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

SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

N,N-dicyclohexylbenzothiazole-2-sulphenamide

Evaluating Member State(s): Germany

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2013

Before concluding the substance evaluation a Decision to request further information was issued on: 29 May 2015

Further information on registered substances here:

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

DISCLAIMER

This 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. The Community rolling action plan (CoRAP) of substances subject to evaluation, 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 Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) 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. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

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

Contents

Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

DCBS was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB properties
- Suspected CMR
- Sensitiser
- Consumer use
- Exposure of workers
- Wide dispersive use

During the evaluation also another concern was identified. The additional concern was:

- Prenatal developmental toxicity.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

N/A.

3. CONCLUSION OF SUBSTANCE EVALUATION

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

Table 1

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	X
Harmonised Classification and Labelling	
Identification as SVHC	X
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

For the concerns 'CMR', 'sensitisation', 'prenatal developmental toxicity', 'consumer use', 'exposure of workers' and 'wide dispersive use', the evaluating MSCA concluded that no further follow-up action at EU level is currently necessary. Further information is provided within the relevant sections of the SEv report.

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Based on the read-across approach to structurally analogue substances, a skin sensitizing potential in humans is suggested for DCBS. The self-classification of DCBS as a skin sensitiser is considered as sufficient and no further action with regards to CLH is recommended by the eMSCA.

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

In a test according to OECD 307 Aerobic and Anaerobic Transformation in Soil ^{14}C-DCBS did not degrade in 120 days and at 12 °C. Maximum mineralization of DCBS was 3.2 % and the shares of NER were up to 19.4 %. DCBS quickly dissipated from the water compartment by adsorption to the sediment. A single first order model describes half-life best and results in a DT_{50} of 314.8 to 614.5 days depending on the soil considered. Thus, DCBS meets the specifications for the half-life in soil given for very persistent substances in REACH Regulation Annex XIII 1.2.1. Persistence. DCBS is very persistent in soil.

DCBS has a log Kow of 5.95 indicating a high bioaccumulation potential. This is confirmed by available bioconcentration tests using *Cyprinus carpio*. In dependence of the used test concentrations the lipid normalized considered steady-state BCFs ranged between 3663 and 12821 L/kg. As reliable experimental BCF values of DCBS lay above the vB criterion (BCF > 5000) of Annex XIII, the substance fulfills the vB criterion.

As the substance is very persistent as proven by the simulation test that was requested during substance evaluation no chronic fish test will be requested.

It must be concluded that DCBS is very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of the Regulation.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

The concerns carcinogenicity, mutagenicity, toxicity to reproduction, sensitisation, prenatal developmental toxicity, consumer use, worker exposure and wide dispersive use were evaluated and concluded that no further follow-up action at EU level is necessary. Further information is provided within the relevant sections of the SEv report.

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

Table 3

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
RMOA is to be finalised	in 2018	DE
Annex XV Dossier for SVHC identification	not yet decided	DE