EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114321165-61-01/F Helsinki, 11 March 2016

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

For Amides, C18-unsatd., N-[3-(dimethylamine)propyl], EC No 800-353-8 (CAS No 1379524-06-7), 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 Amides, C18-unsatd., N-[3-(dimethylamine)propyl], EC No 800-353-8 (CAS No 1379524-06-7), submitted by [redacted] Registrant).
The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnesper year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(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 2016.

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 01 June 2015..

ECHA notified the draft decision to the Registrant and invited them to provide comments. ECHA took into account the comments, which were sent within the commenting period, amended the decision deadline (section II.B) and the reasons are reflected in the section III.A.2 below.

On 21 January 2016, 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

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

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:

1. Composition of the substance (Annex VI, Section 2.3.)
2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **19 September 2016** an update of the registration dossier containing the information required by this decision.

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) 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. Composition of the substance (Annex VI, Section 2.3.)

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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 cornerstone of all the REACH obligations. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

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

More specifically, the Registrant provided a group entry for "[redacted]" as the only constituent with a concentration range of [redacted]% w/w. Additionally there are seven impurities listed. However, based on the sum of the minimum concentration of the main constituent "[redacted]" ([redacted]%) and the maximum concentration of each impurity ([redacted]% combined), the composition provided does not account for 100% of the substance registered.

In addition, the composition information indicated in section 1.2 is not in agreement with the analytical information reported in IUCLID section 1.4 where a concentration of >[redacted]% is given for the main constituent "[redacted]". ECHA notes that there is no direct analysis of the main constituent(s) provided but only details of the methods used to determine the residual starting materials in the substance, namely [redacted]. Consequently, it is not clear how the Registrant identified and quantified all of the constituents listed in section 1.2 of the technical dossier.

Therefore ECHA concludes that the information provided on the composition has not been provided to the required level of detail.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: in Section 1.2 of the technical dossier, all identified constituents and impurities, with their typical concentrations and concentration ranges such that it accounts for 100 % of the registered substance. Furthermore the registrant shall include analytical information that verifies the composition in terms of identity and concentration of all the constituents reported in section 1.2 of the technical dossier. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall report the composition in IUCLID Section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.
For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

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 18 on the ECHA website.

2. High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.)

"High-pressure liquid chromatogram, gas chromatogram" is an information requirement as laid down in Annex VI, Section 2.3.6. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

With the exception of the residual [redacted] the Registrant did not provide chromatographic analyses to allow the quantification of the other constituents reported in section 1.2 of the technical dossier. ECHA notes that there is no direct quantification of the main constituent(s) "[redacted]" and neither is there quantification provided for the following impurities "[redacted]".

ECHA therefore concludes that further chromatographic data are required to verify the composition in section 1.2 of the registration dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct chromatographic data as specifically explained above, that identifies and quantifies each constituent reported in section 1.2 of the technical dossier. Furthermore, a description of the chromatographic method(s) shall be included in section 1.4 of the technical dossier. The method description(s) should be in sufficient detail such that it can be reproduced. The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA acknowledges the Registrant's comments to the draft decision and their intended strategy. The Registrant submitted comments in which an extension to the deadline for submitting the information was requested. The Registrant's justification for this request was the following;"*there are actually technical restrictions to perform the HPLC or GC as required. Indeed, using HPLC-MS, all targeted compounds will not respond in the same ionisation mode (an electrospray ionisation in positive mode is necessary for the main substance,* [redacted] *and* [redacted] *detection and quantification. An electrospray ionisation in negative mode is necessary for* [redacted] *detection and quantification.) In addition, HPLC-MS response factors of those differents chemical families (*[redacted]*) are too different for bringing an accurate quantification. Therefore, a gas chromatography coupled with mass spectrometry (GC-MS) method will be developped to characterize the substance and quantify the main substance and residuals (as* [redacted]*). The GC-MS response factors of those different chemical families are not so different. Quantification will be easier and more accurate using GC-MS. However, a complete chromatographic separation method should be developed. Compared to* [redacted] *chains, a derivatisation using silylation agent could be used in order to have an optimised separation method. To conclude, GC-MS seems the most adapted technique versus to liquid chromatography coupled with mass spectrometry (HPLC-MS)."*

ECHA evaluated the justification provided and decided to change the deadline from 3 months to 6 months. ECHA has amended the draft decision 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.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

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