EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003490-80-03/F Helsinki, 15 October 2013

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

For 4,4'-sulphonyldiphenol, CAS No 80-09-1 (EC No 201-250-5), 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 4,4'-sulphonyldiphenol, CAS No 80-09-1 (EC No 201-250-5), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Sections 2 and 3 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 1 August 2013, 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 6 March 2013.

On 13 May 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 12 June 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision but requesting a 12 month extension to the submission deadline.

The ECHA Secretariat 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 1 August 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 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:

1. Composition of the registered substance (Annex VI, section 2.3.) as further specified in Section III of the present decision;
2. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, section 2.3.7.), as further specified in Section III of the present decision.

B. Information in the technical dossier related to the manufacture and use(s) of the substance

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

3. Brief general description of the identified use(s) of the registered substance (Annex VI, section 3.5.).

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 **15 January 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.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance that shall be sufficient to identify the registered substance.

1. Composition of the registered substance (Annex VI, 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the specific registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, the Registrant identified the substance as the well-defined mono-constituent substance 4,4'-sulfonyldiphenol. The specified minimum purity level indicates that up to 20% of impurities may be present in the substance. However, the sum of the

maximum concentrations of the impurities reported by the Registrant only amount up to 13%. Therefore, 7% of the composition is potentially not accounted for.

Furthermore, the Registrant has not provided a sufficient description of the method used for quantifying the constituents required to be reported in the composition, as specified in section III.A.2. below.

ECHA can therefore not verify that all individual impurities required to be identified have been reported in the composition of the registered substance.

In line with paragraph 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012), the following applies to all mono-constituent substances:

- All the impurities present at ≥ 1 % shall be identified and reported individually; and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually.

For each constituent, including the main constituent and any impurity, the typical, minimum and maximum concentration level shall be specified.

The Registrant is accordingly requested to complete or correct the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of mono-constituent substances in IUCLID are available in paragraphs 2.1 and 2.2.1.1 of the Data Submission Manual 18 – How to report the substance identity in IUCLID 5 for registration under REACH (Version 2.0, July 2012), on the ECHA website.

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

2. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient description of the analytical method used for the identification and quantification of the different constituents present in the composition of the registered substance, which is required according to Annex VI, Section 2.3.7.

More specifically, ECHA notes that the Registrant provided a report from the high pressure liquid chromatographic analysis of a sample of the registered substance. This report includes a peak table with retention times of the peaks and corresponding peak area percentages. However, the peak table does not specify to which impurities the individual peaks correspond. Any peak which corresponds to a constituent present at ≥ 1% shall be identified. Therefore, the identity of impurities corresponding to the peaks in the HPL chromatogram with retention times 2.01 min, 15.78 min and 19.01 min shall be clarified.

The Registrant in his comments pursuant to Article 50(1) stated that the synthesis of calibration standards for the HPLC analysis is expected to be time consuming. ECHA would like to stress that the identification of impurities does not necessarily need to be performed by the use of such calibration standards. Hence, synthesis of all impurities as calibration standards will not be necessary.
Furthermore, the analytical report does not provide details of the protocol followed to translate the results from the chromatographic analysis into concentration values of the constituents present in the sample and of the constituents present in the composition of the registered substance itself.

ECHA therefore concludes that the registration does not include sufficient description of the analytical methods required for the identification of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

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

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In the comments pursuant to Article 50(1), the Registrant agreed with ECHA's draft decision but requested a 12 month timeline instead of the foreseen 3 month timeline. He based this request on the argument that the synthesis of all impurities as calibration standards for the HPLC analysis and potential consideration of alternative analytical methods can be challenging and time consuming. As outlined above, the synthesis of all impurities as calibration standards will not be necessary. Hence the deadline for the submission update has not been changed.

B. Information in the technical dossier related to the manufacture and use(s) of the substance

3. Brief general description of the identified use(s) of the registered substance

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance as specified in Annex VI, Section 3 of the REACH Regulation.

Annex VI, Section 3.5. requires that each Registrant provides a brief general description of the identified use(s) of a registered substance.

The Registrant sought to adapt this standard information requirement by referring to Article 14(4) of the REACH Regulation.

ECHA notes that Article 14 does not allow for an adaptation of the information requirement in Annex VI, section 3.5. Therefore, the Registrant's justification for not providing the information cannot be accepted and the Registrant is requested to provide a brief general description of the identified use(s) of the registered substance and update the technical dossier accordingly. ECHA also notes that the information in the technical dossier and the

Chemical Safety Report must be consistent and that the Registrant should ensure this in updating his registration.

Instructions on how to provide information on identified use(s) of a registered substance can be found in ECHA Guidance on information requirements and chemical safety assessment Part A: Introduction to the Guidance document, section A.2.4.1.2, pp. 18 and 19.

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://echa.europa.eu/appeals/app_procedure_en.asp**. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Jukka Malm
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