EUROPEAN CHEMICALS AGENCY

Helsinki, 29 June 2020

Registrant listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
08/10/2018

Registered substance subject to this decision ("the Substance")
Substance name: Sodium 2-(2-dodecyloxyethoxy)ethyl sulphate
EC number: 221-416-0
CAS number: 3088-31-1

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***6 October 2020***.

1. **Spectral data (Annex VI, Section 2.3.5.);**
   - **Nuclear magnetic resonance or mass spectrum**
2. **High-pressure liquid chromatogram, gas chromatogram (Annex VI, Section 2.3.6.);**
3. **Description of the analytical methods (Annex VI, Section 2.3.7.);**
   - **Identification and quantification of the counter-ion**
4. **Name or other identifier of the Substance (Annex VI, Section 2.1.);**
   - **EC and/or CAS entry, Chemical name**

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.

Approved[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 to request information required under Annex VI of REACH

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

1. Spectral data (Annex VI, Section 2.3.5.)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of REACH. Adequate information needs to be present in the technical dossier for the Substance to meet this information requirement.

The registration dossier contains an Ultra-Violet (UV) spectrum and an Infra–Red (IR) spectrum in section 1.4 of your IUCLID dossier. However, the registration dossier does not include a nuclear magnetic resonance (NMR) spectrum or alternatively to this a mass spectrum (MS). A justification for waiving this information requirement is not provided.

Therefore, the information requirement under Annex VI, Section 2.3.5. is not fulfilled and without the missing spectra it is not possible to verify the identity of the Substance. The NMR (or MS) spectrum is crucial to determine the level of ethoxylation of the Substance, in order to confirm that the substance is the mono constituent substance as registered, and not a multi-constituent or a UVCB substance, which, due to the nature – an ethoxy derivative – and the typical manufacturing process of this type of substances, is possible.

You are therefore requested to submit the missing spectral data (NMR, or alternatively to this one, an MS) for the identification of the Substance. In addition, the description of the analytical methods used for recording the spectra must be specified in the dossier in such details to allow the methods to be reproduced in line with the requirements under Annex VI Section 2.3.7 of REACH. The description of the analytical methods must include details of the experimental protocol followed, any calculation made, and the results obtained.
You must also ensure that the provided information is consistent with the information reported in sections 1.1 and 1.2 of the dossier.

The requested spectral data (and relative method descriptions) must be attached in section 1.4 of your IUCLID dossier.

In your comments to the draft decision, you have provided the following spectral data: [redacted]. However, there is no interpretation of these spectra (i.e. peak identification, explanation of which consituent(s) the mass spectra refer to), as requested in the decision above. In addition, as the identity of the substance is still not fully clarified (see other endpoints), the request in the decision remains unchanged.

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 REACH. Adequate information to enable understanding how the constituents, required to be reported in the composition section of the IUCLID dossier, have been identified and quantified needs to be present in the registration dossier to meet this information requirement.

The present dossier contains the description of the chromatographic method used to quantify the Substance together with the corresponding chromatogram. However, the provided chromatogram displays a broad single peak having a retention time starting from ca. 5 min and ending at ca. 12 min.

This overly broad peak shows that the chromatographic method and conditions is not adequate to obtain a sufficient resolution in order to determine the constituent(s) of the Substance and therefore its composition. Consequently, the identity and concentration levels of the constituents as reported in section 1.2 of your dossier cannot be verified, and it is not possible to confirm that the Substance is the mono constituent substance as registered, and not a multi-constituent or a UVCB substance, which, due to the nature – an ethoxy derivative – and the typical manufacturing process of this type of substances, could be possible.

You are accordingly requested to provide the results of chromatographic analysis which can confirm the identity and purity of the Substance. For the resolution to be considered sufficient, appropriate chromatographic method conditions (including among other a suitable column, the correct injected amount of sample) should be used. In addition to the chromatogram, you are requested to provide a peak table including peak identification, retention times, peak area and area percentage corresponding to the chromatographic analysis used to verify the composition of the Substance as reported in section 1.2. In addition, the description of the analytical methods used for recording the chromatography must be specified in the dossier in sufficient detail to allow the methods to be reproduced in line with the requirements under Annex VI Section 2.3.7 of REACH.

You must ensure that the composition reported in section 1.2 of the dossier is consistent with the analytical results reported in section 1.4. If based on the new analytical data you conclude that the Substance is not a mono constituent substance, the identifiers of the Substance must be revised as outlined in section 4. of this decision.

The requested chromatographic data (and relative method descriptions) must be attached in section 1.4 of your IUCLID dossier.

In your comments to the draft decision, you have provided the requested results of chromatographic analysis including a peak table. The provided chromatographic analysis does indicate that your substance comprises of multiple constituents, and therefore it is not a mono-constituent substance. The identity of the peaks have been reported in a separet a separate document where you state: "[redacted]"
However, it is not clear how these constituents have been identified. The identification of the peaks is not even supported by the provided manufacturing process, as the process does not explain how these specific consituents with the reported concentration ranges would be produced (see section 4 of the decision). Consequently, the identity of the constituents and the identity of the substance cannot be confirmed with these data. Therefore, the request in the decision remains unchanged.

