EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003177-74-02/F Helsinki, 11 March 2013

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

For diisotridecyl adipate, CAS No 26401-35-4 (EC No 247-660-8), 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 concerning standard information requirements relating to substance identity (Annex VI, section 2.1 and 2.3 of the REACH Regulation) of the registration dossier for diisotridecyl adipate, CAS No 26401-35-4 (EC No 247-660-8) submitted by [redacted] (Registrant).

This decision is based on the registration dossier 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 received after 18 December 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 19 July 2012.

On 23 July 2012 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 16 August ECHA received comments from the Registrant agreeing to ECHA's draft decision. The Registrant indicated in his comments that he would address the information required by ECHA through an updated registration dossier.

On 19 October 2012 the Registrant updated his registration dossier. ECHA considered the Registrant's comments received as well as the updated registration dossier. The comments and the update are reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made. The deadline in Section II was however amended.

On 18 December 2012 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

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. Name or other identifiers for the substance (Annex VI, section 2.1 of the REACH Regulation): sufficient information on the registered substance to enable the substance identity to be determined as specified under point III.1)(a);
   b. Composition of the substance (Annex VI, section 2.3 of the REACH Regulation). Any information which is suitable and necessary to allow ECHA to establish and verify the composition of the registered substance, as specified under point III.1)(b)
   c. The description of the analytical methods (Annex VI section 2.3.7. of the REACH Regulation). 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 specified under point III.1)(c) below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **11 June 2013**.

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. The scope of the present decision covers information requirements relating to substance identity (Section 2 of Annex VI of the REACH Regulation). In accordance with Article 10(a)(ii) of the REACH Regulation, any registration made pursuant to Chapter 1 of Title II of the REACH Regulation shall contain this information.

1) Missing information related to substance identity

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. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Name or other identifiers for the substance (Annex VI, section 2.1)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process. According to ECHA "Guidance for the identification and naming of substances under REACH and CLP" (Version: 1.2, March 2012) UVCB substances cannot be sufficiently identified by their chemical composition and the main identifiers for UVCB substances are related to the source of the substance and the specific manufacturing process used, including final or most relevant steps of the processing. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, additional information on the manufacturing process was provided in the latest updated registration dossier. The Registrant specified in IUCLID section 3.1 that the registered substance is "manufactured by the esterification of >[redacted]% [redacted] [redacted]% [redacted]".
ECHA considers this information not sufficient for the purpose of identifying the registered substance and invites the Registrant to further clarify the starting material used. Indeed, ECHA notes that the compositional information, provided in IUCLID section 1.2, indicates that two different starting materials are involved in the production of the registered substance. More specifically, the two grades included in IUCLID section 1.2 indicate that one starting material consisting of [redacted] 100% is used for manufacturing the first specified grade, named "diisotridecyl adipate", while a second starting material consisting of [redacted] including [redacted], whose variable concentration is inherent to the manufacturing process, is used for manufacturing the second specified grade, named "[redacted]".

In addition, ECHA notes that no details on the manufacturing process were provided in IUCLID section 1.1 and, as indicated in the above paragraph, the description given in IUCLID section 3.1 is still not sufficient, as information on the reactants and their ratio is not sufficiently detailed. Information on the operating parameters (temperature and pressure) is also missing.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, then the detailed description of the manufacturing process shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the processing steps and/or processing parameters are different.

The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

ECHA accordingly requests the Registrant to provide additional details on the manufacturing process, including details on the identity and composition of the starting materials and ratio ([redacted]) vs [redacted]). The origin of the variability in the proportions of the acids used and information on the distribution and type of branching of [redacted] shall be provided. The operating parameters shall be specified as well.

The Registrant shall ensure that the information specified in IUCLID section 1.1 and in the Chemical Safety Report as well as the composition indicated in IUCLID section 1.2 are consistent with the chemical name and EC and CAS identifiers assigned to the registered substance.

Regarding how to report the chemical name and description of the UVCB substance, the information shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively. Further technical details on how to report the identifiers of UVCB substances in IUCLID are available in paragraphs 2.1 of the Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

(b) The composition of the 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 information that is sufficient for establishing the composition of the registered substance, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, ECHA notes that the registration dossier contains two different compositions named "diisotridecyl adipate" and "[redacted]
With regard to the composition "diisotridecyl adipate", ECHA observes that in the latest registration update, the Registrant provided information on the typical concentration of each constituent, whereas concentrations ranges (minimum and maximum values) have not been included in the IUCLID dossier. Moreover, with respect to the composition "[redacted]", the Registrant provided information on the concentration ranges of each constituent, however no information was included on the typical concentration of each constituent.
Therefore, without this information, ECHA cannot conclude on the variations in the composition of the registered substance, which are inherent to the specific process used for its manufacturing.

Therefore, the Registrant is requested to provide any information which is suitable and necessary to allow ECHA to establish and verify the composition of the registered substance. The Registrant shall ensure that information on minimum, maximum and typical concentration values of the constituents present in the substance is specified in the registration dossier. The concentration ranges must be representative for the registered substance as manufactured. The Registrant shall clarify how the minimum and maximum values for each group of constituents were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used etc.). Without this information ECHA is not able to conclude on the representativeness of these values and the identity of the substance covered by the registration cannot be established.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

(c) The description of the analytical methods (Annex VI, section 2.3.7.)

ECHA observes that the Registrant did not provide appropriate 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, as requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided information on the analytical methods used to identify and quantify the generic group of constituents of the composition named "diisotridecyl adipate". However no information was given on the methods used for analyzing the generic group of constituents of the composition named "[redacted]".

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of all the constituents required to be reported in the composition "[redacted]" 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.

However, ECHA underlines that, in the event the variability in the source used ([redacted] in concentration [redacted] (w/w) and [redacted] in variable concentrations) likely leads to the manufacture of two different substances, those should be registered separately.

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

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
Director of Regulatory Affairs