CEPE comments on the public consultation on BIT (CAS 2634-33-5) with regard to the SCL for classification as a skin sensitiser

CEPE, the European Council of Paint, Printing Ink and Artists' Colours Industry, would like to draw your attention to the essential need of effective in-can preservatives and to the precedent set for the previous classification of substances which belong to the same isothiazolones family (CMIT/MIT, OIT, DCOIT, MBIT, MIT)..

Wet coatings and inks need be protected against microbial deterioration to ensure shelf-life.
BIT is one of the few remaining effective in-can preservatives and has long been used in Europe (>30 years) to protect millions of tons of waterborne products every year. It has a harmonized classification for skin sensitisation with a SCL of 0.05% (500 ppm). BIT is effectively used at concentrations less than this Substance Concentration Limit (SCL). Currently, while we are not aware that such limit has caused any induction of skin sensitisation from its presence in our products, setting a lower limit could have severe consequences under the Biocide Product Regulation for consumer use of treated articles like paints or inks.

OIT also had a SCL of 500 ppm until RAC decided to set a default low limit of 15 ppm for isothiazolinones (15th ATP), based on similarity to CMIT/MIT.

We believe that this default low threshold ignores the real skin sensitisation potency of the isothiazolinone substances. CMIT/MIT is well known to be the most potent one.
CLP aims at classifying skin sensitizing substances for their <u>induction</u> threshold. CLP thereafter sets the EUH 208 sentence to take into account the <u>elicitation</u> of an allergic response in a pre-sensitized person.

A number of local lymph node assays **(**LLNAs) clearly show that BIT is a moderate sensitiser (EC3 > 2%), less potent than CMIT/MIT. Also, although false positives (i.e. irritation) may occur at 500 ppm and above a Human Repeat Insult Patch **Test** (HRIPT) study showing 0% being sensitised at 360 ppm BIT and 9% at 730 ppm indicates that a SCL of 500 ppm may be appropriate. The diagnostic patch testing (on patients) can not be used to find an induction threshold for which a SCL can be set. At best this diagnostic patch testing could be used for finding an elicitation threshold.

In the dossier there is also a reference to a report indicating that BIT has caused skin allergies from PVC gloves containing 20-30 ppm of BIT. Again this is based on diagnostic patch testing, and where all patients had displayed hand dermatitis for years. These findings in those *who already have hand dermatitis* are likely to be due to elicitation or irritant effects and are thus not relevant for setting a SCL for induction of sensitising. We note that the dossier submitter acknowledges this.

CLP reflects the outcome of scientific assessment of hazard characterisation. Any exposure concerns are taken into account in risk assessments addressed in legislative tools such as the Biocide Product Regulation.

We call for a careful examination of data leading to induction of skin sensitization from which a sound SCL can be set.

Overall, we do support the SCL of 500 ppm proposed by the dossier submitter.

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