EUROPEAN CHEMICALS AGENCY

Helsinki, 27 May 2020

Addressees
Registrants of JS_SLI_7381-01-3 listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision
16 February 2015

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Sodium 2-sulphonatoethyl laurate
EC number: 230-949-8
CAS number: 7381-01-3

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

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***4 December 2023***.

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method EU B.13/14. / OECD TG 471) with the Substance

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method EU C.2./OECD TG 202) with the Substance

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201) with the Substance

4. Ready biodegradation (Annex VII, Section 9.2.1.1.; test method OECD TG 301B/C/D/F or OECD TG 310) with the Substance

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) with the Substance

2. Only if a negative result in [Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.] is obtained,]In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490) with the Substance

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203) with the Substance

4. Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method OECD TG 209) with the Substance

5. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1., test method: OECD TG 111) with the Substance

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method EU C.20./OECD TG 211) with the Substance

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance

5. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method EU C.24./OECD TG 308) at a temperature of 12 °C with the Substance

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method OECD TG 305) with the Substance

D. Requirements applicable to all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method OECD TG 414) in a second species (rat or rabbit), oral route with the Substance

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.; test design: OECD TG 218 or OECD TG 225 or OECD TG 233) with the Substance

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.
To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach

for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

The studies relating to biodegradation and bioaccumulation (requests A.4 and C.5 to C.7) are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in section Strategy for the PBT/vPvB assessment of Appendix E.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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, has to 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.

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 on general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the following standard information requirements listed below by applying read-across approaches in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

ECHA has considered the scientific and regulatory validity of your read-across approaches in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have provided a read-across justification document as an annex to your CSR entitled [redacted]

A. Predictions for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties: "
"The Isethionate substances have similar structures and functional groups, and toxicokinetic data of Dodecanoic acid, 2-sulfoethyl ester, sodium salt show that breaking of the isethionate/laurate ester bond and oxidation of the resultant lauric acid is the major route of metabolism. The other product produced by hydrolysis of the ester bond would be sodium isethionate. Since no systemic toxicity is expected from the fatty acid part, read across is justified to the sodium isethionate and related fatty acid isethionates.
For topical effects decreasing fatty acid chain length is expected to result in increased irritancy; read-across from Fatty acids, coco, 2-sulfoethyl esters, sodium salts CAS 61789-32-0 is justified based upon the relative proportions of the lower molecular weight species present in the two substances."

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The toxicological properties of your Substance are predicted to be quantitatively equal to those of the source substance. Furthermore, you argue that the target and the source substances have similar bio-transformation products.

You intend to predict the properties of the Substance from information obtained from the following substances defined by you as:

Isethionate source chemicals

1. Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl isethionate (SCI) (EC no. 263-052-5 / CAS no. 61789-32-0) for:
   - In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.); [redacted] (1991),
   - In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.); [redacted] (2008) and [redacted] (1991).,
   - In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.); [redacted] (2007).
   - Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.); [redacted] (1995)

2. Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ MILLED SLI (76)/SLI (76) stripped/- for (EC no. 287-024-7 / CAS no. 85408-62-4) for:
   - Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.); [redacted] (2008).
   - Pre-natal developmental toxicity study (Annex IX, Section 8.7.2); [redacted] (2008).

Breakdown product source chemical

3. Sodium isethionate (EC no. 216-343-6/CAS 1562-00-1) for:
   - Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.); [redacted] (2009)

Concerning the predictions of toxicological properties based on the source substances identified above, ECHA notes the following shortcomings:

1) Read-across hypothesis contradicted by existing data

As indicated above, your read-across hypothesis is based on the similar, rapid (bio)transformation of the Substance and of the isethionate source substances to a common compound (i.e. sodium isethionate used in your read-across as a breakdown product source chemical). In this context, information characterising the rate and extent of the hydrolysis of the Substance and of the source substances needs to confirm the similar and rapid formation of the proposed common hydrolysis product and to demonstrate that the impact of the exposure to the parent compounds is negligible.

In that respect you explain that based on the data obtained with Dodecanoic acid, 2-sulfoethyl ester, sodium salt, which is the main constituent of the Substance and one the main constituents of the isethionate source chemicals, "*breaking of the isethionate/laurate ester bond and oxidation of the resultant lauric acid is the major route of metabolism. The other product produced by hydrolysis of the ester bond would be sodium isethionate. Since no systemic toxicity is expected from the fatty acid part, read across is justified to the sodium isethionate and related fatty acid isethionates.* "

You have provided a hydrolysis study in artificial fluids (i.e. simulated gastric fluid, simulated intestinal fluid & porcine liver esterase) with ^{14}C radiolabelled sodium lauryl isethionate (SLI) and sodium stearyl isethionate (SSI). You report that after 6 hours:

(i) SLI and SSI showed respectively 30% and 40% degradation in gastric fluid,
(ii) SLI showed 10% degradation while SSI was stable in intestinal fluid, and
(iii) SLI was almost completely degraded in porcine liver esterase while SSI only showed 20% degradation

However, the data you submitted does not support your claim that the Substance and source substances undergo the same, rapid biotransformations *in vivo*. The data rather show that there is significant exposure to the parent substance and that the two source substances used in these studies have different degradation behaviour in similar artificial fluids. This contradicts your read-across hypothesis that the target and source substances undergo the same, rapid biotransformations in vivo. Therefore, you have not demonstrated and justified that the properties of the source substances and of the Substance are likely to be similar despite the observation of these differences.

2) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substances is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substances.

However, your dossier does not contain any toxicology data on the Substance for any health endpoint.

Therefore, a direct comparison of the toxicological potency of the Substance and source substances for the endpoints under consideration is not possible. In the absence of such information, you cannot establish that the Substance and the source substances are likely to have similar properties. Consequently, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

B. Predictions for ecotoxicological properties

i. Aquatic toxicity

You have provided the following reasoning for the prediction of aquatic toxicity: "*The toxicity to aquatic organisms is expected to increase with increasing alkyl chain length, which is also substantiated by modelling with ECOSAR 1.00 (US EPA)*". You provide a table showing the results of ECOSAR predictions (based on predicted log Kow) for short-term toxicity to aquatic invertebrates and fish and for growth inhibition to algae for fatty ester sulfonates ranging from C8 to C18 which you consider supportive of your hypothesis. You further state that "*aquatic toxicity data for* [SLI and SCI] *have been used for read across. The robustness of the prediction is demonstrated in the figure below, where the measured 48 hour logEC50 values for sodium octanoyl isethionate and sodium decanoyl isethionate are correlated with the predicted logEC50 values derived from the EU TGD polar narcosis QSAR*". You consider that the log-log relationship between Kow and toxicity is linear from C8 to C18.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on an identified trend within the group.

You intend to predict the properties of the Substance from information obtained from the following source substances:

1. Fatty acids, coco, 2-sulfoethyl esters, sodium salts / Sodium Cocoyl isethionate / DEFI (EC no. 263-052-5 / CAS no. 61789-32-0) for:
   - Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.); [redacted] (1984) and (2003) and [redacted] (2008)
   - Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.); [redacted] (1985)
   - Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.); [redacted] (1984) and [redacted] (1986)
   - Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4.); [redacted] (1994)

2. Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ SLI (76) stripped (EC no. 287-024-7 / CAS no. 85408-62-4) for:
   - Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.); [redacted] (2008)
   - Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.); [redacted] (2010)
   - Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.); [redacted] (2009);

ECHA notes the following shortcoming with regards to prediction of aquatic toxicity:

1) Characterisation of the source substances

Annex XI, Section 1.5 of the REACH Regulation provides that *"substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."*

According to the ECHA Guidance, *"the purity and impurity profiles of the substance and the structural analogue need to be assessed"*, and *"the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded"*. The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[2] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, whenever the Substance and/or the source substances are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the category members needs to be provided; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable (ECHA Guidance R.6, Section R.6.2.5.5).

You have not provided information on purity and/or quantitative information on the C-chain length distribution of the test material used to conduct the following studies:
- Short-term toxicity testing on aquatic invertebrates by [redacted] (1984; 2003)
- Short-term toxicity testing on fish by [redacted] (1986)

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1

- Activated Sludge respiration inhibition testing by [redacted] (1994)

Without adequate compositional information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substance can be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

2) Adequacy and reliability of source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

You have provided the following studies in your technical dossier:

- Short-term toxicity studies on aquatic invertebrates by [redacted] (1984; 2003)and [redacted] (2008)
- Growth inhibition study to algae and cyanobacteria by [redacted] (1984) and [redacted] (2008)
- Short term toxicity testing to fish by [redacted] (1984; 1986)
- Long-term toxicity testing on aquatic invertebrates by [redacted] (2010)

None of these studies provides adequate coverage of the key parameters expected to be investigated in studies performed according to the corresponding OECD TG. This is explained further below under the corresponding endpoint sections.

3) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that fatty ester sulfonates ranging from C8 to C18 follow a trend for the prediction of the properties under consideration. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm a conservative prediction of the properties of the Substance from the data on the source substance(s). Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

To support your read-across hypothesis you have provided, in Section 3.0 of Appendix A and in Appendix A.3 of your CSR, a plot relating predicted Log Kow values using ClogP (EPI Suite) and acute toxicity to *Daphnia magna* using the EU TGD polar narcosis QSAR. You also report experimental acute toxicity data on *Daphnia magna* for Sodium octanoyl isethionate (i.e. C8) and Sodium decanoyl isethionate (i.e. C10). You conclude that these experimental evidences support the reliability of the modeling approach and consider that the log-log relationship between log Kow and *Daphnia magna* EC_{50} shows a linear negative trend for compounds ranging from C8 to C18 in the homologous series. You state that "*surfactant toxicity normally increases logarithmically with increase in chain length of the hydrophobic tail*" and that "*the measured toxicity of a commercial surfactant, therefore, may be driven predominately by a limited number of the more hydrophobic homologues* [...]".

