EUROPEAN CHEMICALS AGENCY

Helsinki, 15 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114347664-43-01/F
Substance name: Octadecanoic acid, sulfonated, potassium salt
List number: 942-903-0
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 12 February 2016
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Identification and quantification of the constituents**

2. **Name(s) in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1.) of the registered substance;**
   - **EC and/or CAS entry, chemical name**
   - **Manufacturing process**

You are required to submit the requested information in an updated registration dossier by **22 March 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirement(s) of Annex VI, Section 2 of the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

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.

Appendix 1: Reasons

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.)

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

ECHA notes that you identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). In that respect, according to chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.4, Jun 2016) – referred to as "the Guidance" thereinafter, you should note that for UVCB substances presenting a large number of constituents, such as the registered substance, the following applies:

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

Furthermore 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, should 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, should be reported in the appropriate fields in IUCLID.

In section 1.2 of the IUCLID dossier you have reported the composition as consisting of [redacted]% of the substance itself, i.e. "[redacted]" but did not provide any information on the identity and concentration levels of the constituents or groups of constituents present in the composition. At the same time, the analytical report, "[redacted]" included in section 1.4 of the IUCLID dossier contains information indicating the presence of several constituents/group of constituents. Among them "[redacted]", for example, were reported with an area % >10%.

Because you did not provide information on the identity and concentration levels of the constituents or groups of constituents present in the composition while at the same time indicating presence of several constituents/group of constituents, you have not reported compositional information to the level of detail required to unambiguously identify the substance and as described by the Guidance as mentioned above.

You are accordingly requested, pursuant to Article 41(1) and (3) of the REACH Regulation, to revise the information on the composition of the registered substance in order to establish a precise chemical representation of what the substance consists of. In particular you shall include all the constituents identified and quantified in the report provided in IUCLID section 1.4.

Regarding how to report the composition in section 1.2 of IUCLID, the following applies:

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 – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

In the comments to the draft decision according to Article 50(1) you have agreed with the requests in the draft decision. In addition, you have indicated your intention to revise IUCLID Section 1.2 and address the requests in an update of the registration by identifing and reporting all the constituents present in the substance with a concentration of ≥ 10 %. ECHA will examine such information only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted. ECHA reminds you also of the above compositional information requirements referring also to constituents other than those present at ≥ 10%.

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

According to Annex VI, Section 2.1. of the REACH Regulation, the naming of UVCB substances shall consist of two parts: (a) the chemical name and (b) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance. Other identifiers, including any CAS number (if available) and EC number (if available and appropriate) corresponding to the substance, shall also be reported.

ECHA notes that you did not provide appropriate and consistent information on the naming and description of the manufacturing process of the substance as explained under points (a) and (b) hereinafter.

(a) Information on the chemical name and numerical identifiers to be submitted

ECHA notes that you have identified your substance with the IUPAC name "Octadecanoic acid, sulfonated, potassium salt". No CAS information was provided for the substance. Instead a CAS entry (67968-63-2) was included in the relative CAS information field. In addition, the name "[redacted]" was used in the "Reference substance name" field and, furthermore, the name "[redacted]" was provided in the "synonyms" field.

According to the analytical information provided in IUCLID Section 1.4, the IUPAC name "Octadecanoic acid, sulfonated, potassium salt" would refer only to a part of the composition of the registered susbtance (i.e. the group of constituents identified as "[redacted]") and therefore this name does not reflect the overall identity of the registered substance. In addition, the identifiers containing the locators "9(or 10)" present certain ambiguities that prevent ECHA from concluding on their correctness in the identification of the registered substance.

As a consequence of the limited compositional information provided in Section 1.2 of the IUCLID dossier, and of the ambiguity of the various names provided in the dossier, ECHA considers that the identifiers used are not representative of the registered substance.

Therefore, you are requested to revise the chemical name assigned to the registered substance. You shall ensure that the chemical name is representative of the specific substance which is the subject of this registration.

You shall revise the IUPAC name currently specified under the relevant headers of the reference substance in Section 1.1 of IUCLID and report instead consistent chemical identifiers corresponding to the registered substance. You 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. The provided analytical data in Section 1.4 of the IUCLID dossier must be in line with the reported chemical identifiers in Section 1.1 of the IUCLID dossier.

(b) A detailed manufacturing process description to be submitted

ECHA observes that the description of the manufacturing process "[redacted]" provided in Section 3.1 of the IUCLID dossier is generic and not sufficiently detailed for the identification of the registered UVCB substance. More explicitly, no information has been specified on the identity of the reactants (i.e. type of fatty acids, sulfonation agent used for the production of the substance), the description of relevant steps and other reagents (i.e. solvents and catalysts), the manufacturing process parameters (i.e. pressure, temperature, etc.) which determine the composition of the registered substance and therefore its identity. The additional information provided in the description of the reference substance in section 1.1 of the IUCLID dossier on the starting material ("[redacted]") does not provide details on the ratio of such fatty acids.

As the abovementioned elements of the manufacturing process are expected to determine the composition of the registered UVCB substance, and given also the very limited information on the composition in the current dossier, ECHA considers that they are necessary for the identification of the registered substance. Without such information, the identity of the substance remains unclear.

You are therefore requested to provide the missing information on the manufacturing process description. This information shall include:

- The identity and ratio of the reactants; in particular, the generic starting materials reported as "[redacted]" shall be clearly identified using a chemical name that accurately reflects their identity. Also the sulfonation agent shall be clearly reported.
- The relevant process steps and parameters such as temperature and pressure, including also the parameters determining the level of sulfonation in the constituents of the manufactured substance.
- Any other relevant steps (i.e. purification) that would determine the composition of the substance.

Please note that 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.

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

You shall ensure that the chemical name, the identifiers and the manufacturing process description to be reported according to Annex VI, Section 2.1 of the REACH Regulation are consistent with each other and with the composition required to be provided according to Annex VI, Section 2.3 of the REACH Regulation.

In the comments to the draft decision according to Article 50(1) you have agreed with the requests in the draft decision. In addition, you have indicated your intention to revise IUCLID Sections 1.1 and 3.1 and address the information requirement in an update of the registration. You have also proposed a new name for the substance. ECHA will examine such information, including the adequacy of the proposed substance name, only after the deadline set in the adopted decision has passed and all the substance information requested in this decision has been submitted.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 10 March 2016.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comments into account and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.