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International Association for Soaps,
Detergents and Maintenance Products

Enzyme Safety Management

A series of web based training and Information Sessions developed and presented by the AISE Enzyme Safety Task Force

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Webinar 3a: End User Safety

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Developing products containing enzymes

Enzymes can bring significant benefits to detergent products, including improved efficiencies and other benefits.

However, prior to introducing an enzyme preparation into a product, a risk assessment must be conducted to ensure the safe use by the end user.

Each company that intends to use enzymes in its products has to play its role in understanding and managing the risk associated with enzymes.

If the risk is not appropriately managed, the consequences for the end user's health may be significant and may spread beyond a single product or company.

It is therefore essential that companies using enzymes in products consider very carefully how they are ensuring end user safety

Risk assessment of consumer products containing enzymes

AISE has developed a guideline for how to conduct a risk assessment on an enzyme containing product prior to launch.

The guideline on 'Developing Consumer Products Containing Enzymes' can be downloaded from the AISE webpage https://www.aise.eu/cust/documentrequest.aspx?DocID=2785

Hazard identification

Respiratory allergy is the main concern

This will be the focus for this presentation

Skin irritation may be a concern for certain enzymes

For information on this issue please consult the HERA document HERA Subtilisin (http://www.heraproject.com/files/22-F-07_PROTEASE_HERA_Final%20Edition%20(unsecured%20-%20PDFA-1b).pdf)

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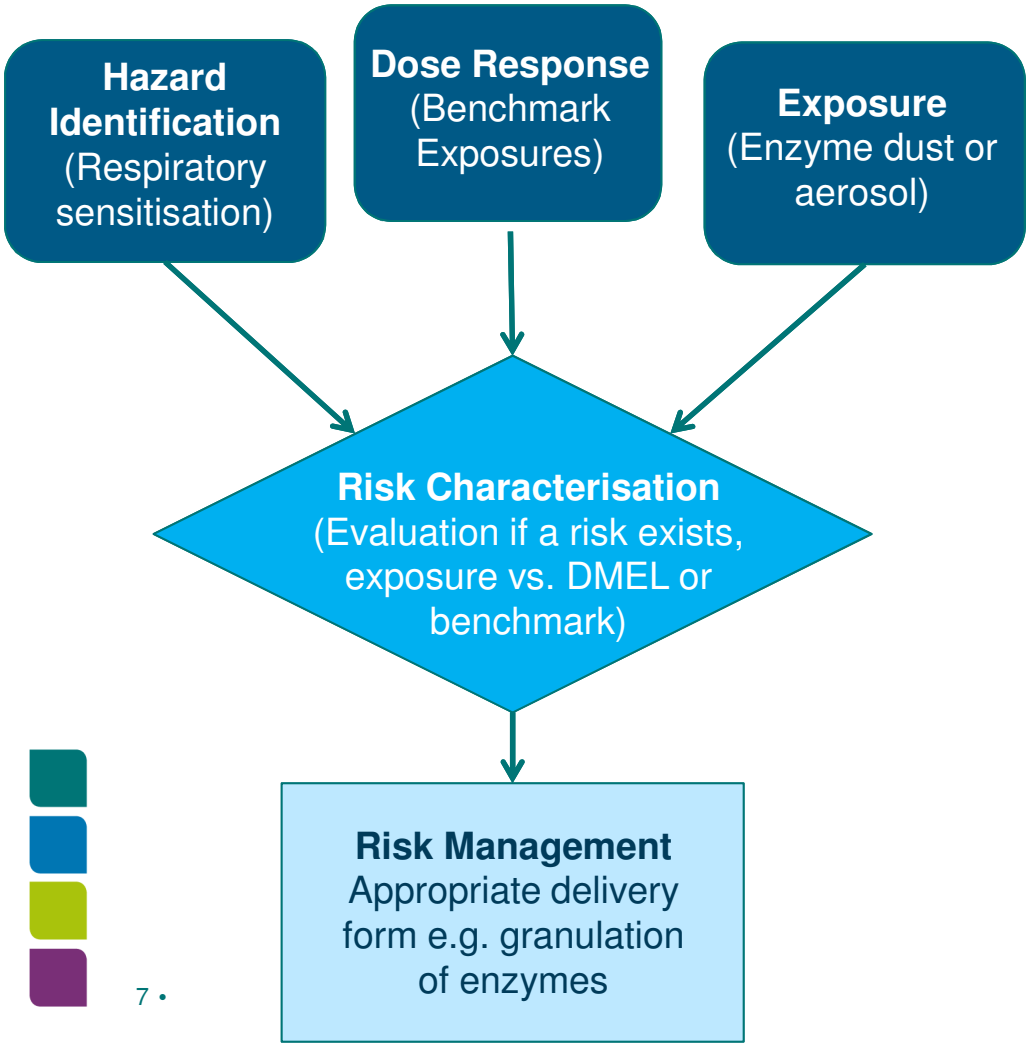
Risk assessment process



In EU, risk characterization of enzyme applications documenting compliance to the Derived Minimal Effect Level (**DMEL**) must be described in Exposure Scenarios for all down stream uses according to REACH.

