EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002595-69-07/F Helsinki, 30 April 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For di(morpholin-4-yl) disulphide, CAS No 103-34-4 (EC No 203-103-0), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for di(morpholin-4-yl) disulphide, CAS No 103-34-4 (EC No 203-103-0), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VIII, Section 9.2.2.1. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100-1000 tonnes per year. This decision does not take into account any updates submitted after 3 January 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 30 July 2013.

On 30 September 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 30 October 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 3 January 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(d), 13 and Annex VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the substance subject to the present decision:

> Hydrolysis as a function of pH (Annex VIII, 9.2.2.1; test method: Hydrolysis as a function of pH, EU C.7/OECD 111).

Pursuant to Article 41(4) of the REACH Regulation, the Registrant shall submit the information in the form of an updated registration to ECHA by **6 November 2014.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement. In accordance with Articles 10(a)(vii) and 12(1) of the REACH Regulation, any registration for a substance manufactured or imported in quantities of 10 tonnes or more per year per manufacturer/importer shall contain information on hydrolysis as a function of pH. This is a standard information requirement as laid down in Annex VIII, Section 9.2.2.1. of the REACH Regulation.

The technical dossier contains data for this standard information requirement, containing information on hydrolysis at pH = 7 only. According to the test method used, namely Method C.7 in Commission Regulation (EC) No 440/2008, "The hydrolysis test should be performed at pH values of 4, 7 and 9" (Section 1.8.3 of the method). As the information reported in the technical dossier do not contain all the values prescribed by the method, it is not adequate to fulfil the standard information requirement.

Therefore, the Registrant is requested to provide information on the hydrolysis as a function of pH using the appropriate test method and the registered substance and to submit the resulting information.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the study required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 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 ECHA's internet page at http://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Leena Ylä-Mononen
Director of Evaluation