Decision number: CCH-D-2114308423-60-01/F Helsinki, 6 October 2015

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

For C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9, 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 C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the requirements regarding the identification of the substance (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 tonnes per year. This decision does not take into account any updates after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 04 February 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 on 23 September 2013.

On 22 September 2014 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 23 October 2014 ECHA received comments from the Registrant on the draft decision.

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 23 July 2015 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

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. Name or other identifier of the substance (Annex VI, 2.1.);
2. Composition of the substance (Annex VI, 2.3.);

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 **13 January 2016**.

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.

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. Name or other identifier of the substance (Annex VI, 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant identified the registered substance as of a Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substance. However, the composition reported in section 1.2 of the registration dossier and the corresponding analytical data are not consistent with this identification.

In accordance with section 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" hereinafter, it is stated that UVCB substances cannot be sufficiently identified by their chemical composition because the number of constituents is relatively large and/or the composition is, to significant part, unknown and/or the variability of composition is relatively large or poorly predictable. Where the chemical composition of a UVCB substance is known, the substance should rather be identified as a well-defined substance. In accordance with section 4.1 of the Guidance any deviation from the substance identification rules and criteria requires justification.

More specifically, the Registrant reported *C16-18-(even numbered, saturated and unsaturated)-alkylamines* as the chemical name for the registered substance in the IUPAC

name field of the registration dossier. Whilst this chemical name reports, in generic terms, different groups of alkyl amine constituents and corresponds to a UVCB substance, it does not accurately reflect the identity and predominance of the constituents actually listed in the peak table given in the report of chromatographic analysis as reported in section 1.4 of the registration dossier.

According to the chromatographic analysis information attached in section 1.4 of the registration dossier, the constituent [redacted] is present in the substance with a total concentration of [redacted] % (w/w). No other constituents are present with concentration values higher than 10%. This indicates that the substance is of well-defined structure.

Furthermore, the Registrant included the name and numerical identifiers corresponding to the well-defined mono-constituent substance *(Z)-octadec-9-enylamine (CAS number 112-90-3; EC number 204-015-5)* in the Synonyms field of section 1.1 of the registration dossier.

In the absence of a robust justification for identifying the registered substance as a UVCB, ECHA concludes that the name and numerical identifiers reported in section 1.1 are not representative of the substance registered.

Therefore the Registrant is requested to revise the name, molecular formula and other identifiers of the registered substance to refer to a substance of a well-defined composition.

For a well-defined mono-constituent substance, the identity of the registered substance shall be based on the main constituent identified on the basis of the information contained in section 1.2 and 1.4 of the registration dossier. The structural and molecular formulae in section 1.1 of the registration dossier shall be revised to refer to this constituent. In addition, the EC number, name and other identifiers in section 1.1 of the registration dossier shall be revised to refer to this constituent.

If the substance is manufactured such that the composition is highly variable and as a consequence, the substance cannot be identified based on individual constituents, the substance shall be rather identified as UVCB substance (a substance of Unknown or Variable composition, Complex reaction products or Biological materials). Examples of UVCB substances of this kind are outlined in section 4.3.2.1 of the Guidance. However, as outlined above and based on the information contained in the dossier, the Registrant would need to provide supporting documentation as to why the substance registered is better identified as a UVCB rather than a well-defined substance.

Should the substance be identified as a UVCB substance, further information is required to appropriately identify the registered substance in accordance with section 4.3 of the Guidance, section 4.3 specifically refers to UVCB substances. More specifically, the naming of a UVCB substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. Accordingly, the Registrant will need to specify a chemical name of the substance that is representative of the registered substance and to provide details of the process used for the manufacturing the registered substance.

The description of the manufacturing process shall include, as appropriate:

- Information on the identity, and in particular the composition, of the source. In particular, the description shall include information on the exact identity and concentrations of the individual constituents/groups of constituents of the source

that are currently described in the dossier as "[redacted]" and as "[redacted]". Detailed information on the source may not be necessary to allow ECHA to establish the identity of the registered substance if the registrant is able to further clarify the composition of the substance in section 1.2 of the IUCLID dossier (subdivision of the constituents into saturated and unsaturated), as described in section III.2 of this decision.

