Downstream Users of Chemicals Co-ordination group

Extension of the GRA

AMFEP & A.I.S.E. example

13 May 2022

Enzymes are…

- **biological proteins** produced by fermentation.
- **act as catalysts -** make and improve nearly 400 everyday consumer and commercial products (food and beverage, animal nutrition and textiles through to household cleaning, biofuels and energy generation).
- **readily biodegradable**
- exhibit no specific environmental toxicity - **not classified for the environment**
- **have an excellent safety profile -** no risk of acute toxicity, repeat dose toxicity, genotoxicity, carcinogenicity or reproductive and developmental toxicity

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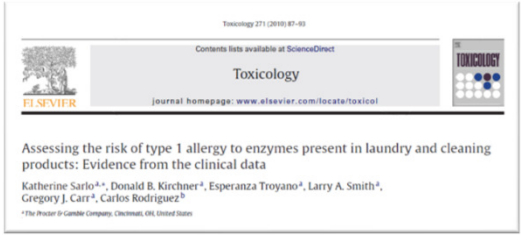
The safety of enzymes

- Enzymes are classified as Respiratory Sensitizer Category 1
- Despite this intrinsic hazard, **the use of enzymes has been documented safe**:

  - No reporting of enzyme allergies to consumers for 50+ years*

  - Occupational exposure leads to very limited number of enzyme allergies. Few incidents have been reported where exposure control has not been in place.

  - **REACH evaluation** conducted (CoRAP and RMOA) for all technical applications of alpha-amylase 2015-2018. **Concluded that the uses of enzymes are safe to both consumers and workers, and that this conclusion can cover all enzyme classes.**


Toxicology 271 (2010) 87–93

Contents lists available at ScienceDirect

Toxicology

journal homepage: www.elsevier.com/locate/toxicol

Assessing the risk of type 1 allergy to enzymes present in laundry and cleaning products: Evidence from the clinical data

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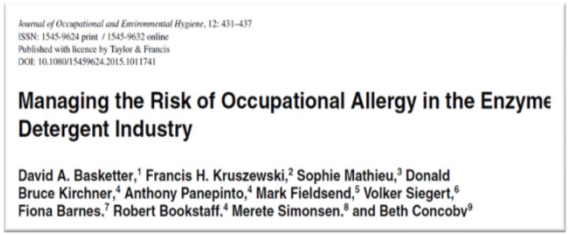
Journal of Occupational and Environmental Hygiene, 12: 431–437

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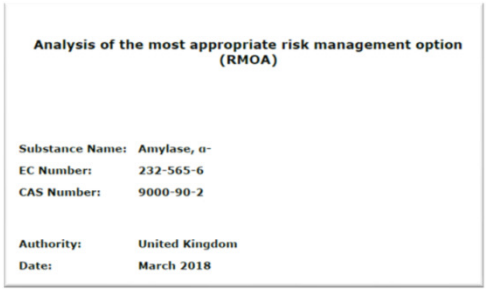
Managing the Risk of Occupational Allergy in the Enzyme Detergent Industry

David A. Basketter,[1] Francis H. Kruszewski,[2] Sophie Mathieu,[3] Donald Bruce Kirchner,[4] Anthony Panepinto,[4] Mark Fieldsend,[5] Volker Siegert,[6] Fiona Barnes,[7] Robert Bookstaff,[4] Merete Simonsen,[8] and Beth Concoby[9]


Analysis of the most appropriate risk management option (RMOA)

Substance Name:	Amylase, α-
EC Number:	232-565-6
CAS Number:	9000-90-2
Authority:	United Kingdom
Date:	March 2018

