CEPE Guidance on labelling decorative paint with skin sensitizing biocides

Final, 28 October 2014

The EUH 208 sentence

With the second adaptation of the CLP Regulation 1272/2008 to technical and scientific progress (Commission Regulation 286/2011), the conditions for labelling of mixtures containing sensitising substances are changing. Specifically, provision is now made for the part of the population that has developed skin allergy and that is more sensitive to subsequent exposure. The levels for elicitation are lower than the level for sensitisation. Under the new table 3.4.6 one can read:

> *Note 1:*
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> 'This concentration limit for elicitation is used for the application of the special labelling requirements of Annex II section 2.8 to protect already sensitised individuals. A SDS is required for the mixture containing a component 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.';

The new supplemental hazard statement triggered by this new limit for elicitation reads as follows:

> EUH208 — "Contains (name of sensitising substance). May produce an allergic reaction".

The change in labelling information must be implemented by June 1st 2015. Biocides are among the skin sensitising substances that are affected by this change. The biocide substances may or may not already be officially classified in Europe in Annex VI of the CLP. Biocide suppliers provide overviews on their actives based on the specific concentration limits established. Some actives do not have specific concentration limits, but the case of the isothiazolinone family illustrates that the new EUH 208 statement will hardly be avoidable:

Active	Skin sensitizer,H317, specific concentration limit	EUH208 required for formulations containing more than
BIT (2634-33-5)	500 ppm	50 ppm
CMIT/MIT (55965-84-9)	15 ppm	1,5 ppm
DCOIT* (64359-81-5)	250 ppm	25 ppm
MIT* (2682-20-4)	1000 ppm	100 ppm
OIT (26530-20-1)	500 ppm	50 ppm
* Self classification only		

BIT: benzisothiazolinone; MIT: methylisothiazolinone; CMIT/MIT: Methylchloroisothiazolinone and methylisothiazolinone (3:1); DCOIT: Dichlorooctylisothiazolinone; OIT: Octylisothiazolinone

What parameters have to be considered for labelling?

Raw materials

Most water borne raw materials are preserved and these amounts of preservatives need to be taken into account when calculating the concentrations of each active. Today the nature and concentration of the actives may not have to be declared (the CLP legislation only requires their disclosure as from 0.1% or a specific concentration limit in Annex VI), but companies within our industry should pro-actively ask raw material suppliers what biocides they used to protect their products. The amount of preservatives added in the raw materials might already be above the new limit for labelling without any addition of this active in production. Examples:

- A formulation consisting of 50% binder preserved with 10 ppm CMIT/MIT adds 5 ppm CMIT/MIT in the final paint; this is above the 1.5 ppm labelling limit and the phrase "Contains CMIT/MIT. May produce an allergic reaction" must be added.

Only direct analytical measure of the real content of each production batch would reveal the exact concentration of the in-can preservatives, which is a costly option.

Tinting pastes

Tinting pastes contain preservatives. It is hard for each paint producer to control what tinting pastes are actually used for in shop tinting, but all producers have a standard system that is used for colour matching, making tinting recipes etc. The preservatives used in this system should be included when classifying the end product. A representative percentage of tinting pastes added to a formulation needs to be calculated and the corresponding preservatives added when calculating the classification.

The Industry cannot ignore the amount of skin sensitizing substances already included in the raw materials, and if relevant in the tinting pastes.

When all actives from raw materials and biocides added to the formulation during production are identified and the total concentration of each active is calculated, the EUH208 phrase mentioning all actives above the elicitation limit must be added to the label.

Examples:

- A formulation consists of 50% binder preserved with 50 ppm MIT and 10 ppm CMIT/MIT. During production the formulation is preserved with 50 ppm BIT and 100 ppm MIT. This adds up to a total of 50 ppm BIT, 125 ppm MIT and 5 ppm CMIT/MIT in the formulation and the phrase "Contains Benzisothiazolinone, Methylisothiazolinone and Chloromethylisothiazolinone/Methylisothiazolinone. May produce an allergic reaction." must be added.

The specific case of MIT

As shown in the table earlier, some actives do not yet have an official classification. Unfortunately MIT (methylisothiazolinone) is widely used and is among the self-classified actives. It is going to be classified officially in the future, but the EU procedure will take several years. Today the suppliers maintain a classification at 1000 ppm, which means 100 ppm for the EUH 208 sentence. It is likely that this level will be reduced in future once the substance is officially classified. We have currently followed the biocide suppliers' recommendations as they are responsible for its official classification. However, the number of growing cases of allergies during the past years led CEPE to agree on a voluntary product stewardship measure to communicate on the presence of MIT in decorative paint at lower concentrations than 100 ppm.

We do recognize that the high increase of allergies to MIT is probably mainly driven by its use in cosmetics, however the use in other products like paint is identified as an additional cause of allergy for sensitized consumers not informed on the presence of MIT on paint labels. Recently the EU Committee evaluating cosmetics (SCCS) have suggested banning MIT in leave-on cosmetics and reducing the concentration to 15 ppm for rinse-off products. If this is implemented the stop of use in cosmetics should help prevent more people getting sensitized but the part of the population that is already sensitized needs to be informed of the presence of MIT in paint because they can develop allergies at much lower concentrations also from our products.

In addition to the consumer protection, we consider that MIT is an essential active substance for effective in-can preservation and we also want to safeguard its future by using it in a responsible way. In order to achieve this objective, CEPE decided that it is the interest of our industry to communicate on its presence below the proposed limit for the EUH 208 statement of 100ppm, and above 15 ppm, as follows:

15 ppm[1] (0.0015% w/w) ≤ 'Contains Methylisothiazolinone' < 100 ppm (0.01% w/w)

This is not a sentence derived from legal obligations and hence it is advised to locate it on the label but outside the location of the legal classification part, in a clear and readable manner.

The EUH 208 sentence applies from 100 ppm.

NB: in the case where CMIT/MIT is already mentioned through the use of the EUH 208 sentence (from 1.5 ppm "Contains Methylchloroisothiazolinone and methylisothiazolinone. May produce an allergic reaction") the MIT is already mentioned and it is not necessary to add our voluntary labeling 'Contains methylisothiazolinone'.

[1] Some CEPE Members have indicated that they will start this even at lower concentration than 15 ppm (around 1 ppm) as a precautionary approach as there are currently uncertainties for selecting a limit.

Additional labelling information for skin sensitizer sentences from the Biocide Product Regulation (BPR)

You may be aware that since October 2013 the approval regulations of skin sensitizing biocide substances contain the following provision:

> '*Where a treated article has been treated with or intentionally incorporates xxx (the biocide active substance), and where necessary due to the possibility of skin contact as well as the release of xxx under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.*'

Under the BPR a chemical mixture is considered to be a treated article. Despite the fact that only the CLP legislation should apply, the EU Commission is imposing this additional labelling requirement. No threshold is considered. The entry into force of such additional labelling is substance and Product Type specific and limited to the treated article that was directly treated with (or in which a biocide was intentionally incorporated). For additional information, see the 'CEPE guidance BPR Art 58(3)'.