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

REGULATORY MANAGEMENT OPTION ANALYSIS CONCLUSION DOCUMENT for

Substance	EC-no	CAS-no
2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethyl-butyl)phenol (UV-329)	221-573-5	3147-75-9
2-(2H-benzotriazol-2-yl)-4,6-bis(2-phenyl-2-propanyl)phenol (UV-234)	274-570-6	70321-86-7
2-(2H-benzotriazol-2-yl)-6-(1-methyl-1-phenylethyl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-928)	422-600-5	73936-91-1
2-(2H-benzotriazol-2-yl)-4-methylphenol (UV-P)	219-470-5	2440-22-4
2-(2'-hydroxy -3' -tert-butyl-5'-methylphenyl)-5-chloro benzotriazole (UV-326)	223-445-4	3896-11-5

Member State(s): Germany
Dated: 07 April 2022

Disclaimer:
Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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 other 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

The German CA already prepared an RMOA-document on phenolic benzotriazoles in 2012 and 2015. Since then new information on some substances became available due to compliance checks and testing proposals for UV-326, UV-234, UV-329, UV-P. Therefore, Germany decided to update the RMO-analysis on the phenolic benzotriazoles UV-P, UV-234, UV-326, UV-329, and UV-928. This document is the RMOA conclusion for UV-326, UV-234, UV-329, UV-P and UV-928.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information, where appropriate.

Conclusions	Tick box
Need for follow up regulatory action at EU level	x
Harmonised classification and labelling	x
Identification as SVHC	x
Authorisation	tbd
Restrictions	tbd
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

For one of the benzotriazoles (UV-P) the aMSCA proposes the preparation of a CLH dossier. UV-P is correctly self-classified by the registrant as aquatic chronic 1 (M=1). However, as there are deviating C&L notifications harmonisation of the classification and labelling is recommended. This will support the argumentation in section 3.1.2 that the whole group of substances is of concern and UV-P is no reasonable substitution candidate for the other four benzotriazoles.

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation or restriction)

The aMSCA is of the opinion that there is sufficient evidence that UV-326, UV-234, UV-329 (and potentially also UV-928) can be considered to fulfil the criteria for vPvB substances according to Annex XIII of the REACH Regulation. UV-P can be considered vP,

borderline T but not B based on a BCF obtained from a fish test. Concern for terrestrial bioaccumulation and mobility remain for UV-P and need to be further investigated.

The objective of further risk management is in the long term the substitution of the assessed benzotriazoles with substances or technologies of less concern. This could be achieved by an SVHC-identification under REACH in a first step. The subsequently triggered obligation will generate information on articles that contain the identified SVHCs. Based on that information the aMSCA intends to revisit these substances in order to decide on the best follow up management option after SVHC identification.

In the case of UV-326, the lead registrant already communicates the vPvB properties. Therefore, the use of UV-326 is assumed to decrease, due to substitution by other benzotriazoles e.g. UV-234, UV-329, UV-P, UV-928. However, these potential substitutes are of similar concern with regard to their environmentally hazardous properties. Consequently, there is a need to avoid substitution by similar concerning substances out of the same group. Therefore, SVHC identification (first step towards authorization or restriction) of at least UV-326, UV-234 and UV-329 in a group is considered to be the most appropriate first step risk management option. Subsequently, further regulatory risk management could follow addressing the whole group of substances.

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 intention	Actor
Annex XV dossier (SVHC) for at least UV-326, UV-234 & UV-329	2023	Germany
CLP Annex VI dossier (UV-P)	2022	Germany