

Helsinki, 27 April 2016

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

## **DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006**

**For dimethyl disulphide, CAS No 624-92-0 (EC No 210-871-0)**

**Addressees: Registrant(s)<sup>1</sup> of dimethyl disulphide (Registrant(s))**

This decision is addressed to the Registrant(s) of the above substance with active registration pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by Federal Institute for Occupational Safety and Health (BAUA) as the Competent Authority of Germany (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 20 June 2015, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates, which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

### I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Germany has initiated substance evaluation for dimethyl disulphide, CAS No 624-92-0 (EC No 210-871-0) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to exposure of the environment and high (aggregated) tonnage, dimethyl disulphide was included in the Community Rolling Action Plan (CoRAP) for substance evaluation to be evaluated in 2014. The updated CoRAP was published on the

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<sup>1</sup> The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

ECHA website on 26 March 2014. The Competent Authority of Germany was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 25 March 2015.

On 05 May 2015 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

### **Registrant(s) commenting phase**

By 10 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. The evaluating MSCA considered the comments received from the Registrant(s) and the dossier update.

On basis of this information, Section II was amended. The Statement of reasons (Section III) was changed accordingly.

### **Commenting by other MSCAs and ECHA**

In accordance with Article 52(1) of the REACH regulation, on 29 October 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, ECHA submitted a proposal for amendment to the draft decision.

On 4 December 2015 ECHA notified the Registrant(s) of the proposal for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The proposal for amendment was reviewed by the evaluating MSCA. As result of the review the evaluating MSCA decided to remove the following parts from the Information request:

- Information on tonnages manufactured and used
- Review of environmental exposure and risk assessment under consideration of aggregated environmental background concentrations for all manufacturers of dimethyl disulphide (DMDS).

### **Referral to Member State Committee**

On 14 December 2015 ECHA referred the draft decision to the Member State Committee. By 4 January 2016, in accordance to Article 51(5), the Registrant(s) provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant(s) into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 18 January 2016 in a written procedure launched on 8 January 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

## II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision:

### **Information on technical measures reducing emissions to the environment**

Further information on emission reduction measures capable of achieving the efficiencies provided in the Chemical Safety Report

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **3 August 2016** an update of the registration(s) containing the information required by this decision, including an update of the Chemical Safety Report.

## III. Statement of reasons

### **Information on technical measures reducing emissions to the environment:**

Further information on emission reduction measures capable of achieving the efficiencies provided in the Chemical Safety Report

The review of the Lead Registrants exposure scenario number 2 – “use of the substance: use as intermediate in chemical synthesis” where the description of Operational Conditions reads that the use conducted by downstream users occurs “not under strictly controlled conditions” – lead to the conclusion that there are doubts whether the risks for the environment are adequately controlled. The doubts refer to the following:

The initial release rates from the process are identical with the generic release factors of ERC 6a. The Registrant assumes on-site pre-treatment of wastewater and release to municipal sewage treatment plant afterwards. The mandatory on-site physico-chemical treatment is stipulated with an effectiveness of 99.99 percent. The exposure scenario does not contain any further information how the physico-chemical treatment might work or if it is capable of achieving the efficiency in particular for dimethyl disulphide (DMDS).

From the evaluating MSCA’s point of view the Registrant(s) did not provide enough information for the measure to be used for wastewater treatment. It is unclear what is the specific method intended to be used and if it is capable of reaching the high efficiency of 99.99 percent. Assuming a worst-case (or lower bound) efficiency of 80 percent emission reduction by the on-site measure would result in 2000-fold higher PECs for all aquatic compartments (surface and marine water and related sediments). This assumption is reasonable because of the linearity between release and PEC.

In an email correspondence<sup>2</sup> the Registrant(s) stated that “the risk assessment for this use was carried out without specific information from downstream users”. Also the “waste water treatment efficiency necessary to achieve a safe use was calculated (with a result of 99.99%).”

ECHA acknowledges the Registrant(s)’ comment on the difficulties with regard to seeking information on operational conditions and common emission reduction measures in place

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<sup>2</sup> Email from the lead registrant sent to German MSCA received on 3 September 2014.

together with technological specifications like efficiencies. ECHA acknowledges the Registrant(s)' efforts to gain further information by a survey on downstream users' level and the Registrant(s) are welcome to update the dossier once the new information becomes available. However, at this moment the relevant information is not yet provided and the uncertainties on this point are still not clarified.

In summary, no information is provided by the Registrant(s) regarding the specific technical measure, which is capable of achieving a substance specific emission reduction rate (efficiency) of 99.99 percent for DMDS in waste water. Without further information ECHA considers the efficiency of the mandatory emission reduction measure specified in the Exposure Scenario 2 as inconclusive and risks for the aquatic compartments cannot be ruled out.

Therefore the Registrant(s) are requested to specify the intended technical measure and provide detailed information that the emission reduction efficiency achieves 99.99 percent.

#### **Note for consideration**

The information received following the request in the current decision or the announced survey on efficiency of emission reduction measures at downstream user level will be used by the evaluating MSCA in the follow-up stage, in the review of information on environmental exposure and risk assessment from all up-to-date registrations. A derived aggregated PEC (regional) will be used at this stage.

#### **Deadline for the requested information**

Whereas initially a longer timeline of 9 months was considered appropriate to provide the information as set out in the draft decision, the amendments incorporated during the decision making process resulted in information requests that can be met within a shorter period of time. ECHA considers that a period of 3 months is appropriate to provide the information requested in this decision.

#### **IV. Information on right to appeal**

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at <http://www.echa.europa.eu/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised<sup>[5]</sup> by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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<sup>[5]</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.