FABI Formaldehyde Biocide Interest Group

Brussels, 23 January 2015

Statement supporting the comments provided by Schülke concerning the proposed harmonised classification for reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

The following represents a common statement of all EU formaldehyde-releaser producers participating in the Biocidal Products Regulation (BPR) Review Programme, as represented by the Formaldehyde Biocide Interest Group (FABI) which is a CEFIC registration group.

Reaction products of paraformaldehyde and 2- hydroxypropylamine (ratio 3:2) (MBO) belongs to a category of biocidal actives known as formaldehyde-releasers (or formaldehyde-donors). These substances control microbial growth in a water-containing product or equipment by the slow release of formaldehyde directly into the matrix.

A proposal has been published to classify MBO as Carcinogen Category 1B and Mutagen Category 2, and by analogy this classification would be applicable for all formaldehyde releasers.

The rationale for the harmonised classification and labelling proposal for MBO is not based on the inherent hazard of MBO but is based on the potential for local formaldehyde effects following hydrolysis of the formaldehyde releasing molecule where it comes into contact with moisture either in the preserved product or human tissue. However, this proposal does not consider the physico-chemical properties of the parent compound nor the safe use which could be demonstrated within the dossiers submitted under the BPR.

The hypothesis used to justify the proposal to classify MBO (and by analogy all formaldehyde releasers) as a potential carcinogen and mutagen (i.e. its complete, instantaneous hydrolysis to release ***sufficient*** bound formaldehyde) is strongly disputed by FABI members. There follows a short statement summarizing our counter-arguments.

1. Adequate exposure:

The current proposal for classification as CMR is solely based on exposure arguments of released formaldehyde and does not take into account the physico-chemical properties of the substance as placed on the market, or in the form in which it can reasonably be expected to be used (i.e. the intended use). Hence, exposure under use conditions should be taken into account.

- We argue that the weight of information available to RAC members demonstrates that it is not scientifically substantiated that humans will be exposed to sufficient levels of MBO either in the form in which it is placed on the

market (as a non-volatile liquid) or in which it can reasonably be expected to be used to cause adverse effects justifying classification as CMR.

- We also argue that the weight of information available to RAC members demonstrates that it is not scientifically substantiated that repeated exposure of workers to MBO under conditions described above will result in the *local release* of a *sufficient* amount (threshold) of formaldehyde to cause tumour formation in nasopharyngeal region, or to result in genotoxic effects in germ cells. Both events would be necessary to justify classifying MBO as a carcinogen and a mutagen.

2. Local effects only (based on RAC's previous opinion on formaldehyde):

As RAC previously provided their opinion that formaldehyde has no direct genotoxic effect on germ cells nor causes tumour formation at a site distant to the site of inhalation exposure, any adverse effects distant to the site of exposure are irrelevant and should not be considered as part of the classification decision.

3. In accordance with CLP Regulation and published guidance:

We urge that the RAC should not make decisions outside the framework of what is allowed by CLP, and should follow ECHA guidance when classifying for germ cell mutagenicity and carcinogenicity. Additional supporting legal arguments are laid out in the FABI Legal and Regulatory Statement on MBO.

In accordance with accepted classification guidance, MBO (and all formaldehyde-releasers) should therefore be classified as placed on the market on the basis of the amount of 'free' (unbound) formaldehyde present, and we argue that the parent molecule cannot be considered as carcinogenic or mutagenic in its own right.

We would like to highlight to the RAC, although not in its remit, the significant downstream consequences of classification of MBO (and by analogy all formaldehyde releasers) as a carcinogen category 1B as a precautionary measure. These consequences are linked to the direct impact of such classification on the evaluation process under the Biocidal Product Regulation (EU) 528/2012, and more specifically the application of Articles 5 and 10 which provide that carcinogens cat. 1A or 1B meet the exclusion criteria and are therefore candidates for substitution).

Due to EU worker safety legislation, downstream users who have relied on this category of biocide to provide protection against microbial contamination for several decades for industrial applications and have a history of safe use of this chemical category would be forced to seek alternatives, despite having full knowledge that this category of substances releases low levels of formaldehyde into the fluid/equipment being protected. This is likely to significantly restrict the availability of suitable biocidal protection for certain product types due to the nature of the Biocides Product Regulation and the limited number of different substances for which product authorisation is being sought.

For further information, please contact:
Flore Cognat – Phone: +32 2 676 7203 – Email: fco@cefic.be