DMEL has been settled as follows:

- Occupational exposure: 60 ng/m^3
- Professional exposure: 15 ng/m^3
- Consumer exposure: 15 ng/m^3

All DMEL values are starting points. The actual limit will depend on the product format, exposure frequency & duration, and application as such

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Dose-response relationship, benchmarks

For respiratory enzyme allergy no animal model is available to settle a dose-response relationship.

Risk characterization will have to be based on human exposure and via benchmarks.

Benchmarks have been obtained via clinical studies and via historical data from long-term uses.*

*) Some benchmarks can be found in the SDA document on Risk Assessment Guidance for Enzyme-Containing Products. See slide 13. Other benchmarks will have to be found in relevant scientific papers.

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Exposure assessment

A discipline that requires technical knowledge in regards to air sampling methodology and specific skills in regards to quantification of enzyme material on air sampling filters.

Knowledge on:

- What is the formulation and delivery mechanism of the product being assessed?
- How is the product going to be used under normal conditions and what may be the conditions of foreseeable misuse (including frequency and duration) or accidental exposure?
- Where will the product be used?
- How is the product user exposed?
- Design of exposure study that can give a realistic estimate of exposure during all foreseeable uses.

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Risk characterization and risk management

The risk characterization process for enzymes relies on comparing potential exposure to benchmark or limit derived from a DMEL value causing irritation or development of sensitization.

If the value generated for the new exposure is at or below an applicable no effect benchmark or limit derived from a DMEL value, then the risk may be judged acceptable.

The objectives of the risk management process are to determine the significance of risks to human health, and to ensure that the product use is and remains within the acceptable risk.

Risk management approaches should be based on critical evaluation of the risks associated with the use of the product and the data generated from the quantitative risk assessment process.

Examples of results from risk characterizations

Examples of safe use:

- Laundry
- Automated dishwashing

Examples of problematic use:

- Shampoo
- High pressure cleaning agents

Examples of uses where case by case risk characterization is necessary:

- Spray cleaners incl. devices
- Ultrasonic cleaning

Spray applications

Enzyme containing trigger spray products can give raise to unacceptably high enzyme exposures during use.

For each enzyme containing trigger spray product safety clearance should be given based on exposure assessment of the final product according to the AISE protocol on: “Exposure measurements for enzymes for risk assessment of household cleaning spray products” (2013) (can be found on A.I.S.E. website using the key words ‘spray protocol’:
https://www.aise.eu/library/publications.aspx)

Once a safety clearance has been obtained neither the product formulation nor the spray device can be changed without performing a new risk assessment.

Ultrasonic cleaning

Enzyme containing cleaning agents can create unacceptably high levels of enzyme aerosols if used in an open ultrasonic bath.

This can be seen e.g. in cleaning of medical devices.

Medical device cleaners should hold an instruction that ultrasonic cleaning must only be made in containment, and that the bath must remain closed for at least 5 min after the sonication has ended in order for the aerosols to settle.

The labels on medical device cleaners should hold the information that the product contains enzyme.

Amfep guidance - Safety in the use of enzyme containing reagents for medical device cleaning (http://www.amfep.org/content/amfep-guidance-safety-use-enzyme-containing-reagents-medical-device-cleaning)

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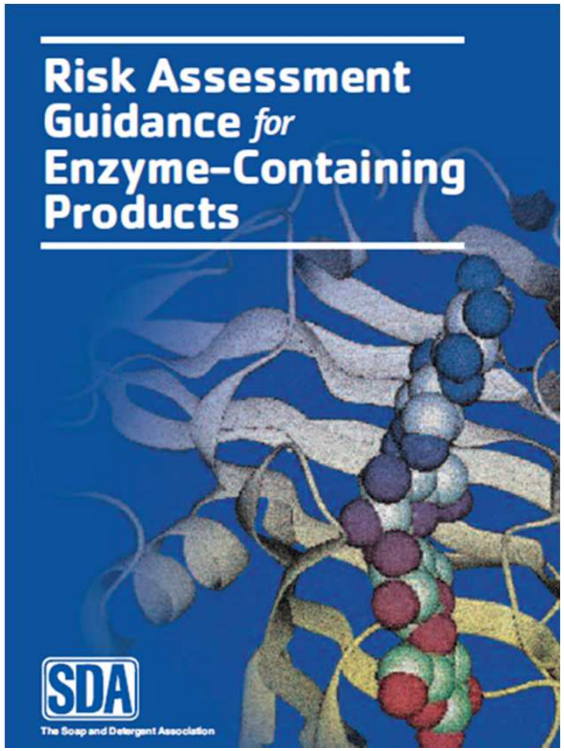
Further reading



A comprehensive guideline on risk assessment of enzyme containing products has been provided by ACI (former SDA) and it can be downloaded from the ACI webpage.

Risk Assessment Guidance for Enzyme Containing Products (http://www.aciscience.org/docs/SDA_Enzyme_Risk_Guidance_October_2005.pdf)

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On behalf of the AISE Enzyme Safety Task Force

Thank you for visiting this presentation

We will appreciate your feedback or further questions to:

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