EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 18 May 2021

Addressees
Registrant(s) of fish oil sulfonated Na as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
10/01/2011

Registered substance subject to this decision ("the Substance")
Substance name: Oils, fish, oxidized, bisulfited, sodium salts
EC number: 307-037-4
CAS number: 97488-98-7

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***23 August 2023***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., Column 2)

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

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., Column 2)

C. Information required from all the Registrants subject to Annex IX of REACH

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

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

D. Information required from 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) by oral route, in a second species (rat/rabbit)

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes VII to X of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 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.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

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

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix A: Reasons to request information required under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided two Short-term toxicity testing on aquatic invertebrates (test method OECD TG 202) studies on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, the water solubility of the substance or its constituents is below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

You have provided information which indicates that the Substance includes constituents that are poorly water soluble; i.e. the water solubility estimated to be <1mg/l in section 4.8 of your dossier.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.3.

In your comments on the draft decision you agree to conduct this study.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2).

You have provided the following information:

- Growth inhibition study aquatic plants (test method OECD TG 201) key study on the Substance
- Growth inhibition study aquatic plants (test method OECD TG 201) supporting study on the source substance Rape oil, bisulfited, sodium salt (EC 281-975-1), OECD TG 201, [redacted] (2010)

We have assessed this information and identified the following issues:

A. Assessment of the study provided on the Substance

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

Reporting of the methodology and results

- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;

- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

Characterisation of exposure
- a reliable analytical method for the quantification of the test material in the test solutions must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

Additional requirements applicable to difficult to test substances
- if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions is determined;
- if water-accommodated fractions (WAFs) are used, a preliminary study must be conducted to determine that saturation has been achieved.

Your registration dossier provides an OECD TG 201 key study on the Substance showing the following:

Reporting of the methodology and results
- the method used to determine algal biomass is not reported;
- tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

Characterisation of exposure
- loading levels were analysed by total organic carbon (according to DIN EN 1484) measured as non-purgeable organic carbon, but this method is not specific for the Substance, i.e. it determines the total organic carbon present in the test medium, not only the Substance; neither did you provide a justification why the analytical monitoring of exposure concentrations of the Substance itself is not technically feasible;

Additional requirements applicable to difficult to test substances
- the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions has not been determined;
- a preliminary study to determine that saturation has been achieved in the WAFs has not been conducted.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically:
- in the absence of a compound-specific analytical method, you have not demonstrated that measured concentrations provide a reliable estimate of exposure to the test material during the test;
- the Substance is difficult to test because it is poorly water soluble and the maximum dissolved concentration in the test solution under the test conditions has not been determined. Furthermore, the saturated concentration in the WAFs used for testing have not been established.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, the method to determine algal biomass is not reported. Furthermore, in the absence of tabulated data on the algal biomass, it is not possible to verify whether or not the validity criteria of the OECD TG 201 were met.

In your comments on the draft decision you provided the following information:

- a justification why the analytical monitoring of exposure concentrations is not technically feasible.
- the maximum dissolved concentration that can be achieved and the saturated WAF concentration.
- the method to determine algal biomass and tabulated data on algal biomass.

ECHA has assessed the information against the requirements in OECD TG 201. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

Therefore, the requirements of OECD TG 201 are not met.

B. Assessment of your adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances')

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[2].

You have provided a read-across justification document in the CSR. You have formed a group (category) of 'Fat Liquor and Lubricants (FLL)', with the following six members of the sub-category of 'Sulfited Fat Liquors':

- Oils, fish, oxidized, bisulfited, sodium salts (EC 307-037-4)
- Oils, animal, sulfonated, sodium salts (EC 305-979-0)
- Rape oil, bisulfited, sodium salt (EC 281-975-1)
- Rape oil, sulfonated, sodium salt (EC 293-618-7)
- Rape oil oxidized (EC 305-871-3)
- Oils, lard, oxidized, sulfited, sodium salts (EC 297-185-5)

You have provided the following reasoning for the prediction of aquatic toxicity: *" Given the structural similarities of all of the FLL Substances (i.e., they are all triglyceride molecules that have been subjected to a sulfonation process), it is expected that substances manufactured from the same type of source oil will have similar physicochemical and toxicological properties, and that these properties are also likely to be similar even among different source oils".*

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 to be quantitatively equal to those of the source substance.

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

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1

1) *Applicability domain of the category*

According to the ECHA Guidance, a category (grouping) hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint*".[3] Particularly, "*the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members*".[4] Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

You describe the applicability domain of the substances covered by the grouping as: "*triglyceride molecules that have been subjected to a sulfonation process*".

This applicability domain does not introduce unambiguous inclusion/exclusion criteria within which reliable estimations can be made for the Substance because it does not cover:

- the range acceptable of the number of sulfited groups in the reaction product, and
- the range acceptable of unreacted starting material in the composition of the group members.

