

Development of Legislation and Other Instruments

BPC-10: SE minority opinion on Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) (CMIT/MIT) in product type 13 (Working or cutting fluid preservatives)

The Swedish Competent Authority¹ notes the potent sensitising effect of CMIT/MIT and considers that CMIT/MIT in product type 13 should be identified as a candidate for substitution in accordance with Article 10(1)(e)² of the Biocidal Products Regulation (EU) No. 528/2012 (BPR).

CMIT/MIT is a very potent sensitizer to which a proportion of the population is already sensitised. The concern is not only the risk of new cases of sensitized individuals from exposure to biocidal products and treated articles containing CMIT/MIT but also the increasing reports of elicitation from exposure to the preservative. We consider that the use of CMIT/MIT in biocidal products should be limited as far as possible, especially where exposure is not minimized by, for example, the use of automated processes. We understand from comments supplied so far by stakeholder representatives that it may not be easy to substitute CMIT/MIT completely but substitution should be pursued where it is possible.

For product type 13, control of exposure to CMIT/MIT in biocidal products is not complete since some of the professional uses described are not fully automated. There is an unacceptable risk of causing sensitization upon exposure which cannot be mitigated due to safety considerations meaning that gloves cannot always be worn since they can get caught in machinery). However, reducing risks by other means wherever possible should be a condition of the approval of CMIT/MIT in product type 13.

¹ The comments are from the Swedish Competent Authority at the time of writing this letter. We are awaiting confirmation of this position as a Swedish position but this will not be available until the meeting.

² (e) there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;

Swedish Chemicals Agency

| Mailing address | Visit & delivery | Invoicing address | Phone & fax | Internet | VAT No |
|---|---|--------------------------------------|---|-----------------------------|----------------|
| Box 2 SE-172 13 Sundbyberg Sweden | Esplanaden 3A SE-172 67 Sundbyberg Sweden | FE 124 SE-838 80 Frösön Sweden | Phone +46 8 519 41 100 Fax +46 8 735 76 98 | www.kemi.se kemi@kemi.se | SE202100388001 |

We agree with the CA meeting's position that criterion (e) of Article 10(1) should be applied sparingly, in exceptional circumstances but we consider that the approval of CMTT/MIT in product type 13 is a particularly appropriate case since the other provisions of the BPR, for example paragraph 66 of Annex VI, will not be sufficient to maintain a high level of protection for humans.

Since the majority opinion of the BPC does not identify CMTT/MIT as a candidate for substitution in product type 13 Sweden submits a minority opinion.