As explained above our read-across hypothesis rely on predictions from the ClogP (EPI Suite) and EU TGD polar narcosis QSARs. As specified in Annex XI, Section 1.3. the use of QSARs require that the following conditions are met:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model; and
3. adequate and reliable documentation of the applied method is provided.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model and to verify that the Substance falls within the applicability domain of the model.

You have not provided sufficient documentation for the QSAR prediction. In particular, you have not included:

- a QMRF and/or a QPRF in your technical dossier supporting that fatty ester sulfonates ranging from C8 to C18 fall in the applicability domains of the selected QSARs and that the predictions are reliable;
- adequate supporting information to demonstrate that the relationship between log Kow and acute toxicity to aquatic invertebrates is linear for substances ranging from C8 to C18 as you have only provided experimental data from homologues ranging from C8 to C10 to validate your predictions. While the hypothesis that there may be a trend of increasing acute aquatic toxicity with increasing chain length is plausible, it may also be expected that there is a cut-off value in terms of hydrophobicity where no aquatic toxicity is seen due to decreasing water solubility. Therefore, the relationship may not be monotonous;
- any information that similar trends can be expected for the other aquatic toxicity endpoints covered by your read-across adaptations.

In the absence of this information, ECHA cannot establish whether your hypothesis is supported by scientifically valid predictions. Whilst this information may constitute relevant information in support of the read-across approach, considering the complexity of the endpoints under consideration these QSAR predictions cannot be seen, on their own, as evidence of a regular trend in the properties of these constituents. The data set reported in the technical dossier does not include relevant, reliable and adequate information on the properties under consideration for your Substance and the source substances, e.g. bridging studies of comparable design and duration. In the absence of such information, you have not established that the Substance and of the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

ii. Biodegradation

You have not provided any reasoning for the prediction of biodegradation and you only state that the Substance, SCI and SI are "*all three* [...] *readily biodegradable*".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have similar properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts / Sodium Cocoyl isethionate/ DEFI (EC no. 263-052-5 / CAS no. 61789-32-0), which is used as a source substance for ready biodegradability (Annex VII, Section 9.2.1.1.); [redacted] (1994), [redacted] (1983) and [redacted] (1983).

You also intend to predict the properties of the Substance from information obtained from Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ SLI (76) stripped (EC no. 287-024-7 / CAS no. 85408-62-4), which is used as a source substance for Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2); [redacted] (2010).

ECHA notes the following shortcoming with regards to your prediction on biodegradation:

1) Characterisation of the source substances

Annex XI, Section 1.5 of the REACH Regulation provides that *"substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."*

According to the ECHA Guidance, *"the purity and impurity profiles of the substance and the structural analogue need to be assessed"*, and *"the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded"*. The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[3] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, whenever the Substance and/or the source substances are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the category members needs to be provided; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable (ECHA Guidance R.6, Section R.6.2.5.5).

You have not provided information on purity and/or quantitative information on the C-chain length distribution of the test material used to conduct the following studies:

- Ready biodegradability (Annex VII, Section 9.2.1.1.) by [redacted] (1983).

Without adequate compositional information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substance can be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

2) Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

However, none of the studies provided on ready biodegradability was not performed according to the testing specifications set out in the corresponding OECD TG. The specific reasons are explained further below under the information requirement for ready biodegradability.

3) Missing supporting information to compare properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances have similar fate properties. In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary. Such information can be obtained, for example, from

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1

bridging studies of comparable design and duration for the Substance and of the source substance(s).

In your technical dossier you have provided ready biodegradability studies on Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl isethionate (EC no. 263-052-5 / CAS no. 61789-32-0). You have not provided any ready biodegradability study on the Substance.

However, as already explained under issue 1) above, you have not provided any reliable studies on the selected source substance. In addition, your dossier does not include any relevant information on ready biodegradability for the Substance. Therefore, the data set reported in the technical dossier does not include such relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

C. Conclusions on the read-across approach

As explained above, you have not yet established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

In your comments on the draft decision you consider that it is possible to significantly improve the read-across justification and documentation. You also state that "*new data may be generated on the substance and/or source substances to either add weight to the read across hypothesis (bridging studies) or addresses outstanding issues with existing study design or reporting*". Finally you note that in some cases, "*additional data from studies not requested (including New Approach Methods (NAMs)) may be provided if they add to the WoE for a particular endpoint*".

ECHA acknowledges your intention to improve the read-across justification and documentation taking into account the issues raised in the decision. You are encouraged to refer to ECHA Read-across assessment framework (RAAF, March 2017)[7].

(ii) Strategy for aquatic testing

Due to lack of reliable acute aquatic toxicity data on invertebrates or on fish it is not possible to determine the sensitivity of species. Therefore, the Integrated testing strategy (ITS) outlined in ECHA Guidance, Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable and the long-term studies on both invertebrates and fish are requested.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

An *In vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1991) corresponding to an *in vitro* gene mutation study in bacteria performed according to OECD TG 471 with SCI with EC no. 263-052-5

For the reasons detailed in the General considerations section the read-across approach to SCI is rejected.