2) *Characterisation of the group members*

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, "*in identifying a category, it is important that all potential category members are described as comprehensively as possible*", because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[5] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; 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.[6]

You have defined the applicability domain of the category as explained above. Your read-across justification document contains compositional information for the members of your category. The category members are UVCBs sulphonated fatty acids of various carbon chain lengths. The ranges of the sulphonate content and the lipophilic fraction are given.

No information on the number of sulphonated groups of the individual constituents of the

[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.1.2
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[6] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

category members is provided.

Without consideration of the number of sulphonated groups amongst constituents with different carbon chain length, no qualitative or quantitative comparative assessment of the compositions of the different category members can be completed. Therefore, the category membership cannot be confirmed.

3) Data density

Annex XI, Section 1.5. provides that "*substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances.*

According to the ECHA Guidance, one of the factors in determining the robustness of a category is the density and distribution of the available data across the category.[7] To identify a regular pattern and/or to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

You have provided algal toxicity data on two category members. Based on these studies you claim that there is no toxicity at a WAF loading rate of 100mg/l.

Information for one two category members in the sub-category of six 'Sulfited Fat Liquors' is not sufficient to establish a trend across the category. Therefore, the information provided is not sufficient to conclude that ecotoxicological properties are likely to follow a regular pattern.

4) 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), in this case the OECD TG 201,

The study on the source substance Rape oil, bisulfited, sodium salt (EC 281-975-1) shows the same deficiencies as the key study on the Substance (see issue A. above) and therefore it does not meet the information requirement.

Conclusions on the grouping of substances and read-across approach

As explained above, you have not 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 provided new information to support this read-across adaptation. However, as noted above under issue A. you have already provided information which would address the incompliance identified by means of the key study on the Substance. As already explained above, the information is currently not available in your registration dossier and so the data gap remains. You should therefore submit this information covered under issue A. in an updated registration dossier by the deadline set out in the decision.

[7] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.1.5.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility (<1 mg/L). OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided two short-term toxicity testing on fish studies (one using test method OECD TG 203 and the other according to ISO 7346-1), but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, the water solubility of the substance or its constituents is below the detection limit of the analytical method of the test material (ECHA Guidance R.7b, Section 7.8.5).

As already explained under Section A.1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided in your dossier and comments, as well as the selection of the requested test and the test design are addressed under section C.4.

Appendix C Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

You have provided a waiver based on results of OECD TG 422: "*There was no evidence of toxicity in the 8-week test; however, it is uncertain whether significant absorption occurred. Given the low hazard found for all human toxicology endpoints, it is considered highly unlikely that toxicity would be observed in the 90-d study. Therefore, conducting this test is not considered necessary.*"

ECHA understands that you are providing an adaptation according to Annex IX, Section 8.6.2, Column 2.

You have also included the following studies:

i) [redacted] (2010), key study, according to OECD TG 422, with the Substance
ii) [redacted] (2010), supporting study, according to OECD TG 422, with the analogue EC 281-975-1

We have assessed this information and identified the following issues:

Under Annex IX, Section 8.6.2, Column 2, a study may be omitted if, coupled with limited human exposure, and a set of cumulative conditions are met, including the following:

i) there is not evidence of absorption, and
ii) there is no evidence of of toxicity in a 28-day 'limit test'.

However, you did not provide any toxicokinetic data with the Substance to prove that there is no evidence of absorption. Instead you indicate that the following processes with the Substance are important: "*Digestion in digestive tract followed by absorption of unmodified fatty acids and (potentially) absorption of modified fatty acids*"; and "*Absorption through the digestive tract and skin*". Moreover, in the OECD TG 422 study there were some effects noted in rats (such as increase in thyroid weight and changes in clinical chemistry) which could indicate that the Substance is absorbed. Also, in your waiver you state that "*it is uncertain whether significant absorption occurred*".

In addition, as regards human exposure, consumer uses are reported in the dossier.

Based on the above, you have neither demonstrated that there is no evidence of absorption/ of toxicity in a 28-day 'limit test' nor that there is limited human exposure.

Therefore, your adaptation is rejected and the information requirement is not fulfilled.

In your comments on the draft decision you agree to conduct this study.

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 liquid of very low vapour pressure (0.2 Pa at 25°C) and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

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 in one species

A Pre-natal developmental toxicity (PNDT) study in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

You have provided a waiver based on results of OECD TG 422: *"There was not evidence of systemic or reproductive toxicity in the 8-week combined test. Given the low hazard found for almost all human toxicology endpoints, it is considered highly unlikely that reproductive toxicity would be observed in this study. Therefore, conducting this test is not considered necessary."*

ECHA understands that you have provided an adaptation according to Annex IX, Section 8.7., Column 2.

