EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002783-70-11/F Helsinki, 27 August 2014

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

For bis(4-chlorophenyl) sulphone, CAS No 80-07-9 (EC No 201-247-9), 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 bis(4-chlorophenyl) sulphone, CAS No 80-07-9 (EC No 201-247-9), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2.3.5. of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted] for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 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.

The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2015.

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 04 September 2013.

On 6 November 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.

On 09 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments.
The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 6 March 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

The present decision relates solely to a compliance check requesting further information in form of spectral data. The other information requirement for a two-generation reproductive toxicity study (Annex X, 8.7.3.) is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

- Spectral data (Annex VI, 2.3.5.), as specified under section III.1. below.

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 **4 December 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 requirements.

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Spectral data (Annex VI, Section 2.3.5.)

ECHA observes that the registration dossier does not contain any of the spectral data required according to Annex VI Section 2.3.5. of the REACH Regulation to support the identity of the registered substance. ECHA points out that the spectral data Ultra-Violet (UV), Infra-Red (IR) and in addition either a Nuclear Magnetic Resonance (NMR) or a Mass Spectrum (MS) are an information requirement under Annex VI, Section 2.3.5. of REACH.

ECHA notes that the Registrant attached a document in IUCLID section 1.4 with file name "DCDPS Identity determination" and that this document refers to and describes proton NMR, carbon-13 NMR, infra-red and ultra-violet spectral analysis of the substance in addition to chromatographic analysis. However, ECHA observes that only a gas-liquid chromatogram is actually attached in IUCLID section 1.4. while the spectral data for UV, IR and NMR or MS are missing from the IUCLID dossier. The data provided is not sufficient to identify the substance. ECHA notes that the Registrant has not provided any argument why the submission of spectral data is technically not possible or scientifically not necessary (Section 2 of Annex VI).

The Registrant is therefore requested to submit a UV spectrum, an IR spectrum and an NMR spectrum, such as a 1H-NMR or a 13C-NMR. As an alternative to an NMR spectrum, mass spectra (MS) generated as part of mass spectroscopic analysis for the elucidation of the structure of the constituents in the substance can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

The Registrant shall ensure that the description of the analytical methods used for the recording of the UV, IR and NMR or MS spectra are specified in the dossier, in line with the requirements under Annex VI, Section 2.3.7.

ECHA notes that the Registrant in his comments indicated that the spectral data, which was missing in the technical dossier, would be included by means of an update of the registration. As the registration was not updated, the request was maintained in the decision.

2. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested another study (two-generation reproductive toxicity study, Annex X, 8.7.3). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 3 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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