~~Confidential~~

Helsinki, 20 September 2021

Addressees
Registrant(s) of Sodium Lauroyl Glutamate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
10/03/2020

Registered substance subject to this decision ("the Substance")
Substance name: Sodium hydrogen N-(1-oxododecyl)-L-glutamate
EC number: 249-958-3
CAS number: 29923-31-7

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 ***27 March 2023***.

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

The scope of this compliance check is limited to physical chemistry, environmental fate and behaviour and aquatic environment.

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

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

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

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

1. Justification for an adaptation of short-term toxicity testing on fish (Annex VIII, Section 9.1.3.) based on the results of the Long-term toxicity testing on fish requested below (Annex IX, Section 9.1.6.)

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

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

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX 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;

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

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". 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 on Reasons common to several requests

1. **Assessment of your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) 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 (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

A. **Predictions for ecotoxicological properties**

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances, L-Glutamic acid, N-coco acyl derivs., monosodium salts [redacted] EC No. 269-087-2 (CAS No. 68187-32-6) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties: "the read across of ecotoxicological data from an analogue is justified on the basis of their similar chemical structures, structure activity, patterns of physico-chemical properties, toxicological and ecotoxicological profiles".

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 shortcoming(s) with regards to prediction(s) of aquatic toxicity.

1. Read-across hypothesis

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. 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 (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substance(s).[4] It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structure and in some of the physicochemical/ ecotoxicological/ toxicological properties between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance for other endpoints. However, you have not provided an explanation of how the differences in the chemical structures (i.e. difference in the alkyl chain length) may affect the prediction of the properties of your Substance for the relevant endpoints.

In your comments to the initial draft decision, you indicate that the current read-across justification was done originally before 2013. In this time, both the scientific and regulatory understanding of read-across approaches has changed considerably, leading to today's understanding and interpretation by authorities of what is considered necessary to form a robust basis and justification of a scientifically robust read-across approach. Specifically, it was only in 2017 that ECHA published for the first time its Read-Across Assessment Framework (RAAF) document on UVCB substances which details scientific principles for the evaluation of read-across approaches proposed for use by registrants to establish scientifically their read-across cases. Moreover, the technical documentation of read-across approaches in registration dossiers has changed significantly with the introduction of version 6.2 of IUCLID. For these reasons, and in order to further substantiate and justify the read-across approach, you will include additional analytical data and details on the structures and compositions of the analogue and target substances considered in an updated read-across justification document. In addition to an updated description of the structure and composition of the acyl glutamate substances, further characterization of test materials used to generate source data will be provided in an updated dossier to the extent that this is technically possible.

In summary you provided your intentions for future data. No information could be assessed. So this information does not change the outcome of ECHA's assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

Similarity in chemical structure and similarity of some of the physicochemical/ ecotoxicological/ toxicological properties does not necessarily lead to predictable or similar ecotoxicological properties in other endpoints. As described above, a well-founded hypothesis is needed to establish a reliable prediction for an ecotoxicological property, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

[4] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.

2. Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)". For this purpose "it is important to provide supporting information to strengthen the rationale for the read-across". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include bridging studies to compare properties of the Substance and source 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 substance(s) is necessary to confirm that both substance 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 substance(s).

As explained in the respectable ecotoxicological endpoints below, the data set reported in the technical dossier currently does not include relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

In addition, in the read-across justification you stated that the source substances are very identical to that of the target substance but only differ in the alkyl chain length. You claim that the difference in the fatty acid alkyl chain length distribution is not likely to have significant impact on toxicity. However, you have no supporting information in the technical dossier to substantiate this.

In addition, in your comments to the initial draft decision, you indicate that for some endpoints new experimental data may also be generated on the substance itself if this either adds weight to the read-across hypothesis (bridging studies) or addresses the alleged issues with existing experimental studies or reporting. You will update and enhance the quality of the read across justification in your dossier accordingly.

In summary you provided your intentions for future data. No information could be assessed. So this information does not change the outcome of ECHA's assessment.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

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.

3. 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:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

As explained in the Request A.1, A.2 and B.1 below, the source studies that you have used in your read-across approach for the toxicity to algae, biodegradation and short-term aquatic fish endpoints, currently do not provide an adequate coverage of some key parameters expected to be investigated in a study performed according to the respectable OECD guidelines: OECD TG 201, OECD TG 301, OECD TG 203, respectively.

B. Conclusions on the 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.

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

1. 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 adapted this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. of REACH. In support of your adaptations, you have provided the following source of information:

i. Key study: OECD TG 201 (2001) with N-cocoylglutaminsäure-mono-Na-Salz (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

We have assessed this information and identified the following issues:

As explained in Section 1 of the Appendix on Reasons common to several requests your adaptation under Annex XI, Section 1.5. is rejected. In addition, the following endpoint-specific deficiencies have been identified in your read-across adaptation:

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. Therefore, the following specifications must be met:

- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*.

In your technical dossier, you did not indicate that the validity criteria were fulfilled nor did you provide raw data to verify the validity criteria as outlined above are met.

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

On this basis, the information requirement is not fulfilled.