- Explanation of how the fatty acids used are derived from the indicated sources "[redacted]" and "[redacted]". In addition, clarification on how the use of a synthetic source would lead to a substance including only even number carbon chains; This is, in particular, relevant as the current name refers solely to constituents that have an even number alkyl chain length (C16 and C18). This would not be typical for substances derived from synthetic sources where all carbon lengths, both odd and even are usually present.
- Specification of the manufacturing process parameters (e.g. temperature, pressure, reaction time);
- Details of the reaction mechanisms involved in the first process step; [redacted]. For each catalytic reaction, details of the type of catalyst(s) used in terms of reaction(s) that they catalyse (including detailed information on the selectivity of the catalyst towards the reaction products, reaction mechanisms etc.). The information on how the use of the specific catalyst affects the composition of the registered substance should also be included; Reporting of certain process details may not be necessary to allow ECHA to establish the identity of the registered substance, if the registrant is able to further clarify the composition of the substance in section 1.2 of the IUCLID dossier (subdivision of the constituents into saturated and unsaturated), as described in section III.2 of this decision.
- If a purification step is applied (e.g. distillation), then the relevant process parameters need to be provided (pressure and temperature ranges must be specified in case distillation is applied);
- Furthermore, the Registrant shall provide information on any other relevant process steps and parameters that are required for identifying the substance.

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 required hereinabove 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.

This is particularly relevant as in section 3.1 of the registration dossier the Registrant identified the source used for the manufacturing of the registered substance as "[redacted]". The registrant should clarify how a natural source and synthetic source can result in the same substance based on the fact that the sources are likely to have different compositions.

Regardless of whether the substance is identified as a well-defined substance or a UVCB substance, the Registrant shall note that the CAS entry used in the registration dossier (CAS number 1213789-63-9) can cover substances that contain even numbered alkyl chains and both even and odd alkyl chains. However, the registration dossier can cover only one substance and it shall thus be clearly identifiable for ECHA from the information in the dossier to which substance the registration refers. This information must be consistent throughout the registration dossier.

Regarding how to report the requested information in IUCLID the following applies:

- The revised chemical name shall be included in the IUPAC name field in Section 1.1 of IUCLID.
- Where the substance manufactured is identified as a mono-constituent/multi-constituent substance:
    - the revised molecular and structural formula and other identifiers shall be included in their respective fields in Section 1.1 of IUCLID;
    - the relevant CAS entry (i.e. 112-90-3 or 1838-19-3) shall be included in the "CAS information" field. The current CAS entry (i.e. 1213789-63-9) should be reported under the "Related CAS information" field in IUCLID section 1.1. For technical reasons the Registrant is requested, at this stage, not to revise or remove the list number 627-034-4 which is in the EC number field of the registration dossier. The reason is that the registration is linked to this list number in REACH-IT, the IT system will not accept the updated dossier as an update when the EC/list number is changed. The Registrant shall instead include the following in the "Remarks field" of the reference substance: *"This list entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons"*.
- Where the substance manufactured is best identified as a UVCB substance, the description of the manufacturing process of the UVCB substance shall be included in the Description field in Section 1.1 of IUCLID. Where different grades are manufactured, details of the process parameters for each grade shall be reported in the description field.
- Regarding the name to be reported in section 1.1, the substance will be named based on each constituent, of defined alkyl chain length, present at concentration ≥10% (based on the maximum concentration of the concentration range). For this purpose constituents shall be grouped based on alkyl chain length and separated into saturated linear, saturated branched and unsaturated constituents (e.g. C16 saturated, C16 unsaturated, C18 saturated, C18 unsaturated, etc.). The groups of consituents to be considered for naming shall compose at least 80%(w/w) of the substance.
- The revised name, based on the guidance in the above bullet point, shall be reported in the IUPAC name field in section 1.1 of IUCLID. The appropriate CAS entry shall be included in the "CAS information" field, if available. Where the current CAS entry (CAS number 1213789-63-9) does not identify the registered substance, it should be reported under the "Related CAS information" field in IUCLID section 1.1 . Similarly where the current list number (627-034-4) does not correctly identify the registered substance, it will need to be revised. For technical reasons the Registrant is requested at this stage, not to remove or revise the list entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant shall instead include the following in the "Remarks field" of the reference

substance: "*This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons.*"
- The justification for identification of the registered substance as UVCB, not as well-defined substance, should be provided in the Remarks field in Section 1.1 of IUCLID.