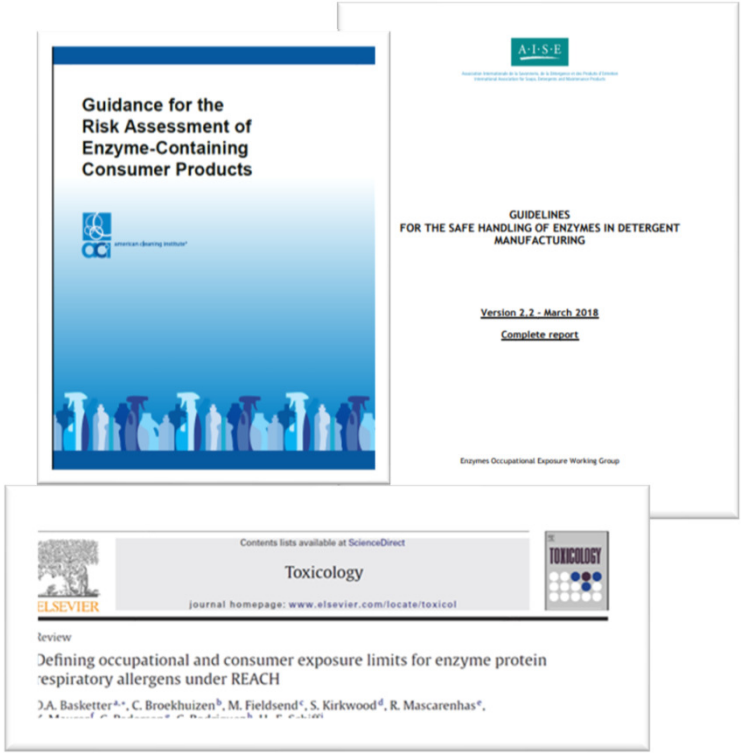
*) Prevalence of sensitization in population very rare, 0.126% in 1977-2010

Product Stewardship

- A Derived Minimal Effect Level (**DMEL**) **has been set for all enzymes,** e.g. in the cleaning & laundry uses:
  - 60 ng/m³ for workers
  - 15 ng/m³ for consumers

Based on published clinical studies, and data generated for decades*

- **Focus on product design, low-dusting and non-volatile**
- **Development of publicly available guidance material:**
  - Comprehensive guidance document
  - Webinars introducing specific subjects
  - Posters for professional workers (17 languages)
  - Guidance document for risk assessment of enzyme-containing consumer products



*) 40 years at the time of establishing the DMELs

Sustainability benefits of enzymes in cleaning products

Highly targeted bio-catalysts used in detergents
for **better** stain removal, whiteness, fabric and colour care and overall cleaning performance

Significant environmental benefits

- **Washing at low temperatures**
- **Innovating compact products**
- **Alternative technology to phosphates**
- **Readily biodegradable- no environmental impact**

…9 g per wash CO_2 reduction per wash (11 time lower)*
… 1.4 million tonnes CO_2 reduction due to compaction
* If surfactants are replaced with enzymes

… 2,300 GWh/year in Europe – Cold wash
equivalent to the electricity consumption of more than 300,000 inhabitants

… 5.2 m3 CDV reduction per wash**
**CDV = the critical dilution volume, used for Ecolabel criteria

… 30 million tonne saving due to compaction
… 3.8 g surfactant saving per wash (30% reduction)***
*** if surfactants are replaced with enzymes

Source: A.I.S.E. Fact sheet 2019 20190410111600-aise_factsheet-2019_compaction_def.pdf
Surfactant replacement with enzymes | Whitepaper by Novozymes (2020)
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GRA extension and enzymes

The issue:

- The Chemicals Strategy for Sustainability (CSS) - Proposal to **extend the current GRA** to uses by professionals and to additional chemicals e.g. those affecting the respiratory system.
- Enzymes are classified as **Respiratory Sensitizers Category 1** under the CLP Regulation.

Our view:

- It is a **far reaching extension of the GRA**, based only on the intrinsic properties of substances, without consideration of risk assessment and proven safe use
- a blanket ban on these ingredients simply due to their hazard would have a **huge impact** on the enzyme industry and its downstream users (the detergent industry) – **depriving them of important environmental, societal and technological benefits.**
- The sector would need a workable procedure with a meaningful derogation process to be designed and implemented.

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In conclusion

- **Enzymes**: a successful example - ahead of its time (1960s) - of innovative ingredients in cleaning products, with wide-ranging functionalities and significant sustainability benefits

- **Opportunity**: Enzymes – enablers for multiple sectors to become aligned with EU sustainability policy ambitions:
  - Green Deal, EU Taxonomy, CSS, Farm to Fork, Zero Pollution, ESPR

- **Risk**: if GRA is extended to include respiratory sensitizers used in consumer (and professional) uses:
  - Sustainability benefits will be lost for the Cleaning sector – after decades of safe and sustainable performance
  - Leaves the sector with no other sustainable alternatives for their products, thereby impacting consumers' demands.
- **Our Ask: Carefully assess the demonstrated safe use and sustainability benefits of substances, such as enzymes, prior to inclusion in the scope of the GRA.**

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