Für Mensch & Umwelt

As of 15 March 2021

INFORMATION

Evaluation of 2-mercaptobenzothiazole (2-MBT) as starting substance for manufacturing of elastomers in contact with drinking water

English translation – only the German document version is legally binding

1 Introduction

2-Mercaptobenzothiazole (2-MBT) is used as a vulcanisation accelerator in the crosslinking of rubber. In addition, 2-MBT is formed as a reaction product from some vulcanisation accelerators in elastomer production.

The positive list of the Elastomer Guideline[1] Part 1 contains 2-MBT and its zinc salt. In Part 2 of the positive list, two sulfenamides and dibenzothiazyl disulfide (dimeric 2-MBT) are listed, from which 2-MBT is formed as a vulcanisation reaction product.

Products made from sulphur-crosslinked elastomers are commonly used for seals in drinking water distribution and for equipment fittings such as membranes in expansion tanks.

[1] https://www.umweltbundesamt.de/en/document/guideline-for-hygienic-assessment-of-elastomers-in

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2 Preliminary parameter value

Preliminary evaluation of 2-MBT as contaminant in drinking water led to a value of 250 µg/l as migration restriction (expressed as Drinking Water Positive List Limit (DWPLL) in the Elastomer Guideline; corresponding to Maximum Tolerable Concentration at the tap (MTC_{tap}) in the KTW evaluation criteria document) for products in contact with drinking water that are to be assessed in terms of drinking water hygienic suitability according to the Elastomer Guideline. This specification will remain valid until transposition of the Elastomer Guideline into the KTW evaluation criteria.

Oral intake of up to 5 mg/kg 2-MBT in food is accepted according to the principles of the EFSA Note for Guidance, 2008[2]. Conversion to exposure by consumption of drinking water results in a **provisional migration restriction of 250 µg/l**. Current toxicological assessments by US EPA (1994)[3], SCF (2000)[4], BG RCI (2000), Whitaker et al. (2004)[5], BfR (2008)[6], REACH-SER (2014)[7] and HBM (2015)[8] declare 2-MBT as predominantly not mutagenic and not carcinogenic.

3 Test certificates according to Elastomer Guideline

For the assessment of sulphur-crosslinked elastomers according to Elastomer Guideline requirements, 2-MBT has to be determined by applying standard DIN EN 12873-1. The provisional migration restriction to be observed is 250 µg/l as mentioned above. Test certificates and test reports referring to Elastomer Guideline must keep record that assessments made use of the abovementioned provisional migration restriction.

4 Future restriction

The German Environment Agency (UBA) aims at incorporating elastomers into the scope of the KTW evaluation criteria document by virtue of its 3rd amendment being in preparation. After the Elastomer Guideline will have been transposed into the KTW evaluation criteria, only fully evaluated vulcanisation agents for sulphur crosslinking will be accepted.

On the basis of the expert opinion of the International Agency for Research on Cancer (IARC), who has classified 2-MBT as suspected group 2A carcinogen, UBA together with the Federal

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[2] http://www.efsa.europa.eu/en/efsajournal/pub/rn-21

[3] Reregistration Eligibility Decision (RED) Sodium and Zinc Salts of 2-Mercaptobenzothiazole, EPA 738-R-94-027, September 1994

[4] Trade association of raw materials and chemical industry, Summary of toxicological assessment No. 70 2-Mercaptobenzothiazole Issue 11/2000

[5] Human health risk assessment of 2-mercaptobenzothiazole in drinking water, Toxicology and Industrial Health 2004; 20: 149-163

[6] Auxiliary material for the production of rubber air mattresses has an allergenic potential, Opinion No. 033/2008 of BfR of 24 June 2008

[7] Substance Evaluation Report for Benzothiazole-2-thiol (2-MBT), Version Number 1.2, June 2014

[8] Substance monograph for 2-mercaptobenzothiazole (2-MBT) and HBM values for 2-MBT in the urine of adults and children, Federal Health Gazette 2015, 58: 1027-1040

Institute for Risk Assessment (BfR) came to the conclusion that the current migration restriction for 2-MBT has to be lowered.

Reasons:

For 2-MBT, human relevance of observed thyroid gland effects as cited in studies referred to by IARC cannot be clarified sufficiently. An endocrinal potential and possible effects of developmental toxicity or neurotoxicity of 2-MBT cannot be excluded.

For these reasons possible migration of 2-MBT into drinking water must be limited to the extent best achieved by technical means. Currently this is reflected by an approximate value of 100 µg/l. Evaluation of 2-MBT is to be considered preliminary until open questions will be clarified.

Other possible reaction products of 2-MBT have not been considered in this evaluation.

The migration restriction (Maximum Tolerable Concentration at the tap, MTC_{tap}) for 2-MBT will be lowered to <u>100 µg/l</u> at transposition of the Elastomer Guideline into the KTW evaluation criteria.