baua:

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Buta-1,3-diene

EC No 203-450-8

CAS No 106-99-0

Evaluating Member State(s): Germany

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Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014

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

The substance is classified as carcinogen 1A and mutagen 1B. Therefore it may qualify for identification as SVHC under Art 57(a and b).

Buta-1,3-diene is a high production volume chemical. The substance is produced with very high tonnage (> 1,000,000 t/a).

Buta-1,3-diene was chosen for substance evaluation in 2014 under article 44 (1) REACH Regulation because of the potential high exposure to workers.

Although by far most of the uses of butadiene are handled in closed systems with little potential for exposure, there were some uses mentioned in the registration dossier indicating that there are also uses in (partly) open systems, or exposure may happen during interruption of processes and handling of crude products. The details of these uses and the potential exposure risk needed to be clarified in order to decide which risk management is appropriate.

Some uses (PROCs) mentioned in the CSR indicated that potential worker exposure might occur. Exposure scenarios to these uses needed to be evaluated for the quality of data and plausibility. The levels of exposure were compared with available DMEL/DNEL and exposure risk relationships.
Present data indicated that the DMELs calculated may give rise to exposures well above a risk ratio of 4: 1,000.

During the evaluation an additional concern was identified:

- Indication of an identified consumer use within the registration data for buta-1,3-diene.

2. CONCLUSION OF SUBSTANCE EVALUATION

Worker

The eMSCA has assessed at first the concern initiating the substance evaluation, the potential exposure risk for workers. It has been concluded that the initial concern was clarified. The available data suggest that the occupational exposure risk is in an acceptable range and that there is no need for further activities.

Nevertheless, the eMSCA identified an aspect of risk assessment which had to be studied more in detail.

Considering the physicochemical properties of buta-1,3-diene and its industrial uses, workplace exposure occurs via inhalation. The registrants have provided an estimated $DMEL_{long\text{-}term,\ inhalation,\ systemic}$ of 1 ppm (2.21 mg/m^3) for occupational exposure. According to the registrants, this results in a mortality rate from leukemia of 0.39×10^{-4} which corresponds to approximately 4:100 000. This has also been proposed as the future acceptable limit for occupational risk in Germany (AGS, 2008).

However, in Germany, the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe - AGS) currently determined values for tolerable (4:1,000) and acceptable (4:10,000) risk for buta-1,3-diene with 2 ppm and 0.2 ppm, respectively (see Table 1). This is a range where further measures of risk management are needed to minimise the occupational risk for the worker.

Table 1: Exposure-risk relationship for buta-1,3-diene according to the derivation by Working Group "Limit Values and Classification of Carcinogenic and Mutagenic Substances" (AK CM) in view of the justification for an occupational exposure limit (OEL).

Buta-1,3-diene concentration, long-termin mean, 35-40 years of occupational exposure		**Exposure-related lifetime leukaemia risk**
ppm	**µg / m³**	
15	33,660	3%
5	11,220	1%
2	4,488	4 to 1,000
1	2,244	2 to 1,000
0.5	1,122	1 to 1,000
0.05	112	1 to 10,000
0.005	11	1 to 100,000

The eMSCA carried out an evaluation of both approaches, from registrants and AGS. The risk calculation of the registrants is not supported. Nevertheless, the proposed DMEL of 1 ppm (2.21 mg/m^3) has been taken for risk assessment. Based on the registrants' DMEL of 1 ppm the reported exposure values do not exceed this DMEL in general. Within the AGS concept the reported exposure values are between the tolerance level of 2 ppm and the acceptance level of 0.2 ppm. Due to the fact that the exposure values are closer to the acceptance level both approaches lead to the conclusion that there is no need for further activities like the initiation of a restriction or an authorisation procedure.

Consumer

Based on epidemiological studies in workers exposed to butadiene an inhalative DMEL for consumers was derived with 1.50 µg/m^3 (0.0007 ppm).

During the substance evaluation an additional concern was identified due to a potential use of the substance by consumers as given in registration dossiers. In the dialogue with representatives of the lead registrant the representatives clarified the indicated consumer use to be an erroneous indication of a consumer related article service life in the registration dossiers.

