

7 July 2017

Minority opinion of the German Competent Authority (CA) regarding the derivation of toxicological reference values for MBIT, PT 6

The German CA does not agree with the toxicological reference values derived for MBIT and agreed by the Working Group Human Health. In the assessment of MBIT, choices made regarding the starting point for AEL derivation and assessment factors for ARfD and ADI derivation are leading to an unequal assessment of this substance compared to very similar substances of the isothiazolinone group that were assessed only recently. This different assessment was performed although there are no significant differences in the toxicity profiles between these substances.

For MBIT, systemic effects in animals were assumed to be secondary to local effects and considered irrelevant. For the other isothiazolinones, however, it was concluded at the same level of evidence, that relevance of these unspecific systemic effects cannot be excluded with certainty. This results in an inconsistent assessment for these highly similar active substances. The AELs derived for MBIT are several factors higher than those derived for the other isothiazolinones. DE is of the opinion, that the AELs for MBIT should be derived from the same NOAEC that was used for ARfD and ADI derivation.

In addition, the German CA does not agree with reducing the assessment factors for ADI and ARfD derivation. In case of the ARfD, the assessment factor was reduced from 100 to 25. The Biocides Guidance Volume 3 Part B Chapter refers, in this matter, to REACH Guidance Chapter R.8.4.3.1., which clearly states that "However, once the concentration (e.g., ppm in diet) has been converted into a dose (e.g. mg/kg/day), an allometric scaling factor has to be used." As this is the case here, an interspecies toxicokinetic factor of 4 would apply. Another issue to be taken into account is the unequal treatment of MIT and MBIT. For MIT, assessment factors of 100 and 200 were used for ARfD and ADI derivation, rather than the lower values of 25 and 100 proposed for MBIT despite similar effects.