

# ENZYMES REACH PRE-CONSORTIUM

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ERpC/09/05

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## Calculation of Tonnage for Enzyme Substances

Each registrant of substances under REACH has to calculate the yearly tonnage of the relevant substance produced or imported in EU in order to establish the applicable deadline for registration.

The larger the tonnage, the earlier the registration deadline.

The basis for the tonnage calculation is the substance as defined under REACH. ECHA has specifically addressed the issue of identification of enzyme substances, cf. section 4.3.2.3 of ECHA's Guidance on Substance Identification.

The relevant paragraphs of this guidance are inserted below. ERpC advises you to ascertain that your company has calculated the tonnage of the relevant enzyme substance correctly.

*The enzyme substance should be regarded as a 'UVCB<sup>1</sup>-substance' due to its variability and partly unknown composition.*

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*Enzyme substances are identified by the enzyme protein (IUBMB nomenclature) and the other constituents from the fermentation.*

...

*The enzyme substance typically contains 10-80 % (w/w) of the enzyme protein. The other constituents vary in percentage and depend on the production organism used, the fermentation medium, and operational parameters of the fermentation process as well as the downstream purification applied, but the composition will typically be within the ranges indicated in the following table.*

Active enzyme protein	10 - 80%
Other proteins + peptides and amino acids	5 - 55%
Carbohydrates	3 - 40%
Lipids	0 - 5%
Inorganic salts	1 - 45%
Total	100%

Tonnage shall thus be calculated as:

[enzyme protein] + [other constituents]

This calculation excludes water and any other solvent. It also excludes any ingredients that may be added to the enzyme substance in order to make it into a commercial preparation.

Any questions about the above can be addressed to the ERpC coordinator on a confidential basis:

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<sup>1</sup> Substances of Unknown or Variable composition, Complex reaction products or Biological materials