3. Description of the analytical methods (Annex VI, Section 2.3.7.)

According to Annex VI, section 2.3.7 of REACH, a registration dossier must report a description of the analytical methods or the appropriate bibliographic references for the

identification of the substance and where appropriate for the identification of impurities and additives. The reporting must be given in sufficient detail to allow the methods to be reproduced.

You have identified the Substance as "Sodium 2-(2-dodecyloxyethoxy)ethyl sulphate", which indicates that sodium counter-ions are present in the Substance. However, you have not reported the description of the method(s) used to identify and quantify the sodium counter-ions.

The missing information on how you identified and quantified the sodium counter-ion in the Substance mass balance is necessary for the verification of the substance identity information reported in sections 1.1 and 1.2 of your dossier.

Consequently, you are requested to report the description of the method(s) used to identify and quantify the sodium counter-ion present in the Substance. The description of the method(s) must be given in such detail that the method(s) may be reproduced and must include details of the experimental protocol, any calculations made and the results obtained. The information must be sufficient to enable the verification of the identity of the Substance as reported in your dossier.

The requested information must be attached in section 1.4 of your IUCLID dossier.

In your comments to the draft decision, you have provided the results for quantification of sodium present in your substance. While the provided analytical results do in principle meet the request outlined in this decision, there are other issues related to the substance identity. ECHA is not in a position to confirm that the provided analysis is fully consistent with the other provided information. Therefore, the request in the decision remains unchanged.

4. Name or other identifier of the Substance (Annex VI, Section 2.1.)

Annex VI, section 2.1 of REACH requires that the registration contains the name or other identifier of the registered substance, including the appropriate European Community (EC) name and number if available.

You have identified the Substance with EC number 221-416-0 and the corresponding EC name "sodium 2-(2-dodecyloxyethoxy)ethyl sulphate". As explained in section 1 and 2 and 3 above, the analytical information which you have attached in IUCLID section 1.4 does not allow the verification of the identity of the Substance. More specifically, it is not possible to verify if the Substance is the mono-constituent substance corresponding to the identifiers above, or if it is a more complex substance, i.e. a multi-constituent or a UVCB substance, which which, due to the nature – an ethoxy derivative – and the typical manufacturing process of this type of substances, is possible.

As outlined in the sections 1. and 2. above, the analytical data provided are not sufficient to confirm the identity and the composition of the Substance and additional analytical data are requested.
If the analytical results can confirm that the Substance is the mono-constituent identified with EC number 221-416-0, no revision of section 1.1 of the IUCLID dossier is needed.

On the other hand, if the analytical results shows that the Substance is not a mono-constituent substance, but a more complex one (multi-constituent or UVCB substance), then

the current identifiers are not appropriate for the Substance and section 1.1 of the IUCLID dossier must be updated accordingly.

Therefore, if the current identifiers are not appropriate to describe the Substance the following actions must be done:

- Remove the current CAS entry from the CAS information associated with the Substance. The current CAS entry may however be quoted in the dossier as related CAS information.

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

- 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 221-416-0 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. Any available CAS entry for the Substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

- Specify the appropriate chemical name in the "IUPAC name" field in IUCLID section 1.1.

- In case the Substance is a UVCB substance, you will need to provide the description of the manufacturing process in IUCLID section 1.2

You should note that ECHA has established a process, subject to certain conditions, that enables 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.

In any case, you should note that the application of the process of adapting the identifier does not affect your obligation to fulfil the requirements specified in this decision.

As for the reporting of the information in IUCLID:

- The chemical name must be specified in the "IUPAC name" field in IUCLID section 1.1.
- Any available CAS information must be reported under the CAS information header of the reference substance in IUCLID section 1.1. The CAS entry with

CAS number 8007-24-7 can be reported under the "Other identifiers" field in section 1.1 of the IUCLID dossier.
- The manufacturing process description must be reported in the "Description of composition" field in section 1.2 of the IUCLID dossier

In your comments to the draft decision you agreed to consider your substance as a UVCB substance and to identify it as "[redacted]). ECHA acknowledges your intention to change the chemical identifiers.
However, prior to this, you should ensure that in your dossier update you are able to provide sufficient information which allows ECHA to confirm the identity of the substance. ECHA notes that based on the CAS numbers of the consituents identified in the GC analysis (see section 3 of this decision), your substance includes [redacted]. However, based on the provided numerical identifiers no constituents with [redacted] are present in your substance composition, whereas constituents with [redacted] (and higher) would be present. Based on the provided manufacturing process, it is not clear how a composition where constituents with [redacted] are not present when consituents with no [redacted] and constituents with [redacted] (or higher) can be obtained. Therefore, further information on the identity of the constituents present in your substance composition is needed. In addition, further information on the manufaturing process description, such as the ratio of the starting materials ([redacted], etc.) would be relevant as it influences the formed constituents. Therefore, this information should be included in the description of the manufacturing process.
Consequently, as the identity of the substance is still not fully clarified (see also other endpoints), the request in the decision remains unchanged.

Once the substance identity is clarified, and the IUCLID sections 1.1, 1.2 and 1.4 are updated and are consistent to each other, ECHA will inform you when and how the identifier adaptation process can be initiated.

Appendix B: 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 REACH.

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

The compliance check was initiated on 24 July 2019.

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 whereas ECHA will send the decision to the actual registrant.