Therefore the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2003) corresponding to a short-term toxicity study on aquatic invertebrates performed according to OECD TG 202 with Fatty acids, coco, 2-sulfoethyl esters, sodium salts/SCI (EC no. 263-052-5);
(ii) a key study by [redacted] (2008) corresponding to a short-term toxicity study on aquatic invertebrates performed according to OECD TG 202 with Fatty acids, coco, 2-sulfoethyl esters, sodium salts/SCI (EC no. 263-052-5);
(iii) a supporting study by [redacted] (1984) corresponding to a short-term toxicity study on aquatic invertebrates performed similar to OECD TG 202 with Fatty acids, coco, 2-sulfoethyl esters, sodium salts/SCI (EC no. 263-052-5).

You have also adapted this information requirement according to Annex XI, Section 1.3. of the REACH Regulation and you have provided:

(iv) a QSAR prediction using the polar narcotic model described in EU TGD; [redacted], 2013
(v) a short-term toxicity study on aquatic invertebrates performed according to OECD TG 202 with octanoyl isethionate used to support the reliability of the prediction; [redacted], 2013
(vi) a short-term toxicity study on aquatic invertebrates performed according to OECD TG 202 with decanoyl isethionate used to support the reliability of the prediction; [redacted]

[redacted], 2013

ECHA has evaluated the provided information according to Annex XI, Section 1.2.
We have assessed the information from your dossier and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 202 require(s) that the following conditions are met (among others):
   - a clear description of the test material, including impurities;
   - fulfilment of the validity criteria of the test guideline (i.e. < 10% immobilisation or showing any signs of disease or stress by the end of the test in the control);
   - adequate information is available on test organisms including their life stage;
   - adequate information on the test medium composition and preparation is available;
   - analytical monitoring of exposure concentrations is available;
   - a description of the analytical monitoring method (e.g. calibration, recovery and sensitivity determination) and of the preparation of the test samples for analysis is provided;
   - the effect concentrations must be based on measured values rather than nominal values unless the test concentrations are maintained within 20% of the nominal concentrations throughout testing.

   For study (i) and (iii) above, you have not provided any monitoring of test concentrations throughout testing. No information is available on the life stage of the organisms used to conduct the test. You have not provided adequate information on the composition of the test medium including the nature of the medium (fully mineral or natural water), the concentration in DOC and in suspended solids.
   For study (ii) above, you have not reported information C-chain length distribution of the test material. You report that an analytical monitoring of exposure was conducted "*using the small scale MBAS method (Methylene Blue Spectraphotometric method)*". You have not reported any performance parameters for the analytical monitoring method including the limit of quantification and a justification that the method allows a specific quantification of the non-hydrolysed form of the test substance.

   Based on the above, none of the studies used to support your read-across adaptation (i.e. studies (i) to (iii)) meets the conditions listed above and therefore these studies do not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 202 study.

B. For the reasons detailed in the General considerations section your read-across and QSAR adaptations are rejected.

Therefore the information requirement is not fulfilled.

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) A key study by [redacted] (2008), corresponding to a growth inhibition study to algae and cyanobacteria performed according to OECD TG 201 with the source substance

Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ SLI (76) stripped (EC no. 287-024-7);

(ii) A supporting study from [redacted] (1985), corresponding to a growth inhibition study to algae and cyanobacteria performed according to OECD TG 201 with the source substance called Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ DEFI (EC no. 263-052-5).

A. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 201 require(s) that the following conditions are met (among others):
   - an adequate description of the test material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the distribution of the c-chain length for the active substance) is provided,
   - the algal biomass in each flask is determined at least daily during the test period and the biomass for each flask at each measuring point must be reported (along with the method for measuring biomass).

   For study (i) above, you have not reported information on the purity of the test material, the distribution of the C-chain length of constituents or the presence of co-solvent (if any). You have provided biomass data at 0h, 48h and 72h. However, you have not provided biomass data at 24h.

   For study (ii) above, you have not reported information on the purity of the test material, the distribution of the C-chain length of constituents or the presence of co-solvent (if any). You report that an analytical monitoring of exposure concentrations was conducted but you have not specified the method used and you have not reported any performance parameters for the analytical monitoring method including the limit of quantification and a justification that the method allows a specific quantification of the non-hydrolysed form of the test substance. You indicate that a vehicle was used but the chemical identity is not specified. You have not provided the algal biomass data in for each flask at each measuring point.

   Based on the above, none of the studies reported in your technical dossier meets the conditions listed above and therefore these studies do not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 201 study.

B. For the reasons detailed in the General considerations section the read-across approach to Fatty acids, coco, 2-sulfoethyl esters, sodium salts and [redacted], sodium salts is rejected.

Therefore the information requirement is not fulfilled.

4. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Ready biodegradability is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (1994) corresponding to ready biodegradability study performed according to OECD TG 301E with the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl Isethionate (EC no. 263-052-5);

(ii) a supporting study by [redacted] (1983) corresponding to ready biodegradability study performed according to OECD TG 301B with the source substance Fatty acids, coco,

2-sulfoethyl esters, sodium salts/ Sodium Cocoyl Isethionate (EC no. 263-052-5);

(iii) a supporting study by [redacted] (1983) corresponding to a ready biodegradability performed according to OECD TG 301B with the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl Isethionate (EC no. 263-052-5).

A. Appropriate test guidelines are selected based on the applicability domain of the test guidelines and properties of the substance (ECHA Guidance Chapter R.7b, Section 7.9. and OECD TG 301 and OECD TG 310). For highly adsorptive substances the test guideline OECD TG 301E is not considered applicable unless an abiotic control is included in the study.

Your key study (i) was performed as per OECD 301E method. The Substance has a high adsorption potential as it is a surfactant. Therefore estimating biodegradation based on DOC removal is not valid.

B. according to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). OECD TG 301B requires that all the following conditions are met (among others):

- adequate information need to be provided on the identity of the tests material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the distribution of the C-chain length for the active substance,
- the calculation of the $ThCO_2$ needs to be provided,
- data on inorganic carbon (IC) content of the test substance suspension in the mineral medium need to be provided,
- data on the inoculum concentration used to conduct the test need to be provided (in mg/L SS and in approx. cells/L),
- the source of the inoculum and any adaptation to the test substance must be described,
- CO_2 production data in tabular form must be provided.

For study (ii) above, you have not provided a description of the C-chain length distribution of the test material. You have not reported how the $ThCO_2$ was calculated. You have not reported data on inorganic carbon (IC) content of the test substance suspension in the mineral medium. You describe the inoculum as *"sewage microorganisms"* but you have not specified the source of the inoculum and whether or not it was adapted to the test substance. You have not specified the incolcum density at the start of the test period. You have not provided a detailed reporting of the CO_2 production data in tabular form.

Therefore study (ii) is not appropriate to conclude on the ready biodegradability of the selected source substance.

C. Tests on substances must be conducted in accordance with the OECD test guidelines or other internationally recognised test method (Article 13(3) of REACH). OECD TG 301 specifies that degradation must be followed by the determination of parameters such as DOC, CO2 production and oxygen uptake.

In study (iii) above, the parameter monitored is the disapperance of the test substance as measured using the Methylene Blue Anionic Surface active spectrophotometry (MBAS). Therefore it does not provide a measure of the mineralization of the test substance.

Therefore study (iii) is not appropriate to conclude on the ready biodegradability of the selected source substance.

D. For the reasons detailed in the General considerations section the read-across approach to Fatty acids, coco, 2-sulfoethyl esters, sodium salts is rejected.

Therefore the information requirement is not fulfilled.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

i. a key study by [redacted] (1991) corresponding to an *in vitro* mammalian chromosome aberration test performed similar to OECD TG 473 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)
ii. a key study by [redacted] (2008) corresponding to an *in vitro* mammalian cell micronucleus test performed according to OECD TG 487 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)

For the reasons detailed in the General considerations section on the read-across approach to Sodium Cocoyl Isethionate is rejected.

Therefore the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

2. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, in vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2007) corresponding to an *in vitro* mammalian cell gene mutation assay performed similar to OECD TG 476 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5)

For the reasons detailed in the General considerations section on the read-across approach to Sodium Cocoyl Isethionate is rejected.

Therefore the information requirement is not fulfilled.

Your dossier contains no data for *in vitro* gene mutation study in bacteria and for *in vitro* cytogenicity study in mammalian cells.

The result of the requests for information A.1 and B.1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

Study design

To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. and you have provided in your dossier:

(i) a key study by [redacted] (1984) corresponding to a short-term toxicity to fish study performed similar to OECD TG 203 with the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl Isethionate (EC no. 263-052-5);

(ii) a supporting study by [redacted] (1986) corresponding to a short term toxicity testing to Fish performed according to OECD TG 203 with the source substance Fatty acids, coco, 2-sulfoethyl esters, sodium salts/ Sodium Cocoyl Isethionate (EC no. 263-052-5).

We have assessed this information and identified the following issues:

A. Tests on substances must be conducted in accordance with the OECD test guidelines or another internationally recognised international test method (Article 13(3) of REACH). OECD TG 203 requires that all the following conditions are met (among others):
   - an adequate description of the test material including purity, the presence (or not) of any co-formulant, the relative abundance of unreacted material(s), the distribution of the C-chain length for the active substance) is provided,
   - an analytical monitoring of exposure concentrations is provided (including method description and results),
   - an adequate description of the test medium is provided (including pH, hardness, Ca/Mg ratio, Na/K ratio, alkalinity, conductivity, DOC and suspended solid content),
   - the spacing factor between test concentrations should not exceed 2.2.

