Comments CLH report of 1,2-benzisothiazolin-3H-one (BIT)

Due 14 May 2021

Comments related to CLH report of 1,2-benzisothiazolin-3H-one (BIT), CAS n. 2634-33-5

No.	Column A Reference to CLH report *	Column B Comment
(1)	Page 8 and 9: "BIT is also used with the following uses: 3. As an ingredient of cosmetics and personal care products"	Point 3 has to be deleted. According to Regulation (EC) 1223/2009 on cosmetic products, BIT is not authorised for preservation of cosmetics and personal care products and is therefore not used for this purpose.
(2)	Page 9 Chapter 6 3. RAC opinion on MBIT CLH-O-0000001412-86-209/F	The basis for classification and labelling is intrinsic data on the relevant molecule. Several complete data sets are available for BIT. Each relevant endpoint is therefore addressed multiple times. It is not necessary, nor is it advisable, to use data from another substance as a basis for the assessment or to include it in the assessment of BIT. The data set on BIT is comprehensive and conclusive. Therefore, the RAC opinion on MBIT should not be a source of data in the context of the BIT classification and labelling process. Any reference to MBIT and any conclusion drawn based on such data should be deleted. MBIT is a new substance for which only basic data are available compared to BIT. Whereas BIT is a substance that has been marketed for decades and therefore a lot of additional and supporting data has been generated during this time.
(3)	Page 9 Chapter 7, table 7	We do agree with the assigned physico-chemical properties, based on the available data.
(4)	Page 17 Chapter 10.1.3 Acute toxicity – oral route	Considering all available data suitable for classification, we do agree with the proposed classification for acute oral.
(5)	Page 17 Chapter 10.3 Acute inhalation Table 9	A relevant study addressing this endpoint is not referenced, but should definitely be included in the CLH report. In 2015, the European BIT Task Force submitted an inhalation study ([redacted]. 2012) and this was shared with the eCA. Based on the results of this study, the LC_{50} for the combined sexes was determined to be 0.50 mg/L. The result of this study should be taken into account when determining the ATE (acute toxicity estimates).

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No.	Column A Reference to CLH report *	Column B Comment
(6)	Page 22 Chapter 10.4.2 and Chapter 10.4.3 Skin corrosion	Considering all available quality data suitable for classification we do agree with the dossier submitter that BIT does not meet EU criteria for classification as skin irritant. We can agree to remove classification as Skin Irrit. 2 (H315).
(7)	Page 32 Chapter 10.7.1 Skin sensitisation	Considering all available data suitable for classification, we do agree to classify BIT as skin sensitizer subcategory 1B. We do also confirm the SCL $\geq$ 500 ppm; H 317 and GHS07; Warning, based on the qualified and suitable data available.
(8)	Page 53 Chapter 11.3	BIT has a low vapour pressure (62.76 x 10^{-4} Pa at 20ºC). It should rather read: BIT has a low vapour pressure (6.28 x 10^{-5} Pa at 20ºC).
(9)	Page 54 Chapter 11.4.	Thor: We propose that the reference to the BCF study with Lepomis macrochirus is taken out completely as the study has a Klimisch score of 3 and is thus not considered to be reliable.
(10)	Page 56 Chapter 11.5.	Thor: The EC50 value of the study Terrell, 1997b is given as 2.44 mg/L in the draft CAR, please adjust the value.
(11)	Page 56 Chapter 11.5.	Thor: The ErC50 and ErC10 values of the studies Smyth et al., 1994, Smyth and Brown, 1991, Kasthuri Raman, 2002 and Oldersma et al., 2002 are not in line with the draft CAR, please adjust the values.