

Information

Evaluation of 2-mercaptobenzothiazole (2-MBT) according to the elastomer guideline (transition regulation)

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1 Introduction

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

The positive list of the Elastomer Guideline¹ 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.

The basis of the current assessment of 2-MBT is the opinion of the SCF² on the assessment of 2-MBT in suckers for toddlers. The potential oral intake of 2-MBT from elastomeric materials is judged to be safe if the value (DIN EN 1400-3:2002 standardised test method) is below 8 mg 2-MBT/kg elastomer after a 24-hour extraction. The 400 µg/kg of elastomer limit for elastomers in contact with drinking water is obtained from an exposure transfer for drinking water (2 litres of drinking water consumption, 10% allocation).

¹ <https://www.umweltbundesamt.de/dokument/leitlinie-zur-hygienischen-beurteilung-von-0>

² Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials, SCF/CS/PM/GEN/M83, 13 November 2000, Toxicology and Carcinogenesis Studies of 2-mercaptobenzothiazole (CAS No. 149-30-4) in F344/N Rats and B6C3F₁ Mice (Gavage Studies), 1988, NTP TR 332, NIH Publication No. 88-2588

Since 2-MBT is a potential reaction product, the 400 µg/kg elastomer additional requirement for 2-MBT, which must be tested with the help of DIN EN 1400-3:2002, applies to all sulphur-crosslinked elastomers according to the Elastomer Guideline. This test measures the migratory content of 2-MBT in the elastomer which can be migrated. The test thus does not correspond to the otherwise usual procedure for testing materials and products in contact with drinking water. The maximum concentration expected in drinking water can be estimated using the test based on DIN EN 12873-1 which is envisaged for this application.

The limitation of the 2-MBT content in elastomers as a requirement of the Elastomer Guideline was applied because an assessment of 2-MBT as a drinking water contaminant was lacking. However, it must be noted that the test according to DIN EN 1400-3:2002 provides a figure for elastomer products and sets a requirement 20 times more stringent than that for suckers for toddlers. The test according to DIN EN 12873-1 is more reasonable for the practical estimation of the maximum concentrations expected in drinking water. However, the 2-MBT concentration in drinking water must be limited. This limit should be derived based on the assessment of 2-MBT as a drinking water contaminant.

2 Transitional regulation

A preliminary assessment of 2-MBT as a drinking water contaminant results in a 250 µg/l restriction as Drinking Water Positive List Limit (DWPLL).

The oral intake of up to 5 mg/kg 2-MBT in food is accepted according to the principles of the EFSA Note for Guidance, 2008³. A conversion to the exposure through drinking water consumption results in a provisional restriction of 250 µg/l. Current toxicological assessments by US EPA (1994)⁴, SCF (2000)⁵, BG RCI (2000), Whitaker et al. (2004)⁶, BfR (2008)⁷, REACH-SER (2014)⁸ and HBM (2015)⁹ declare 2-MBT as predominantly not mutagenic and not carcinogenic.

³ <http://www.efsa.europa.eu/en/efsajournal/pub/rn-21>

⁴ Reregistration Eligibility Decision (RED) Sodium and Zinc Salts of 2-Mercaptobenzothiazole, EPA 738-R-94-027, September 1994

⁵ Trade association of raw materials and chemical industry, Summary of toxicological assessment No. 70 2-Mercaptobenzothiazole Issue 11/2000

⁶ Human health risk assessment of 2-mercaptobenzothiazole in drinking water, Toxicology and Industrial Health 2004; 20: 149-163

⁷ Auxiliary material for the production of rubber air mattresses has an allergenic potential, Opinion No. 033/2008 of BfR of 24 June 2008

⁸ Substance Evaluation Report for Benzothiazole-2-thiol (2-MBT), Version Number 1.2, June 2014

⁹ 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

However, the International Agency for Research on Cancer (IARC) has classified 2-MBT as carcinogenic. The justification for this classification has not yet been published. As soon as the IARC's complete report is available, the German Environment Agency (UBA), together with the Federal Institute for Risk Assessment (BfR), will conclusively evaluate 2-MBT as a drinking water contaminant. This may lead to a stricter assessment of 2-MBT than the preliminary DWPLL value.

3 Test certificates

For the attestation of conformity sulphur-cross linked elastomers as required by the Elastomer Guideline, the 2-MBT emission must now be determined according to DIN EN 12873-1. The provisional DWPLL value shall apply until further notice. The relevant test certificates and test reports must show that the provisional 2-MBT DWPLL has been used for the assessment.