   For study (i) above, you have not reported information on the distribution of the C-chain length of constituents. You report that the free fatty acid content of the test material is 21% while the boundary composition of the substance for Coco fatty acid

is < 15%. Therefore the test material does not fit the Substance Identity Profile (SIP) of the Substance. You report that an analytical monitoring of exposure was conducted "*using the small scale MBAS method (Methylene Blue Spectraphotometric method)*". You have not reported any performance parameters for the analytical monitoring method including the limit of quantification and a justification that the method allows a specific quantification of the non-hydrolysed form of the test substance. You define the test medium as "[redacted]" but you have not provided information on the content in particulate matter, TOC and COD.

For study (ii) above, you have not reported information on the distribution of the C-chain length of constituents and on the purity of the substance. You report that no analytical monitoring of exposure concentrations was conducted. The spacing factor between test concentrations was above 2.2. Finally no information on the composition of the test medium is available.

Based on the above none of the studies reported in your technical dossier meets the conditions listed above and therefore these studies do not provide an adequate coverage of the key parameters foreseen to be investigated in an OECD TG 203 study.

For the reasons detailed in the General considerations section the read-across approach to Fatty acids, coco, 2-sulfoethyl esters, sodium salts is rejected.

Therefore the information requirement is not fulfilled.

4. Activated Sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

Activated sludge respiration inhibition testing is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study from [redacted] (1994) corresponding to an activated sludge respiration inhibition study performed according to OECD TG 209 with the source substance Sodium Cocoyl Isethionate (EC no. 263-052-5),

For the reasons detailed in the General considerations section the read-across approach to Fatty acids, coco, 2-sulfoethyl esters, sodium salts is rejected.

Therefore the information requirement is not fulfilled.

5. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.)

Hydrolysis as a function of pH is a standard information requirement in Annex VIII to REACH.

You have adapted the information with reference to Annex VIII, Section 9.2.2.1., Column 2.

This information requirement can be adapted according to column 2 of Annex VIII, if the substance is readily biodegradable.

You justified the adaptation by stating that the substance is readily biodegradable. However, the information you provided for Ready biodegradability (Annex VII, Section 9.2.1.1.) cannot

be considered to be reliable as explained under request 4.A above. Therefore, it cannot be used to waive the endpoint Hydrolysis as a function of pH.

Therefore the information requirement is not fulfilled.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII to IX to REACH.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2009) corresponding to a sub-chronic toxicity study (90 day) performed according to OECD TG 408 with the source substance sodium isethionate (EC no. 216-343-6)

For the reasons detailed in General considerations section the read-across approach to sodium isethionate is rejected.

Therefore the information requirement is not fulfilled.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a solid and is marketed or supplied in a mixture as cosmetic and personal care products.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study by [redacted] (2008) corresponding to a Pre-natal developmental toxicity (PNDT) study performed according to OECD TG 414 in rat with the analogue substance Milled SLI (76) (EC no. 287-024-7).

For the reasons detailed in the General considerations section the read-across approach to Milled SLI (76) is rejected.

Based on the above, the information you provided do not fulfil the information requirement.

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral (ECHA Guidance R.7a, Section R.7.6.2.3.2.) administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

Long-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study from [redacted] (2010), corresponding to an OECD TG 211 with the source substance Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ "SLI" 76 stripped (EC no. 287-024-7),

We have assessed this information and identified the following issues:

A. Toxicological and eco-toxicological tests and analyses on substances must be carried out in compliance with the principles of good laboratory practice (GLP) provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or ECHA and with the provisions of Directive 86/609/EEC, if applicable (Article 13(4) of REACH). According to Article 141(2), Article 13 applies from 1 June 2008.

However, the provided study was not performed according to GLP.

B. For the reasons detailed in the General considerations section the read-across approach to Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts is rejected.

Therefore, the information requirement is not fulfilled.

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

You have adapted this information requirement according to Annex XI, Section 1.5. of the REACH Regulation and you have provided:

(i) a key study from [redacted] (2009), corresponding to an OECD TG 210 with the source substance Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ "SLI" 76 stripped (EC no. 287-024-7),

For the reasons detailed in the General considerations section the read-across approach to Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts is rejected.

Therefore, the information requirement is not fulfilled.

5. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

and

6. Sediment simulation testing (Annex IX, Section 9.2.1.4.)

Simulation testing on ultimate degradation in surface water is a standard information requirement at Annex IX to REACH.

Sediment simulation testing is a standard information requirement at Annex IX of REACH for substances with a high potential for adsorption to sediment.

The Substance has low surface tension (33.5 mN/m at 20°C), is used in various consumer products with a technical function as surface active agent and is ionisable, indicating high adsorptive properties.

You have also adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. and you have provided:

(i) a key study by [redacted] (2010) corresponding to simulation test – Activated sludge unit according to OECD TG 303A with the source substance Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ "SLI" 76 stripped (EC no 287-024-7) and

(ii) a key study by [redacted] (2010) corresponding to simulation test – Activated sludge unit according to OECD TG 303A and 314D on the Substance.