We have assessed this information and identified the following issues:

Under Annex IX, Section 8.7., Column 2, third indent, a study may be omitted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, two of them being:

- that it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and
- that there is no or no significant human exposure.

You have not provided any toxicokinetic data to show that there is no systemic absorption. Furthermore, the uses of the Substance indicate that there is significant human exposure.

Therefore, your adaptation is rejected.

On this basis, the information you provided does not fulfil the information requirement.

In your comments on the draft decision you agree to conduct this study.

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[8] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information: an adaptation under Annex XI, Section 2 ('Testing is technically not possible') with the following justification: *'Because of the extremely low water solubility of the substances, conventional acute testing was not possible. Long-term testing is not expected to be feasible.'*

We have assessed this information and identified the following issue:

Under Annex XI, Section 2 of REACH, the study may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Article 13(3) and, if applicable, in OECD GD 23, on the technical limitations of the corresponding method must always be respected.

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Your dossier does not include documented evidence as to why a study according to OECD TG 211 is not technically feasible.

OECD TG 211 in conjunction with OECD TG 23 provide guidance on how to test poorly soluble substances. In the absence of evidence that the study cannot be conducted your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision you agree to conduct this study.

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.2.

4. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information: an adaptation under Annex XI, Section 2 ('Testing is technically not possible') with the following justification: '*Because of the extremely low water solubility of the substances, conventional acute testing was not possible. Long-term testing is not expected to be feasible*'.

We have assessed this information and identified the following issue:

Under Annex XI, Section 2 of REACH, the study may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance. The guidance given in the test methods referred to in Article 13(3) and, if applicable, in OECD GD 23, on the technical limitations of the corresponding method must always be respected.

Your dossier does not include evidence as to why a study according to OECD TG 210 is not technically feasible.

You make the following comments on the draft decision:

i) You propose to waive the study on the grounds that the substance is not available in the water column, because you consider that it is 'highly insoluble' (which you indicate could be a water solublity ≤ 0.001 mg/L).
ii) You argue that there is no release to the environment because of complete degradation of residues in effluent in on-site STPs before discharge to drain.
iii) You propose to conduct a quantitative risk assessment for the aquatic compartment using a PNEC derived from the long-term Daphnia study (requested under section A.1 and C.3).

We have assessed this information and identified the following issues:

1. *The legal basis for your adaptation is not clear*

As reiterated by ECHA's Board of Appeal in appeal A-011-2018 (paragraph 35) "*A registrant who submits an adaptation must set out clearly, in the relevant part of its registration*

dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds".

In your comments on the draft decision you have not identified the provision of Annexes VII-XI on which the adaptation you intend to include in the registration dossier is based.

Consequently, in the absence of a clear reference to a provision, ECHA is not in a position to assess the adaptation referred to in your comments and the information gap remains.

Therefore, you have not demonstrated that this information can be omitted.

OECD TG 210 in conjunction with OECD TG 23 provide guidance on how to test poorly soluble substances. In the absence of evidence that the study cannot be conducted your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section A.2.

Appendix D: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies in two species is an standard information requirement under Annex X to REACH (Section 8.7.2.).

ECHA understands that you have adapted the information requirement according to Annex IX, Section 8.7., Column 2, third indent (low toxicological activity).

As explained under Appendix C.2., your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision you state your belief that the study can be waived based on the existing information and information to be generated after this decision. You also indicate that the need to perform this study will be assessed after the generation of the above requested information requirements.

You may perform the study sequentially following the 1st PNDT study. However, as stated above, a PNDT study in a 2nd species is a standard information requirement under Annex X and your current adaptation according to Annex IX, Section 8.7., Column 2, third indent (low toxicological activity) is rejected. Therefore, the data gap remains.

Study design

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

The study shall be performed with oral[9] administration of the Substance.

[9] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix E: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. 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 on How to report robust study summaries[10].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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.

2. Information on the Test Material needed in the updated dossier

a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
b) The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested, in this case the distribution of the C-chain length, the degree of unsaturation, the number of sulphonated groups in the reacted material and the relative abundance of unreacted material.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[11].

[10] https://echa.europa.eu/practical-guides
[11] https://echa.europa.eu/manuals

Appendix F: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituens and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthetize its relevant constituents and/or fractions.

Appendix G: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS.

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

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

The compliance check was initiated on 27 November 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 request(s).

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

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

Appendix H: List of references - ECHA Guidance[12] and other supporting documents

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 where relevant.

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 where relevant.

Read-across assessment framework (RAAF, March 2017)[13]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

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.

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.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[14]

[12] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[13] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix I: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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Registrant Name	Registration number	Highest REACH Annex applicable to you
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Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.