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Development of Legislation and Other Instruments
Mary Iakovidou
EU Co-ordinator, Biocidal Products

Erik van der Plassche
Biocidal Products Committee
European Chemicals Agency
Helsinki
Finland

Minority opinion of Sweden on 2-Methylisothiazol-3(2H)-one for use in product type 13

Sweden considers that 2-Methylisothiazol-3(2H)-one (MIT) is such a potent sensitiser that it should be used only as necessary, especially when used in biocidal products and to treat consumer goods. Sweden therefore considers that MIT should be considered to fulfil criterion e) of Article 10(1) of the Biocidal Products Regulation and should be considered a candidate for substitution.

The Swedish Competent Authority notes the discussion during the 7th meeting of the Biocidal Products Committee on the proposed opinion regarding the approval of MIT for use in product type 13 (working or cutting fluid preservatives). In the first place this discussion investigated whether an active substance can be identified as a candidate for substitution only in relation to a specific product type as opposed to being a candidate for substitution either for all or none of the product types in which it is approved. This would mean that an active substance could be considered for substitution for specified product types where the use pattern leads to exposures that, together with the properties of the substance, still give rise to concern despite the application of relevant risk management measures.

The majority of the meeting agreed that MIT should not be identified as a candidate for substitution for product type 13. However, the use of MIT in product type 13 is not fully automated meaning that professional users may be exposed. There are even situations where it is not possible for professionals to wear gloves to protect them from exposure on grounds of safety when using machinery. For professional products it is appropriate to pursue all possible risk management measures to reduce risk to sensitisation. Where the risk to the active substance can be significantly lowered by using similar products (which may even contain the same active substance) comparative assessment should be applied. In order for comparative assessment to be applied according to Article 23 of the Biocidal Products Regulation (EU) no. 528/2012, the active substance shall be identified as a candidate for substitution according to Article 10 of that regulation.

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

Furthermore the possibility to authorise biocidal products for non-professional use is not explicitly excluded in the opinion. This leaves open the legal possibility for companies to apply for authorisation of such products. Given the potent sensitising effect of this active substance, Sweden considers that the authorisation of products for non-professional use should be excluded in the opinion. In the absence of such a restriction, the identification of MIT as a candidate for substitution will at least trigger the comparative assessment of products proposed for non-professional use at evaluation of applications for product authorisation leading to a consideration of whether suitable alternative products are available.

Identifying an active substance as a candidate for substitution is a first step which should be separate to an assessment of the extent to which an active substance can be substituted at any given time.

In conclusion, Sweden could not support the majority opinion of the BPC on MIT.

Yours sincerely

Mary Iakovidou