We have assessed this information and identified the following issues:

A. For the reasons detailed in the General considerations section the read-across approach to Fatty acids, C12-18 and C18-unsatd., 2-sulfoethyl esters, sodium salts/ SLI 76 stripped is rejected.

B. The information used for the purpose of assessment of the PBT/vPvB properties must be based on data obtained under relevant conditions (Annex XIII). The test conducted must simulate degradation in a relevant environment i.e. regarded as equivalent to a simulation test in surface water or in sediment (ECHA Guidance R.11.4).

   The study by [redacted] (2010) according to OECD TG 303A is a test to simulate degradation in an aerobic sewage treatment plant. The study by [redacted] (2010) according to OECD TG 314D is a test to simulate biodegradation in treated effluent-surface water mixing zone. None of these studies are regarded as equivalent to a simulation test in relevant environment such as fresh or estuarine water, marine water or fresh or estuarine sediment or marine sediment.

Therefore the information requirements are not fulfilled.

Study design

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. Therefore:

- You must perform the OECD TG 309 test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11).

- You must perform the test at the temperature of 12 °C, the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8). Performing the tests at

this temperature is in line with the applicable test conditions of the OECD TG 308 and TG 309.

Non-extractable residues (NER) must be quantified in all simulation studies. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER. Such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance Chapter R.11).

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.), aqueous exposure

Bioaccumulation in aquatic species, preferably fish is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex IX, Section 9.3.2., column 2. You have provided the following justifications for the adaptation:

- *"The log Kow of sodium lauryl isethionate is determined to be equivalent to 0.6. Based on this the substance is considered to have a low bioaccumulation potential"*.
- *"The substance is readily biodegradable and a very high removal has been observed in a sewage sludge treatment plant. Lauryl isethionate is thus degraded before it enters the environment. The faction which may enter the environment is either sorbed or degraded and not dissolved"*.

We have assessed this information and identified the following issue:

A. Annex IX, Section 9.3.2., column 2 specifies that a study does not need to be conducted if the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3). To adapt this information requirement based on low potential to partition to lipids (i.e. log Kow ≤ 3), lipophilicity must be the sole characteristic driving the bioaccumulation potential of a substance. However, for some groups of substances (e.g. organometals, ionisable substances, surfactants) other mechanisms than partitioning to lipids may drive bioaccumulation (e.g. binding to protein/cell membranes). For those substances log Kow is not considered a valid descriptor of the bioaccumulation potential and therefore for measured BCF values are preferred (ECHA Guidance R.7c, Appendix R.7.10-3).

   You have justified the low potential for bioaccumulation because the partition coefficient value (log Kow) was determined to be 0.6.

   The Substance is surface active (with a surface tension in water of 33.5 mN/m) and is ionisable. Hence binding to protein/cell membranes cannot be excluded. Therefore log Kow is not a valid descriptor for assessing the bioaccumulation potential of the Substance and your adaptation is rejected.

B. Annex IX, Section 9.3.2., column 2 specifies that a study does not need to be conducted if direct and indirect exposure of the aquatic compartment is unlikely. As specified in ECHA Guidance R.7c, Section R.7.10.4.5, bioaccumulation is a fundamental part of the assessment of the hazard and fate of a substance and therefore testing may only be omitted on exposure grounds under exceptional circumstances. Such circumstances include cases where it can be reliably demonstrated (by measurement or other evidence) that there is no release to the

environment at any stage in the life cycle.

You have justified that the exposure of the aquatic compartment is unlikely by stating that the substance is readily biodegradable and that it has high adsorptive potential.

However, the biodegradation and adsorption properties of a substance are only indicative of behaviour in the environment. It cannot be regarded as a valid justification that there is no release to the environment at any stage in the life cycle of a substance. Furthermore, in your CSR you report wide dispersive uses including consumer uses (e.g.cosmetics and personal care products). Therefore exposure of the aquatic compartment cannot be ruled out and your adaptation is rejected.

Therefore the information requirement is not fulfilled.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7c, Section R.7.10.3.1). Whenever technically feasible, the aqueous route of exposure (OECD TG 305-I) must be used as the results obtained can be used directly for comparison with the B and vB criteria of Annex XIII of REACH. Therefore, the requested study must be conducted with aqueous exposure. If testing through aquatic exposure is technically not possible, you must provide scientifically valid justification for the infeasibility.

Appendix D: Reasons for the requests to comply with Annex X of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier at a tonnage above 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to REACH.

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

In your dossier you have provided a study [redacted] (2008) corresponding to a Pre-natal developmental toxicity (PNDT) study performed according to OECD TG 414 in rat with the analogue substance Milled SLI (76) (EC no. 287-024-7).

We have assessed this information and identified the following issue(s):

In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

The study provided for information requirement on prenatal developmental toxicity was conducted in one species only (rat) and with analogue substance Milled SLI (76) (EC no. 287-024-7). You have not provided information on pre-natal developmental toxicity (PNDT) on a second species. Furthermore, as explained in the Appendix on general considerations your adaptation for this study according to Annex XI, Section 1.5 is rejected.

