SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Benzothiazole-2-thiol (2-MBT)

EC No 205-736-8

CAS No 149-30-4

Evaluating Member State(s): Germany

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2013

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

Benzothiazole-2-thiol (2-MBT) was originally selected for substance evaluation in order to clarify suspected risks about:

- CMR properties:
  The substance evaluation was intended to clarify whether the available data justify harmonised classification regarding carcinogenicity and/or genotoxicity. The substance is self-classified by some notifiers as Carc.1B. The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area ("MAK-Kommission") assigned 2-MBT in 1999 into their cancer category 3 (possible carcinogen).
- Health risks for consumers from use of consumer articles made of rubber or containing rubber parts:
  With regard to human health 2-MBT is classified as a skin sensitizer (Skin Sens 1, H317 [May cause an allergic skin reaction]) and is used as an accelerator for the vulcanisation of rubber. According to information on ECHA´s database 2-MBT is registered in aggregated quantities of 1,000 - 10,000 tonnes per annum.
  The substance evaluation was intended to clarify whether risks from the use of 2-MBT as vulcanisation agent for rubber and whether possible other uses in consumer products are adequately addressed in the registration dossiers.
  Prior to the current substance evaluation, on the basis of test results on the release of 2-MBT from consumer products (air mattresses) and the maximum possible dermal uptake of the substance, in an evaluation by the German Federal Institute for Risk Assessment (BfR) it was concluded that the emission of 2-MBT from consumer products should be minimised as far as possible. The analysis of migration rates of 2-MBT from air mattresses under realistic conditions revealed that the safety margin between the possible dermal up-take (under worst-case exposure assumptions) and the NOAEL may be below 100 so that a preventive consumer protection is considered necessary.

No initial concern was identified for workers or for the environment. Therefore, the exposure and risk characterisation for workers as well as for the environment was not part of the substance evaluation.

During the evaluation no further concerns to be clarified under the substance evaluation process were identified.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	x
Need for other Community-wide measures	x
No need for regulatory follow-up action	

As available data were considered to be sufficient for chemical safety assessment and covering relevant topics of concern, no new data/tests were considered to be required by the evaluating Member State. Therefore, substance evaluation was finalised after the first year of evaluation.

The concern on any need for harmonized classification and labelling of 2-MBT regarding carcinogenicity and/or genotoxicity was clarified. The available data are sufficient and appropriate to conclude that there is no need for a proposal for harmonised classification and labelling of 2-MBT.

2-MBT is a skin sensitising chemical, a property, which is generally regarded as a threshold effect. However, based on the available human and experimental data it was not possible to derive an appropriate DNEL to compare it with exposure levels resulting from the use of 2-MBT in consumer products. Hence, no risk characterisation ratio could be determined and the level of risk for skin sensitisation and/or allergic skin reactions for consumers could not be estimated.

To assess the exposure of the general public to 2-MBT biomarkers have been identified and the substance will be taken up into biomonitoring programs The choice of further regulatory measures will be dependent on the results of this programs and on cases of sensitisation of consumers/ of the general public identified e.g. by the Information Network of Departments of Dermatology (IVDK). If based on these results exposure of the general population and cases of contact allergy to 2-MBT in consumers are evident, further action is considered necessary and the evaluating Members State will perform a risk management option analysis (RMOA).

[1] The IVDK (www.ivdk.org.de) is an epidemiological surveillance system which continuously monitors contact allergy. It consists of members from dermatological hospitals in Germany, Austria and Switzerland and is a member of the European Surveillance System on Contact Allergies (ESSCA).

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

It is to be noted that the only registered use of 2-MBT relevant for consumers is "Use of tyres and general rubber goods" and its corresponding article service life. While the substance evaluation resulted in the conclusion that health risks of consumer exposure to 2-MBT via the oral, dermal and inhalation route with regard to possible systemic toxic effects are sufficiently controlled, no such conclusion could be drawn with regard to the health risks emanating from the skin sensitising properties of 2-MBT on the occasion of notable dermal exposure via use of articles made of rubber or containing rubber parts. In this respect the initial concern regarding health risks for consumers arising from use of/contact to rubber containing consumer goods was therefore confirmed by the substance evaluation.

Based on the available human and experimental data a DNEL for the skin sensitising property of 2-MBT could not be derived and compared with dermal 2-MBT exposure levels resulting from the use of/contact to rubber containing consumer goods. Therefore, no risk characterisation ratio could be determined and the level of risk for skin sensitisation and/or allergic skin reactions could not be estimated. Consequently it needs to be concluded that in principle any level of dermal exposure is assumed to pose a risk for skin sensitisation/allergic reactions for consumers.

It needs to be noted that the substance evaluation focussed on the use of 2-MBT as vulcanisation agent for articles made of rubber or containing rubber parts designated for consumer use. With regard to the total extent of consumer exposure emanating from the use of such articles it is of significance to note that use of other vulcanisation agents than 2-MBT (e.g. N-cyclohexyl-2-benzothiazole sulphonamide and 2-Mercaptobenzothiazyl disulfide) may also release 2-MBT during their intended use. Hence, registrants should take care to minimise the amount of 2-MBT used for vulcanisation of rubber containing consumer goods as far as possible in order to ensure their safe use.

Beyond that and regarding the health risks for consumers arising from the skin sensitising properties of 2-MBT on the occasion of dermal exposure via use of articles made of rubber or containing rubber parts a need to consider further risk management measures for consumers is envisaged.

3.1.1. Need for harmonised classification and labelling

Not relevant.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

SVHC identification and subsequent authorisation is not considered as an appropriate measure in this case as the observed risk is related to the presence of the substance in articles and import of articles is out of the scope of the authorisation process.

3.1.3. Need for restrictions

Under restriction it would in principle be possible to cover the various sources for 2-MBT release into consumer articles, i.e. to include also other vulcanisation agents that release 2-MBT during their use. Since currently the risk of skin sensitisation/allergic reactions for consumers from 2-MBT or substances releasing 2-MBT cannot be substantiated and for a restriction process the proportionality of the envisaged action needs to be considered, further information is considered necessary. A discussion of a restriction as a regulatory

option will be included in the envisaged RMOA by the evaluating member state after the results of the monitoring programme (Section 2) are available.

3.1.4. Proposal for other Community-wide regulatory risk management measures

Other risk management options also need to be considered to minimise the emission of 2-MBT from consumer products as far as possible (As Low As Reasonably Achievable, ALARA), especially if a restriction under REACH cannot be achieved.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

After the results of the monitoring programme (Section 2) are available a Risk management Options Analysis (RMOA) is envisaged by the evaluating member state.