Classification training – Additional labelling

DELIVERING
GROWTH IN
SPECIALITY CHEMICALS

Megan Wheatley-Darrand
June 2024

Agenda

Background

- Introduction
- Obligatory supplemental labelling information
- EUH phrases
- Non-obligatory supplemental labelling information

EUH208

- EUH208
- Concentration limits
- Specific Concentration Limits (SCLs)
- Examples

Questions

Background

Introduction

CLP Article 25 defines the concept of ‘supplemental information which is intended to incorporate additional labelling information.

This additional labelling information can be divided into two categories; namely obligatory and non-obligatory information.

Obligatory supplemental labelling information

Obligatory supplemental labelling information includes:

- Supplemental hazard statements relating to particular physical and health properties. These are known as ‘EUH’ statements.
- Supplemental statements for certain mixtures. These are also assigned EUH codes as well to align their presentation with the above supplemental hazard statements
- The supplemental statement EUH401 for hazardous substances and mixtures within the scope of Directive 91/414/EEC.
- Label elements result from other EU acts
- Specific response information as referred to within brackets of the P statements.
- For mixtures containing components of unknown acute toxicity at 1% or higher, the statement ‘x percent of the mixture consists of component(s) of unknown acute toxicity’.
- For mixtures for which no useable information on the acute and / or chronic aquatic hazard is available for one or more components, the statement ‘contains x percent of components with unknown hazards to the aquatic environment’.
- A UFI for mixtures relevant to Annex VIII of CLP under CLP Article 45.

EUH Phrases

Supplemental hazard statements relating to certain physical properties	Supplemental hazard statements relating to health properties	Supplemental statements for certain mixtures
• EUH014 – Reacts violently with water • EUH018 – In use, may form flammable/explosive vapour-air mixture • EUH019 – May form explosive peroxides • EUH044 – Risk of explosion if heated under confinement	• EUH029 – Contact with water liberates toxic gas • EUH031 – Contact with acid liberates toxic gas • EUH032 – Contact with acids liberates very toxic gas • EUH066 – Repeated exposure may cause skin dryness or cracking • EUH070 – Toxic by eye contact • EUH071 – Corrosive to the respiratory tract	• Mixtures containing lead – EUH201 • For packaging < 125mg – EUH201A • Mixtures containing cyanoacrylates – EUH202 • Cement/Cement mixtures – EUH208 • Mixtures containing isocyanates – EUH204 • Mixtures containing epoxy constituents with Mn <= 700 – EUH205 • Mixtures sold to the public containing active chlorine – EUH206 • Mixtures containing cadmium (alloys) and intended for brazing or soldering – EUH207 • Mixtures not sensitising but contains at least one sensitising substance – EUH208 • Liquid mixtures containing halogenated hydrocarbons – EUH209 or EUH209A • Mixtures not intended for the general public – EUH210

Non-obligatory supplemental labelling information

In some cases, suppliers may need to include certain elements on the label that are not obligatory but are necessary for the handling and use of the product.
Such information must not be confusing or contradict the obligatory label elements.

EUH208

EUH208

The label on the packaging of the mixtures not classified as sensitising, but containing at least one sensitising substance classified as sensitising and present in a concentration equal or greater than that specific in Table 3.4.6 of Annex 1 shall bear the statement:

EUH208 – ‘Contains (name of sensitising substance). May produce an allergic reaction’.

Mixtures classified as sensitising containing other substance(s) classified as sensitising (in addition to the one that leads to the classification of the mixture) and present in a concentration equal to or greater than that specified in Table 3.4.6 of Annex 1 shall bear the name(s) of that/those substance(s) on the label.

Taken from SDS_IE of Emultex FR 797:

Additional Labeling

EUH208	Contains 1,2-benzisothiazol-3(2H)-one, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.
EUH210	Safety data sheet available on request.
	The treated article incorporates biocidal products.

Table 3.4.6 – Concentration limits for elicitation of components in a mixture

Table 3.4.6

Concentration limits for elicitation of components of a mixture

Component classified as:	*Concentration limits for elicitation*		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/Liquid	*Gas*	All physical states
Respiratory sensitiser Category 1	*≥ 0,1 % (Note 1)*	*≥ 0,1 % (Note 1)*	
Respiratory sensitiser Sub-category 1A	*≥ 0,01 % (Note 1)*	*≥ 0,01 % (Note 1)*	
Respiratory sensitiser Sub-category 1B	*≥ 0,1 % (Note 1)*	*≥ 0,1 % (Note 1)*	
Skin sensitiser Category 1			≥ 0,1 % (Note 1)
Skin sensitiser Sub-category 1A			≥ 0,01 % (Note 1)
Skin sensitiser Sub-category 1B			≥ 0,1 % (Note 1)

Note 1:

This concentration limit for elicitation is used for the application of the special labelling requirements section 2.8 of Annex II to protect already sensitised individuals. A SDS is required for the mixture containing a component at or above this concentration. For sensitising substances with specific concentration limit lower than 0,1 %, the concentration limit for elicitation should be set at one tenth of the specific concentration limit.

Specific Concentration Limits (SCLs)

A **concentration limit** is the minimum concentration of an individual substance that triggers the classification of a mixture or the sum of concentrations of relevant substances where the effect of several substances is additive.

Concentration limits may be general for a hazard class, differentiation or category (generic concentration limit **GCL**) or they may be specific for a particular substance (specific concentration limit, **SCL**). An SCL may be assigned to a substance, based on its potency, to allow the fine tuning of its contribution to the classification of a mixture. The SCL concept mainly applies to health hazards and takes precedence over GCLs.

Classification Examples for Skin Sensitisation

Example 1

Substance X is classified as a Skin Sensitiser Category 1, and is present in Product Y at a concentration of 1.5%.
What classification would Product Y have and does it need any special labelling?

Example 2

Substance Z is classified as a Skin Sensitiser Category 1A, and has a Specific Concentration limit of 0.001%. At what prevalence would a product containing substance Z be classified for skin sensitisation, and what prevalence would lead to an EUH208 phrase?

Example 3

Product A contains two skin sensitising substances (Category 1B). Substance B is present at 1%, and Substance C is present at 0.5%. How should the product be labelled?

Example 4

Product D contains substance E at 0.09%. Substance E is classified as Skin Sensitiser 1. How should the product be labelled?

Questions

Questions

Activity

Classification Examples for Skin Sensitisation

1. **Go to** Additional Special Labelling - GB.xlsx
2. **Determine the special labelling for GB on ‘Load File’ tab. HINT: Check composition in S/4.**
3. **Compare determination with ‘All – S4’ tab and make sure previous assessments for EU and TR are accurate**
4. **Add any missing data for TR and EU as appropriate**

Common Sensitisers;

CMIT/MIT – 55965-84-9
BIT – 2634-33-5
Maleic Anhydride – 108-31-6
MIT – 2682-20-4
Formaldehyde – 50-00-0