Based on the above, the information you provided do not fulfil the information requirement.

Study design

A PNDT study according to the OECD TG 414 study should be performed in rabbit or rat as the preferred second species, depending on the species tested in the first PNDT study (request C.2 in this decision).

2. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1)

Long-term toxicity to sediment organisms is a standard information requirement as laid down in Annex X, Section 9.5.1. of the REACH Regulation.

You have adapted this information requirement Annex IX, Section 9.5.1., Column 2 with the following justification: "*Equilibrium partitioning method applied. According to* [redacted] *2013 (to be published) the Equilibrium partitioning method is also applicable to cationic surfactants.*".

You relied on the results of the short-term and long term aquatic toxicity data included in your dossier to extrapolate the PNECs sediment using the equilibrium partitioning method.

We have assessed this information and identified the following issues:

A. ECHA Guidance R.10, Section R.10.5.2.1. specifies that for compounds with a log Kow greater than 5 or with a corresponding adsorption or binding behaviour not triggered by the lipophilicity (e.g. log Kow) of the substance but by other mechanisms (e.g. ionisable substances, surface active substances, substances forming covalent bound

to sediment, components like e.g. aromatic amines) the equilibrium method is used in a modified way. In such case, the PECsed/PNECsed ratio is increased by a factor of 10.

Based on a study conducted according to OECD TG 115, you report that the surface tension of the Substance is 33.15 mN/m at 20°C. Under section 3 of your technical dossier your report that the Substance is used in various consumer products with a technical function as surface active agent.
In your Chemical Safety Report (CSR) you have not applied an extra assessment of 10 in the calculation of the PECsed/PNECsed ratio for the reported exposure scenarios.

The information in your dossier indicates that the Substance is ionisable and surface active. You have not applied the extra assessment of 10 in the calculation of the PECsed/PNECsed ratios. Therefore your CSR currently underestimates the risks to the sediment compartment by a factor of 10.

B. As specified in Annex X, Section 9.5.1., Column 2, a long-term toxicity to study on sediment organisms must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:
- all relevant hazard information from your registration dossier,
- the outcome of the exposure assessment in relation to the uses of the Substance,
- the outcome of the PBT/vPvB assessment including information on relevant degradation products and constituents present in concentration at or above 0.1% (w/w).

However, to reach the conclusion that the risks are controlled, we understand that you rely on the results of acute aquatic toxicity data included in your dossier to extrapolate the PNECs sediment using the equilibrium partitioning method and the outcome of the exposure assessment showing risk characterisation ratios (RCRs) below 1 for the freshwater and marine sediment compartments.

As specified in request A.2, A.3, B.3 and C.2 and C.3, the data on short-term toxicity to aquatic invertebrates and fish and on growth inhibition to algae and cyanobacteria and on long term aquatic toxicity are not compliant. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance. Furthermore as explained under issue A above, You have not applied the extra assessment of 10 in the calculation of the PECsed/PNECsed ratios and hence your CSR currently underestimates the risks to the sediment compartment by a factor of 10 and you cannot prove that your CSR is adequately covering the risk for sediment compartment.

Therefore the information requirement is not fulfilled.

Study design

The Sediment-water Chironomid toxicity using spiked sediment (OECD TG 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD TG 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Sediment (OECD TG 233) are in principle each considered capable of generating information appropriate for the fulfilment of the

information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses. ECHA considers that it is your responsibility to choose the most appropriate test protocol and to give a justification for the choice. You may carry out more than one of the sediment tests listed above if you consider that further testing is required.

Appendix E: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 12 April 2019.

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 within 30 days of the notification.

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 F: Observations and technical guidance

1. The information requirement under Section 8.7.3. of Annex X to REACH (Extended one-generation reproductive toxicity study, EOGRTS) is not addressed in this decision, because the information from the Sub-chronic toxicity study (90-day), requested in the present this decision, is relevant for the design of the EOGRTS.

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

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

4. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses shall be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries'[4].

5. Test material

   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

[4] https://echa.europa.eu/practical-guides

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[5].

6. Strategy for the PBT/vPvB assessment

You are advised to consult ECHA Guidance R.7b, Section R.7.9., R.7c, Section R.7.10 and R.11 on PBT assessment to determine the sequence of the tests and the necessity to conduct all of them. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

You are advised to first conclude whether the Substance may fulfil the Annex XIII criteria of being P or vP, and then continue with the assessment for bioaccumulation. The sequence of the simulation tests also needs to consider the intrinsic properties of the Substance, its identified use and release patterns as these could significantly influence the environmental fate of the Substance. You shall revise the PBT assessment when the new information is available.

7. List of references of the ECHA Guidance and other guidance/ reference documents[6]

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[7]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

[5] https://echa.europa.eu/manuals
[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

OECD Guidance documents[8]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.
Guidance Document supporting the OECD TG 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD151.

[8] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix G: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.