkwood, S., Kluin, C., Mathieu, S., Rodriguez, C. (2012). Enzymes in cleaning products: An overview of toxicological properties and risk assessment/management. *Regulatory Toxicology and Pharmacology* 64, pp 117–123
2. Kelling, C, Bartolo, R, Ertel, K, Smith, L, Watson, D, Sarlo, K. Safety assessment of enzyme-containing personal cleansing products: Exposure characterization and development of IgE antibody to enzymes after a 6-month use test. *J Allergy Clinical Immunology* 1998;101(2 Pt 1)179-187.
3. Sarlo, K, Adamson, G, Hollis, V, Innis, J, Babcock, L, Kirchner, D. Development of Allergic Antibody to an Enzyme in a Body Lotion: Results of an 18-month Clinical Study. *J Immunotoxicology* 2004;1(2):71-77.
4. Yagami et al. "Outbreak of immediate-type hydrolyzed wheat protein allergy due to a facial soap in Japan" *J Allergy Clinical Immunology* 2017;140(3):879-881.
5. AMFEP and ETA guideline on consumer risk assessments for enzyme containing personal care products and cosmetics ([Link](#))
6. "Risk Assessment Guidance for Enzyme-Containing Products" ACI, 2019 ([Link](#))