



Association of Manufacturers and Formulators of Enzyme Products

Amfep/09/73

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## Amfep Fact Sheet on Enzymes and the CLP Regulation

### General

The new EU Regulation on classification, labelling and packaging of substances and mixtures (Regulation (EC) No 1272/2008, "CLP Regulation") entered into force on 20 January 2009. The Regulation applies the general principles of the UN Globally Harmonised System (GHS) of Classification and Labelling of Chemicals.

[http://ec.europa.eu/enterprise/reach/ghs/index\\_en.htm](http://ec.europa.eu/enterprise/reach/ghs/index_en.htm)

Classification criteria are largely in line with the current EU system but GHS introduces new terminology and labelling e.g. new pictograms and precautionary statements. It keeps the scope as close as possible to the existing legislation and ensures consistency with the transport legislation. It will also affect other obligations in EU legislation (downstream legislation) which refer to classification such as Safety Data Sheets, detergents, ecolabelled products etc.

The CLP Regulation takes over and converts Annex I of the Dangerous Substances Directive (67/548/EEC) to Annex VI, hereby listing the existing harmonised classification and labelling of substances according to the GHS. Carcinogenic, mutagenic and reprotoxic (CMR) substances and respiratory sensitisers will be subject to harmonised classifications under CLP.

The CLP Regulation will, after a transitional period, replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC). The deadline for CLP classification of substances is 30 November 2010 and for mixtures (previously named preparations) 31 May 2015.

### Enzymes and the CLP Regulation

Harmonised classifications for the 17 enzyme entries in Annex I of Dir. 67/548/EEC<sup>1</sup> appear in Annex VI of the CLP<sup>2</sup> cf. attached table (annex to Amfep/09/73). All enzymes are classified as respiratory sensitisers and will be labelled with 'torso' pictogram that also applies to CMR substances. The existing cut-off limit for mixtures containing sensitisers – 1% hazard warning and 0.1% allergy warning – remain under CLP. Subtilisin and other proteases have additional skin/eye irritancy classifications.

For subtilisin, CLP translation of 'serious eye damage' means a reduction of the cut-off limit from 10 to 3% and may result in a 'corrosive' pictogram above this limit. With regard to transport

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<sup>1</sup> As amended up to the 31<sup>st</sup> ATP (Commission Directive 2009/2/EC of 15 January 2009)

<sup>2</sup> As amended up to the 1<sup>st</sup> ATP (Regulation (EC) No. 1272/2008 of 5 September 2009)

regulations, the current subtilisin eye irritancy classification will not lead to a 'dangerous goods' status.

Currently, enzymes not covered by the 17 enzyme entries may be classified in analogy e.g. as respiratory sensitisers and irritants in the case of non-subtilisin proteases.

Industry must follow the existing harmonised classifications of enzymes, including irritancy classifications, unless a proposal for classification change has been accepted by the European Chemicals Agency ECHA. A re-classification proposal (Annex XV dossier) for hazard properties (toxicological endpoints) included in the existing harmonised classification e.g. irritancy can only be submitted by a Member State competent authority. For endpoints not covered, Industry can make a proposal.

In connection with preparing for REACH registration of enzymes, registrants will review available data on relevant enzyme types in the Substance Exchange Information Fora (SIEFs) and may consider if there is a need for revised harmonised classification. Further detailed guidance is available from ECHA.

[http://guidance.echa.europa.eu/docs/guidance\\_document/clp\\_en.htm](http://guidance.echa.europa.eu/docs/guidance_document/clp_en.htm)

GHS is currently being implemented in countries outside the EU. Substance classifications, including for enzymes, may be based on various documentation or previous classifications and therefore differ from the current EU classifications.

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