

# AMFEP Guidance on the Dustiness of Solid Enzyme Products

## Layman's Guide

### Introduction

Enzymes are proteins used in many products, from detergents to food. Similar to other proteins, enzymes may cause respiratory sensitization when inhaled, causing allergies and respiratory issues. This can be avoided by designing the product targeting low dusting potential and implementation of proper handling practices, including the use of personal protection equipment and engineering controls.

In 2023, AMFEP developed a *Guidance on the Dustiness of Solid Enzyme Products* to help ensure the safe handling of solid enzyme products and to mitigate the risk of dust exposure. This layman's guide serves as an accompanying document to the guidance. It is primarily aimed at people in direct contact with downstream users or downstream users themselves to provide them with a broader understanding of the guidance.

### Product Dustiness and Sensitizer Release Score (SRS)

Dustiness refers to the tendency of a material to release particles into the air during handling. High dustiness means more particles can be inhaled, thereby increasing the risk of respiratory issues. The Heubach I method is a test that can be used to measure how much dust an enzyme product creates. A study conducted by AMFEP shows that data from Heubach I on product dust can indicate the relative level of enzyme exposure that persons handling the enzyme product are exposed to.

The risk of enzyme exposure is also related to the concentration of enzyme protein in the enzyme product. This concentration is usually expressed as the percentage of Active Enzyme Protein (FAEP – Fraction of Active Enzyme Protein) in the product.

To account for the effect of both the FAEP and the dustiness measured by Heubach I, the guidance introduces the *Sensitizer Release Score (SRS)* as a quantitative tool that can be used to assess the risk of an enzyme-containing product and to help determine the safety measures needed for handling these products. SRS calculation is based on the concentration of active enzyme protein in the product (FAEP) on one hand and the dustiness of the product, measured by the Heubach I method, on the other hand.

More specifically, the SRS is calculated by multiplying FAEP and the Heubach I dustiness score.

- A low SRS below 10 ppm generally indicates safe handling with appropriate controls.
- A moderate SRS between 10 and 250 ppm calls for a more detailed assessment.
- A high SRS exceeding 250 ppm requires further precautions.

## Step-by-step approach for risk assessment

The guidance furthermore provides a step-by-step approach for risk assessment of all solid enzyme products, considering factors such as air exposure and safety controls in addition to the SRS-value. This Relative Risk Determination consists of the following steps:

### Step 1. SRS Calculation

Calculate the SRS based on dust level (Heubach I) and enzyme concentration (FAEP) to find the initial risk level.

### Step 2. Measuring Airborne Enzyme Exposure levels

If the first step resulted in a medium or high SRS exceeding 10 or even 250 ppm respectively, it is recommended to measure enzyme particles in the air during product handling. This requires specific analytical methods or professional assistance to guide on industrial hygiene and analysis at downstream user's facilities. Three enzyme air exposure levels can be identified based on the air monitoring data in  $\text{ng}/\text{m}^3$ :

- Low relative risk: if the measured air exposure levels are below  $60 \text{ ng}/\text{m}^3$ , the product can be safely handled provided that the general safety precautions are taken into account.
- Medium relative risk: if the measured air exposure levels range between 60 and  $6000 \text{ ng}/\text{m}^3$ , several additional precautionary measures need to be observed.
- High relative risk: if the measured air exposure levels exceed  $6000 \text{ ng}/\text{m}^3$ , there is a high risk for workers to become sensitized and extensive additional enzyme safety controls are needed.

### Step 3. Implement Safety Controls during handling

When handling enzyme products, general safety precautions covering all risk categories should always be in place. These include training (ensuring workers are well-trained in handling enzyme products safely), process design (designing processes to minimize dust creation), hygiene practices (maintaining clean work environments) and wearing protective equipment (using masks and other protective gear as needed).

However, if an SRS is not below 250 ppm and air exposure levels are not below 60 ng/m<sup>3</sup>, additional safety controls are introduced. These specific safety controls are tailored depending on the risk class. Three risk classes are identified based on the SRS-value (step 1) and the Airborne Enzyme Exposure-level (step 2).

1. High Risk products with an SRS > 250 ppm and/or airborne enzyme levels > 6000 ng/m<sup>3</sup> require the highest levels of controls, often combined with RPE (Respiratory Protection Equipment) and expert handling.
2. Medium Risk products with an SRS between 10-250 ppm and/or airborne enzyme levels between 60 and 6000 ng/m<sup>3</sup>, require RPE that can be scaled based on exposure measurements and risk assessment.
3. For Low Risk products with an SRS ≤ 10 ppm and airborne enzyme levels < 60 ng/m<sup>3</sup>, lower levels of engineering controls may suffice combined with administrative controls. RPE mainly serves as backup.

*These safety controls must be clearly communicated to downstream users. If controls cannot be met, the product should be abandoned or redesigned or the application should be redesigned.*

## Considerations for Product Design

Product Design is a control technology used to reduce aerosolization and minimize enzyme exposure risks to workers and consumers. When evaluating product designs for enzyme applications, it is important to think about how the product form can influence the overall dustiness. Enzyme producers and manufacturers should look for safe product designs that keep dust levels to a minimum to lower the risk of sensitization and allergy symptoms.

The guide provides examples of several product designs, including:

- Granule Enzyme products: product form designed to minimize free-flowing fine enzyme particles by incorporating them into larger particles, or granules, which are less likely to break apart and become airborne.
- Coated Enzyme products: enzyme particles in powder form are treated with oils or dedusting agents to reduce the amount of dust they produce.
- Fine free-flowing enzyme powders: product design that is generally not considered safe as they can easily become airborne and thus inhaled by workers during handling. This product form is to be avoided unless it can be handled in completely enclosed systems where there is no direct human contact.

## Conclusion

By understanding and applying the guideline, health risks associated with handling solid enzyme products can be significantly reduced. The goal is to make enzyme products as safe as possible for workers and consumers by minimizing dustiness and ensuring proper handling procedures.

## Annexes (additional information)

- Annex 1. Detailed methods for SRS calculation
- Annex 2. General safety precautions
- Annex 3. Additional information on respiratory protective equipment
- Annex 4. Derivation of boundary SRS scores