The Lower Olefins and Aromatic REACH Consortium has informed the eMSCA that the misindication shall be corrected. Prior to completion of this substance evaluation process, several registration dossiers have been updated. In view of the information given by the Lower Olefins and Aromatic REACH Consortium the additional concern is considered to be clarified. However, at the time of writing the conclusion the latest version of the disseminated dossier(s) on ECHA web-site still included the entry in question.

Buta-1,3-diene monomers remaining in polymers and co-polymers like synthetic rubbers, thermoplastic resins and styrene-butadiene latex lead to a consumer exposure.
The exposure from these sources has already been assessed in the European Risk assessment published in 2002.

The exposure assessment was based on the old data from EU RAR (2002). The two main sources are from indoor air and from butadiene-based food packing materials. Using a Derived Minimal Effect Level for consumers of 0.43 µg/kg bw/day for adults and 0.72 µg/kg bw/day for toddlers (age ≤ 3 years) the RCR for the oral route amounted to the value of 1.67 for toddlers. However, the EU RAR was based on the assumption that the maximum concentration of butadiene in foodstuffs in butadiene-based polymers is < 0.02 mg/kg. Recent regulations (EU 10/2011) lowered concentration limits to a detection limit of < 0.01 mg/kg food. This is supported by the fact that an inquiry of the data from the

German food and commodity safety surveillance retrieved no data on buta-1,3-diene contents in food or commodities.

Using the exposure data from EU RAR (2002) and a DMEL for consumers (inhalative) of 1.50 µg/m^3, the risk characterisation ratio was 1.20 for adults and 0.95 for toddlers. Given that butadiene concentrations in indoor air used for the EU RAR exposure estimates are influenced by further sources besides tobacco smoke, than regarded in the EU RAR. Taking into account, that the calculations in the EU RAR are based on a rough estimation with a simple equation, it is concluded that the RCR values for inhalation exposure are overestimations and will not lead to an unacceptable risk of the consumer.

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

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

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

During the substance evaluation of buta-1,3-diene the eMSCA came to the conclusion that no follow up regulatory actions are needed.

3.2. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	
Hazard and /or exposure was verified to be not relevant and/or	***x***
Hazard and /or exposure was verified to be under appropriate control and/or	***x***
The registrant modified the applied risk management measures.	

Statement of reasons

Buta-1,3-diene is a genotoxic human carcinogen. It has been classified and labelled according to EC 1272/2008 as Muta 1B and Carc 1A. Classification and labelling is considered to be sufficient. There is no need for further information on human health endpoints to evaluate the toxicity of buta-1,3-diene.

Worker

During the substance evaluation of buta-1,3-diene a dialogue between representatives of the registrants' consortium and the eMSCA took place. In this dialogue the registrants explained how they proceed at selecting the uses to create exposure scenarios for the registration dossier. It became clear that the registrants have a different comprehension than the ECHA Guidance Documents of the meaning of "professional uses" at workplaces. The registrants described the relevant uses with potential exposure to workers whereby the working activities by using buta-1,3-diene became more clear for the eMSCA. Based on this knowledge the eMSCA came to the conclusion that there are no professional uses (according to the ECHA definition) which could lead to unacceptable occupational exposure.

Consumer

It could be clarified that buta-1,3-diene is not used as such by consumers and the respective consumer uses were mistakenly included in the registration dossiers as "identified uses". To date several registration dossiers have been updated. Based on the information given by the Lower Olefins and Aromatic REACH Consortium the additional concern is considered to be clarified. However, the latest available version of the dissemination site summarising the registration data still includes the entry in question. Based on current information the residual buta-1,3-diene content in polymers (e.g. synthetic rubbers) will not lead to an unacceptable risk for the consumer.

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

Not applicable.

5. REFERENCES

Ausschuss für Gefahrstoffe	2008	Begründung zu Expositions-Risiko-Beziehung für 1,3-Butadien in BekGS 910	*Expositions-Risiko-Beziehung für 1,3-Butadien*