Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

Risk Management Option Analysis Conclusion Document

Substance Name: N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS)
EC Number: 225-625-8
CAS Number: 4979-32-2

Authority: German CA
Date: June 2022

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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 a further regulatory risk management measures are required.

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

DCBS was assessed by the German CA under SEv in 2013 for the following reasons: suspected CMR, suspected PBT/vPvB, sensitizer, consumer exposure, exposure of workers, wide dispersive use. The SEv has been concluded and the conclusion document has been published in 2018. The data collected during SEv confirmed that DCBS has vPvB properties. For the other concerns, the evaluating MSCA concluded that no further follow-up action at EU level is currently necessary.

2. CONCLUSION OF RMOA

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

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

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

DCBS has been subject to substance evaluation in 2013 with the scope PBT, concern for environment, concern for human health and exposure. The final conclusion of the substance evaluation has been published in July 2018. The evaluating MSCA draws the conclusion that DCBS meets the criteria set out in Annex XIII of REACH as being very persistent and very bioaccumulative. It was suggested to assess the need for risk management in a Regulatory Management Option Analysis.

During the RMOA process the PBT expert group was consulted about the persistency and bioaccumulation potential of DCBS. The PBT experts agreed with the conclusion that based on the data available DCBS is a vPvB substance. Also, the majority of registrants agrees that DCBS has vPvB properties and are considering this in their registrations.

PBTs/vPvBs are considered as substances of very high concern under REACH. For PBT and vPvB substances a "safe" concentration in the environment cannot be established using the methods currently available with sufficient reliability for an acceptable risk to be determined in a quantitative way[1].

Therefore, the emission of these substances to the environment should be minimised throughout the lifecycle of the substance according to Section 6.5 Annex I REACH regulation. Information about the vPvB properties of DCBS should be made available and a substitution with safer alternatives should be aimed for, if possible under socio-

[1] ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment

economic aspects.

DCBS is a vPvB substance and the registrants transparently communicate the vPvB status in the registration dossiers. Based on the available information, emissions appear to be minimized due to the special conditions of use and the management measures already in place. Therefore, there is no urgent need for further emission reduction, but rather a need to communicate the vPvB properties in a transparent, officially recognised way.

3.1 Harmonised classification and labelling

DCBS is considered to be a vPvB substance. There are currently no classification categories for these properties. However, in the context of its "Chemicals Strategy for Sustainability", the European Commission intends to amend the CLP Regulation to include PBT/vPvB criteria. A harmonised classification of DCBS as vPvB is considered to be an option to appropriately label the substance and to make the properties of DCBS transparent. Such a classification might also trigger measures under other legislations.

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**
CLP Annex VI dossier for harmonisation of classification and labelling	TBD – once classification criteria are included in CLP Regulation	German CA