



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis (RMOA)

Conclusion Document

Substance Name: Methyl-1H-Benzotriazole

EC Number: 249-596-6

CAS Number: 29385-43-1

Substance Name: Sodium-Methyl-1H-Benzotriazole

EC Number: 265-004-9

CAS Number: 64665-57-2

Substance Name: 4(or 5)-methyl-1H-benzotriazole, potassium salt

EC Number: 265-002-8

CAS Number: 64665-53-8

Substance Name: 6-Methylbenzotriazole

EC Number: 205-265-8

CAS Number: 136-85-6

Substance Name: Reaction mass of 4-methyl-1H-benzotriazole and 29385-43-1

EC Number: 931-891-2

CAS Number: -

Authority: DE CA (aMSCA)

Date: 20.12.2023

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to assess whether further regulatory management measures are needed.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision-making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

4/5-Methyl-benzotriazole (4/5-methyl-BTA) is currently not listed in Annex VI of the CLP regulation. However, ECHA's Risk Assessment Committee (RAC) adopted an opinion on September 15th 2022 to classify 4/5-methyl-BTA as Aquatic chronic 2. The corresponding inclusion into Annex VI of the CLP regulation is still pending.

Currently no harmonised classification for 4(or 5) sodium/ potassium-methyl-benzotriazole, 6-methylbenzotriazole or the "reaction mass of 4-methyl-1H-benzotriazole and 29385-43-1" exist.

2. CONCLUSION OF RMOA

It is concluded that the substance fulfils the criteria for a persistent, mobile and toxic (PMT), and a very persistent and very mobile (vPvM) substance according to CLP. The T-criteria is assumed to be fulfilled as the substance is also assumed to fulfil the criteria for classification as a reproductive toxicant. This conclusion is based on the REACH and CLP data as well as other available relevant information.

Due to their similarity in structure and properties the criteria described for 4/5-methyl-BTA, as well as the criteria for chronic aquatic toxic effects, are also assumed for the other substances covered in this RMOA.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	x
<i>Harmonised classification and labelling</i>	x
<i>Identification as SVHC (authorisation)</i>	x
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

In the course of this RMOA process it was found that both, the direct uses of 4/5-methyl-BTA as such, together with its use in mixtures cause widespread and high emissions into the environment. To a smaller degree also its use for the manufacturing of articles (e.g. t-shirts, tires) and their subsequent service life may contribute to these emissions. As a result of these emissions, 4/5-methyl-BTA can be found at comparatively high concentrations in the aquatic environment.

Besides its direct release into the environment, including especially de-icing activities on airplanes at airports over winter, major pathways for the emissions of 4/5-methyl-BTA into the environment are discharges from WWTPs to receiving waters. In WWTPs the removal efficacy of conventional wastewater treatment is considered to be insufficient.

The uses contributing most to the emissions from municipal and industrial WWTPs, respectively, are the use of 4/5-methyl-BTA in dishwasher products (households) and as anti-corrosives in industrial processes (e.g. cleaning and as conditioning chemicals in cooling water from cooling or refrigerating towers).

Given its persistence, mobility in the aquatic environment, toxicological profile (reproductive toxicity) and presence in drinking water resources, the aMSCA concludes that 4/5-methyl-BTA poses a serious hazard to the quality of drinking water resources of both bank filtrate and groundwater origin. This results in the necessity to regulate the substance in order to reduce its emissions into and hence risk for the environment.

3.1 Combining regulatory measures under CLP (CLH Dossier) and REACH (SVHC Identification & Annex XIV)

Considering the substance properties and current knowledge on the uses of 4/5-methyl-BTA on its own and as a constituent in mixtures, the aMSCA concludes that its emissions into the environment might be best controlled via (1) a harmonised classification as Repr. 1B (H360D) or 2 (H361) as well as according to the new hazard criteria as PMT (EUH450) and vPvM (EUH451); and (2) a subsequent SVHC identification (on the basis of Art. 57f or depending on the status of the REACH revision process according to separate letters for PMT/vPvM under REACH, followed by (3) an inclusion into Annex XIV.

Using the new and old CLH hazard criteria will allow for the labelling of 4/5-methyl-BTA as a PMT and reprotoxic substance. As a result, producers will be incentivized to substitute 4/5-methyl-BTA in order not to lose customers. Furthermore, 4/5-methyl-BTA will not be allowed anymore in consumer mixtures in amounts >0.3% in case of a classification as Repr. 1B. Both will already reduce the emissions of 4/5-methyl-BTA into the environment (esp. from consumer uses, which have to be considered to be a major emission source). The CLH process will, however, most likely not have sufficient impacts on the use of 4/5-methyl-BTA in industrial applications. Therefore, further measures under the REACH Regulation will be necessary to effectively reduce 4/5-methyl-BTA emissions. Thereby, the importance of 4/5-methyl-BTA for the metalworking industry and the successful green transformation of Europe (use in electric cars and wind turbines) should be taken into account. As no alternative is currently available, it might be adequate to allow for an appropriate transition period for these industries in order for them to find alternatives or submit an application for authorization.

After the substance has been identified as PMT, vPvM and reprotoxic under the CLP regulation, it should be possible to quickly identify 4/5-methyl-BTA also as an SVHC under REACH and subsequently add it to Annex XIV. Considering that 4/5-methyl-BTA is mostly used within mixtures, the identification as SVHC will most likely only result in a minor reduction of 4/5-methyl-BTA emissions from industrial and de-icing activities. However, it will allow to include 4/5-methyl-BTA into Annex XIV, which will then lead to an effective emission reduction.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
CLH Dossier (PMT, vPvM, Repr.)	2024	DE CA
SVHC Dossier	Following CLH	DE CA