ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114299578-25-01/F Helsinki, 6 May 2015

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

For Sulfonium compounds, C11-14-alkylbis(hydroxyethyl), 2-hydroxyethyl sulfates (salts), CAS No 78169-20-7 (EC No 278-855-6), 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 Sulfonium compounds, C11-14-alkylbis(hydroxyethyl), 2-hydroxyethyl sulfates (salts), CAS No 78169-20-7 (EC No 278-855-6), 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 tonnes per year. This decision does not take into account any updates submitted after 05 March 2015, 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 23 May 2014.

On 22 October 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 26 November 2014 ECHA received comments from the Registrant on the draft decision informing that a dossier update would be submitted within two weeks. The ECHA Secretariat considered the Registrant's comments and waited longer than the period of time the Registrant mentioned as needed to prepare and submit an update to the technical dossier. Considering no update has been received to this date, the ECHA Secretariat is continuing with the decision making procedure without further delay.

On 5 March 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

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

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 **13 August 2015** 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) Name or other identifier of the substance (Annex VI Section 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. 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 such as the registered substance shall consist of two parts: (1) the chemical name and (2) a more detailed description of the manufacturing process (including details on the starting materials), as indicated in chapter 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" thereinafter. ECHA observes that the identifiers of the substance provided by the Registrant in IUCLID section 1.1 are not consistent and that the Registrant did not provide sufficient information on the manufacturing process, as explained thereinafter.

- Identifiers of the substance

ECHA notes that the information provided in the dossier regarding the identifiers of the substance is inconsistent:

- The reported EC and CAS entry refer to "*Sulfonium compounds, C11-14-alkylbis(hydroxyethyl, 2-hydroxyethyl sulfates (salts)*", which indicate the presence of a group of constituents (*Sulfonium compounds, C11-14-alkylbis(hydroxyethyl)* with variable carbon chain (C11-C14) in the composition of the substance;
- The reported IUPAC name (*Reaction product of dodecene-1 with mercaptoethanol, ethyleneoxide and sulfuric acid*) refers to a substance that is manufactured using a specific starting material (dodec-1-ene) and therefore no variability on the carbon chain would be expected for the manufactured substance;
- The analytical results provided in IUCLID section 1.4 report a substance essentially based on *Sulfonium compounds, C12-alkylbis(hydroxyethyl)* and *2-hydroxyethyl*; and
- The description of the manufacturing process, provided in IUCLID section 3.1, reports "[redacted]" as starting material, however, the reported name is ambiguous and because no information on the composition of this starting material is provided it is not possible to verify if its identity is in agreement with any of the identifiers provided to identify the substance.

Therefore, the Registrant is required to clarify the identity of the substance by providing consistent identifiers of the substance, and ensure that the information is consistent throughout the dossier.

More specifically, the Registrant is required to provide a specific name and CAS entry (if available) for the substance actually manufactured or imported. If the EC identifier currently assigned to the registered substance does not fully correspond to the substance actually manufactured or imported (e.g. one of the starting materials is actually [redacted] or the substance composition is based on [redacted]), the Registrant shall not remove or modify at this stage this EC entry for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the EC entry currently assigned does not specifically correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

The Registrant should note that ECHA has established processes, subject to certain conditions, enabling Registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that the EC identifier provided in his dossier should be adapted to cover a different substance or if it actually covers several other substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

As for the reporting of the information in IUCLID, the IUPAC name and any available CAS entry for the registered substance shall be reported in the "IUPAC name" field and under the "CAS information" header of the reference substance in IUCLID section 1.1, respectively.

Should this CAS number be related to the registered substance, it may be reported under the "Related CAS information" header in IUCLID section 1.1. If the EC entry currently assigned does not specifically correspond to the registered substance, the Registrant shall indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 278-855-6 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

The Registrant shall ensure that appropriate and consistent identifiers are used throughout the registration whenever reference to the specific substance which is the subject of this registration is made.

Further technical details on how to report the identifiers of UVCB substances in IUCLID are available in paragraph 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) on the ECHA website.

- Description of the manufacturing process

ECHA notes that a description of the manufacturing process was provided in IUCLID section 3.1. However, the description of the starting materials is not considered sufficiently detailed, because:

- it is missing information on the ratio of the starting materials, and
- it is missing information on the constituents of the starting material "[redacted])" (ratio and identity).

ECHA considers that the composition of the starting materials is one of the factors determining the composition of the registered substance. Information on the name and composition of those starting materials (in terms of identity and upper and lower concentration levels of each individual constituent) is therefore normally necessary for the identification of the registered substance.

Therefore, the Registrant is required to provide information on:

- the ratio of the starting materials used for the manufacturing of the registered substance, and
- the identity and ratio of the constituents of the starting material "[redacted])".

The Registrant shall ensure that the information is consistent throughout the dossier, in particular with the name and other identifiers of the substance.
Where the Registrant covers different grades of the substance in a registration, the Registrant shall report separately the source and manufacturing process of each grade. ECHA highlights that grades for which a manufacturing process description is not provided may eventually not be considered being covered by the registration.

Regarding how to report the description of the UVCB substance, the information shall be included in the Description field in IUCLID section 1.1.

2) Composition of the substance (Annex VI, Section 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 cornerstone 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 one generic reference substance covering most of the constituents of the UVCB substance (Sulfonium compounds, C11-14-alkylbis(hydroxyethyl), 2-hydroxyethyl sulfates (salts)) is reported under constituents and two other constituents are reported under impurities in the IUCLID section 1.2.

According to chapter 4.3 of the Guidance, the Registrant shall note that, for UVCB substances such as the registered substance, due to the complexity of the composition, the terms "main constituents" and "impurities" are not regarded as relevant, and therefore the composition breakdown shall be entirely reported under "constituents". Additionally, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.

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

ECHA notes that the registrant has reported a group of constituents identified as *"Sulfonium compounds, C11-14-alkylbis(hydroxyethyl), 2-hydroxyethyl sulfates (salts)"*. This description however lacks information on the identity of the constituents (different anions and cations combinations) that it is meant to cover.

ECHA acknowledges that it is challenging to report specific pairs of cations and anions as constituents. In such cases, providing a generic reference substance in the information on the compositions can be acceptable. Then, however, the Registrant is expected to provide the necessary level of information to accurately describe the identity of the cations and anions covered by the generic reference substance.

The Registrant is accordingly required to provide more information on the identity of the constituents covered by the generic reference substance *"Sulfonium compounds, C11-14-alkylbis(hydroxyethyl), 2-hydroxyethyl sulfates (salts)"* to have a precise chemical representation of what the generic reference substance consists of (e.g. by reporting the identity and concentration ranges of the different cations and anions that are covered by the generic reference substance in the related description field) .

The Registrant shall ensure that the information is consistent throughout the dossier.

Where the Registrant covers different grades of the substance in a registration based on different constituents, the Registrant shall report separately the compositional information

of each grade. ECHA underlines that the reporting of the composition of different grades less than one generic composition may prevent ECHA from verifying that compositions referring to other substances are not covered by this registration. In addition, ECHA highlights that grades for which an individual composition would not be provided may eventually not be considered being covered by the registration.

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: 2.0, July 2012) on the ECHA website. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of that manual.

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.

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