~~Confidential~~

Helsinki, 18 August 2021

Addressees
Registrant listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
28/05/2018

Registered substance subject to this decision
Substance name: N-(2-hydroxyethyl)stearamide
EC number: 203-883-2
CAS number: 111-57-9

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***25 November 2021***.

1. **Name or other identifier of the substance (Annex VI, Section 2.1.);**

   - **EC and/or CAS entry, IUPAC name, description of the manufacturing process**

The reasons of this decision are set out in Appendix A. The procedural history is described in Appendix B.

The scope of this compliance check decision is limited to the standard information requirements of Annex VI, Section 2 of REACH.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[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 A: Reasons for the requests to comply with Annex VI of REACH

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

In accordance with Article 10(a)(ii) of the REACH Regulation, the technical dossier must contain information on the identity of the substance as specified in Annex VI, Section 2 to the REACH Regulation. In accordance with Annex VI, Section 2 the information provided has to be sufficient to enable the identification of the registered substance.

The name and other identifiers required under Annex VI, Section 2.1, are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification. The information requirements listed in Annex VI, section 2.1. include: a name in the IUPAC nomenclature (section 2.1.1.), EINECS or ELINCS number (if available and appropriate) (section 2.1.3), CAS name and CAS number (if available) (section 2.1.4).

You have identified the substance using the EINECS number 203-883-2 and the CAS number 111-57-9. These identifiers correspond to the mono-constituent substance "N-(2-hydroxyethyl)stearamide". The IUPAC name provided and the description of the manufacturing process, reported in IUCLID section 1.2, are consistent with the EINECS and CAS entries.

In IUCLID section 1.1 you have identified your substance as an "Unknown or Variable composition, Complex reaction products or Biological materials" (UVCB) substance and the composition reported in IUCLID section 1.2 and the analytical data reported in IUCLID section 1.4 are consistent with a UVCB type of substance (i.e. "Amides, C16-18 (even-numbered), N-hydroxyethyl", based on the reported composition and supported by the analytical data).

Therefore, the numerical identifiers (EC and CAS entries), the IUPAC name and the description of the manufacturing process (that refer to a substance where C18 (stearamide) is present above [redacted]% w/w in the composition) are inconsistent with the type of substance, composition, and analytical data reported in your dossier (that refer to a UVCB substance with multiple constituents, each with a concentration below [redacted]% w/w).

Therefore, you must revise the information in your dossier in order to provide a correct and consistent identification of the substance you have registered.

You are requested to update the registration dossier as follows:

- Remove the current CAS entry from the "CAS information" header of the reference substance in IUCLID section 1.1 and include the correct CAS entry if available. You can include the current CAS number in the "Related CAS information" field in section 1.1.

- Do not remove or modify the current EC entry (as this registration is linked to the current EC entry in REACH-IT and it cannot be removed at this stage for technical reasons).

- To ensure unambiguous identification of the substance, you must however indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC number 203-883-2 currently assigned does not specifically correspond to the substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons".

- Specify, in the same "Remarks" field, any available and appropriate EC number for the substance.

- Specify in the IUPAC name field, in IUCLID section 1.1, an appropriate name to describe your substance (e.g.“Amides, C16-18 (even-numbered), N-hydroxyethyl”).

- Provide a description of the manufacturing process, in IUCLID section 1.2, consistent with the identity and composition of your substance

You should note that ECHA has established a process, 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.

Pending the resolution of the non-compliances addressed in the present decision, any possible adaptation of the identifier can only become effective once ECHA is in a position to establish unambiguously the identity of the substance intended to be covered by you with this registration.

Should the information submitted by you enable ECHA to identify the substance unambiguously and result in a need to modify the identifier of the substance, ECHA will inform you in due time as to when and how the identifier adaptation process must be initiated.

You can find more information on substance identification and joint submission of data in Appendix 3 of the Guidance on Substance Identification and Naming of Substances under REACH & CLP available on ECHA website at the following link: https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf
Further information on how to report the information in IUCLID6 can be found in the manual “How to prepare registration and PPORD dossiers” available on ECHA website at the following link:
https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf

In your comments to the draft decision, you indicated that you agree with the requests and that you will submit a dossier update in due course.

Appendix B: Procedural history

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 15 December 2020.

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

ECHA took into account your comments and did not amend the requests.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Addressee of this decision

Registrant Name	Registration number
[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.