CEPE and A.I.S.E. proposal
on the specific condition present in the approval of skin sensitisers

March 2015

The present document aims at clarifying how the classification, labelling and packaging Regulation (CLP) applies to chemical mixtures (considered as treated articles under the Biocidal Products Regulation (BPR)), in particular for the skin sensitisation property, and to take the specific example of the isothiazolinone family which seems to be the root of concern for some Member States. This paper then proposes a way forward for mixtures containing skin sensitisers under the BPR.

We refer to previous discussions on this subject and specifically to the CA meeting documents:
- CA-March14-Doc.6.4
- CA-May14-Doc.6.2
- CA-September 14-Doc.6.3

Our concern is linked to the addition of a standard sentence to the approval regulation of all skin sensitising substances since October 2013 as follows:

‘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.’

We maintain that the CLP legislation is designed for and is adequate for informing users on skin sensitisation. BPR Article 2 makes explicit reference to CLP: ‘...without prejudice to... Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures’.

In the March CA paper the Commission rightly stated that:

‘We believe that you raised a very important point. The new, specific condition for skin sensitisers does indeed, literally, concern all products that are ‘treated articles’ within the meaning of BPR, i.e. including substances and mixtures. However, as far as the Commission services are concerned, the condition is intended to address concerns relating to the possible skin contact with articles, i.e. not with substances or mixtures. Labelling of the latter is indeed properly regulated through CLP legislation, and we see little point in duplicating or complementing it through BPR.’
Official (“harmonised”) classification
It is mandatory to apply the official classification of a substance when it has been officially evaluated and included in Annex VI to CLP. This requires the RAC (Risk Assessment Committee of ECHA) opinion, followed by official publication of an Adaptation to Technical Progress to CLP.
For the substances not yet officially classified and for non-harmonised endpoints, it is the responsibility of the supplier to classify until an official classification is available. Biocidal active substances are normally subject to harmonised classification under CLP (Article 36(2)) so an official classification is expected for all biocidal actives.

Threshold to classify mixtures
There are 3 categories for skin sensitising substances: Category 1, Category 1A and Category 1B.
The concentration threshold to classify mixtures containing such substances is the same for skin sensitisation Cat 1 and Cat 1B classifications: 1%.
The substances having a Cat 1A classification are more potent and have lower concentration limits for the classification of mixtures: either a generic limit 10 times lower than for Cat 1 and Cat 1B, or even lower on a case by case basis.

Mixtures classified for skin sensitisation must bear the following label elements (pictogram, signal word and hazard statement H317):
New skin sensitising sentence to apply by June 2015 at lower concentrations

When a person is first exposed to a skin sensitising chemical it requires a certain concentration to provoke the sensitisation (‘induction’). But once the person has developed the allergy to a specific substance it can develop the symptoms, i.e. the allergic reaction, at lower concentration (‘elicitation’). In order to provide sufficient information to users and help them avoid exposure once sensitised, the legislator, through the 2nd ATP to CLP, has added a requirement to apply a sentence at concentrations levels of 1/10th of the classification limit of the substance:

EUH208 — “Contains (name of sensitising substance). May produce an allergic reaction”.

The levels for elicitation are deliberately lower than the level for induction. This information is provided under the table 3.4.6 in the CLP text:

Note 1:

‘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.’;

Hence, substances like IPBC or propiconazole trigger the classification of a chemical mixture from 1% concentration on (with the CLP pictograms/label elements) and between 0.1 and 1% the EUH208 sentence has to be added, even though the mixture is not classified. For a substance like CMIT/MIT that has a specific concentration limit of 0.0015% (15 ppm), chemical mixtures have to be classified as skin sensitiser from 0.0015% (with the CLP label elements) and between 0.00015 (1.5 ppb) and 0.0015% (15 ppb) the EUH208 sentence has to be added.

Other examples from the isothiazolinone family

<table>
<thead>
<tr>
<th>Active</th>
<th>Skin sensitizer, H317, specific concentration limit</th>
<th>EUH208 required for formulations containing more than</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIT (2634-33-5)</td>
<td>500 ppm</td>
<td>50 ppm</td>
</tr>
<tr>
<td>CMIT/MIT (55965-84-9)</td>
<td>15 ppm</td>
<td>1.5 ppm</td>
</tr>
<tr>
<td>DCOIT* (64359-81-5)</td>
<td>250 ppm</td>
<td>25 ppm</td>
</tr>
<tr>
<td>MIT* (2682-20-4)</td>
<td>1000 ppm</td>
<td>100 ppm</td>
</tr>
<tr>
<td>OIT (26530-20-1)</td>
<td>500 ppm</td>
<td>50 ppm</td>
</tr>
</tbody>
</table>

* Self classification only (but harmonised classification expected in the near future)

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

1 COMMISSION REGULATION (EU) No 286/2011
Some concerns have been raised for MIT. All Parties would benefit from having an official classification for that substance. The problem is not the CLP legislation itself but the time needed for the official/harmonised classification process to take place. Pending this, the general rule that CLP applies to chemical mixtures should be recognized and the standard sentence applied since October 2013 in the conditions of the approval regulation of skin sensitising substances should only be used in specific cases.

**Proposed way forward:**
The general rule that CLP is adequate for informing on skin sensitisation hazards of mixtures that are treated articles under BPR should not be waived due to some concerns on a very limited number of substances, and this is true for any classification property. Hence, the standard sentence added to the conditions of the approval of skin sensitising substances should be removed when the substance has an official classification. A sentence could be added in exceptional cases where a serious concern exists and only in a transitional period until the substance is officially classified in Europe.

The proposal would be to modify the sentence as follows:

Where a treated mixture has been treated with or intentionally incorporates xxx the person responsible for placing the treated mixture on the market shall ensure that the label provides information on the risk of skin sensitisation. This information requirement applies until the substance xxx is included in Annex VI of the REGULATION (EC) No 1272/2008 with a harmonized classification for the skin sensitising property

In order to avoid the need for transitional measures we also believe that an accelerated official harmonized classification process for biocidal active substances is the best solution.