Further information on how to report the chemical name, the molecular and structural formulae, other identifiers and the description of the manufacturing process is available in "Data submission manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

The registrant expressed an intention in his comment on the draft decision to update the registration dossier by end of Q1 2015.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. No update was received by that date. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

2. Composition of the substance (Annex VI, 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 composition reported in section 1.2 of the IUCLID dossier is not described to a sufficient level of detail and does not include appropriate information for the identification of the registered substance.

The Registrant identified the substance as a UVCB substance. According to the Guidance, section 4.3 for UVCB substances the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually; for unsaturated constituents, the Registrant shall furthermore specify the level of unsaturation and the position of the double bond on the alkyl chain if it deems appropriate for the registered susbtance;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually;
- Unknown constituents or group of constituents shall be identified as far as possible by a generic description of their chemical nature. For the substance which is the subject of this registration, a distinction of the constituents according to the carbon number and saturation/unsaturation (saturated and unsaturated alkyl chains) is necessary for this purpose as a baseline.

For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The substance is identified as *C16-18-(even numbered, saturated and unsaturated)-*

alkylamines in section 1.1 of the IUCLID dossier. The compositional information, given in section 1.2 of the IUCLID dossier, includes the constituents reported in the name but with insufficient level of detail. The constituent included in the name as *C16-(saturated and unsaturated)-alkylamine* has been reported under one generic identifier as one constituent with a reported range of [redacted] %. The other constituents included in the name *C18-(saturated and unsaturated)-alkylamine* have been reported under one generic identifier as one constituent with a reported range of [redacted] %. Information included in quantitative analytical data reported in section 1.4 on the specific constituents covered by this entries indicates that:

- *C16-(saturated and unsaturated)-alkylamine* contains [redacted] peaks identified as [redacted] with total concentration of [redacted]%; C16 unsaturated constituents are not identified in the chromatogram;
- *C18-(saturated and unsaturated)-alkylamine* contains [redacted] peaks identified as [redacted] (CAS numbers included in the peak table refer to [redacted]) at total concentration of [redacted]%; C18 saturated constituents are not identified in the chromatogram.

In the absence of sub-division of C16 and C18 alkyl chain lengths into saturated and unsaturated constituents and without information on the typical, minimum and maximum concentration levels for C16 saturated, C16 unsaturated, C18 saturated and C18 unsaturated constituents, ECHA is not able to verify the identity of the registered substance. The Registrant is accordingly requested to revise the compositional information reported in the dossier such that saturated and unsaturated constituets are reported separately and typical, minimum and maximum concentration levels are specified.

Should the registrant, in accordance with the findings in section III.1 above, decide to describe the substance as well-defined, then the identity of (each of) the constituent(s) and impurities/additives, including their minimum, maximum and typical concentration shall be fully specified. In ECHA's understanding this also implies that saturated and unsaturated constituents are reported separately.

Regarding how to report the composition of the registered substance in IUCLID, the following applies:

- The Registrant shall indicate the composition of the registered substance 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.
- Where the Registrant covers different compositions of the same substance in a registration (e.g. due to different sources), the Registrant shall report separately the compositional information from each source. This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

The Registrant should also note that multiple compositions may indicate multiple substances and consequently the requirement for multiple registrations.

Further technical details on how to report the composition in IUCLID are available in paragraphs 2.1, 2.2.1 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: 2.0, July 2012).

The registrant expressed an intention in his comment on the draft decision to update the registration dossier by end of Q1 2015.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 March 2015. No update was received by that date. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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.

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation E1

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