In your comments to the initial draft decision, you agree to perform the test with the Substance.

Study design

The Substance is difficult to test due to the fact that the Substance is anionic tensionactive agent (surface tension: 34.4-35.73mN/m). 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 solution.

2. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. of REACH. In support of your adaptation, you have provided the following sources of information:

i. Key study: OECD TG 301E (1989) with N-cocoylglutaminsäure-mono-Na-Salz (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

We have assessed this information and identified the following issues:

As explained in Section 1 of the Appendix on Reasons common to several requests your adaptation under Annex XI, Section 1.5. is rejected. In addition, the following endpoint-specific deficiencies have been identified in your read-across adaptation. To fulfil the information requirement, a study must comply with the OECD TG 301 or 310. Therefore, for a study according to OECD TG 301, the following requirements must be met:

1. The inoculum is not be pre-adapted to the test material;
2. The inoculum is derived from the secondary effluent of a treatment plant or laboratory-scale unit receiving predominantly domestic sewage;
3. The concentration of the inoculum is set to reach a bacterial cell density of approx. 10^5 cells/L in the test vessel;
4. The concentration of added inoculum is ≤ 0.5 mL/L;
5. The difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window is ≤ 20%

In the technical dossier, you did not specify whether the inoculum is pre-adapted to the test material (point 1 above). In addition, you did not specify the source of inoculum covering the specifications as outlined above (points 2-4).

In addition, you did not specify whether the validity criteria were fulfilled nor did you provide raw data to verify the validity criterion as outlined in point 5 above is met.

Therefore, you have not demonstrated that validity criteria were fulfilled and there are critical methodological deficiencies affecting the reliability of the test results, we are not in a position to conduct an independent assessment of the study reliability.

On this basis, the information requirement is not fulfilled.

In your comments to the initial draft decision, you agree to perform the test with the Substance.

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

1. Justification for an adaptation of Short-term toxicity testing on fish based on the results of the Long-term toxicity study on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Annex VIII, Section 9.1.3, Column 2 or a general adaptation rule under Annex XI.

You have adapted this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. of REACH. In support of your adaptation, you have provided the following source of information:

i. OECD TG 203 KS (1990) with analogue substance N-cocoylglutamic acid-monosodium salt (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

We have assessed this information and identified the following issue:

As explained in Section 1 of the Appendix on Reasons common to several requests your adaptation under Annex XI, Section 1.5. is rejected. In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

To fulfil the information requirement, a study must comply with OECD TG 203 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test. Therefore, the following specification must be met:

- the analytical measurement of test concentrations is conducted

Your registration dossier provides an OECD TG 203 showing the following:

- no analytical measurement of test concentrations was conducted

Based on the above, the validity criterion of OECD TG 203 is not met.

In your comments to the initial draft decision, in order to prevent unnecessary animal (vertebrates) testing, you outline your future testing strategy:

- Using a recent OECD TG 203 (2011) with analogue substance EC 269-087-2;
- Using existing valid acute fish toxicity study data for C8 (EC 948-708-7) and C14 (EC 253-981-4) glutamates and improving your read across;
- Demonstrating that fish are not the most sensitive aquatic species.

In order to substantiate this claim you will consider generating additional data including, but not limited to, New Approach Methods (NAM) and/or in silico/QSAR modelling.

You outlined your intentions. No information was assessed.

It does not change the assessment for the reasons described in the Appendix on Reasons common to several requests above.

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI to REACH.

On this basis, the information requirement is not fulfilled.

The present decision requests the registrant(s) concerned to conduct and submit a long-term toxicity study on fish (OECD TG 210; see Appendix C.1 for details). According Annex VIII, Section 9.1.3., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study on fish does not need to be provided.

Because you still must comply with the information requirement in Annex VIII, Section 9.1.3., you are requested to submit a justification for the adaptation provided in Annex VIII, Section 9.1.3., Column 2, second indent.

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

1. 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 a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: a long-term toxicity test shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on fish. The hazard assessment on Substance suggests that fish is not the most sensitive organism. Therefore, and for reasons of animal welfare, a long-term toxicity test in fish is not provided.

We have assessed this information and identified the following issue:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

In your comments to the initial draft decision, in order to prevent unnecessary animal (vertebrates) testing, you outline your testing strategy:

1. You propose using results of the new non vertebrate animal tests on the Substance in combination with a new enhanced read-across considering available studies on acyl glutamates with alkyl lengths ranging from C8-C18, to demonstrate that fish are not the most sensitive species;

You outlined your intentions. No information was assessed.

It does not change the assessment for the reasons described in the Appendix on Reasons common to several requests above.

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI to REACH.

You invoke animal welfare, as a reason to avoid testing. It does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – IX or a valid adaptation to these information requirements.

2. Instead of the testing you propose to use the results of the chronic Daphnia tests performed on the Substance to derive PNECs and demonstrate acceptable environmental risks according to the CSA. You outline that according to ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first (and a chronic

daphnia study is already available for the Substance). If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study will need to be conducted.

As outlined above Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Therefore, ECHA understands you propose an adaptation under Annex XI, Section 3.2(a).

We have assessed this information and identified the following issue:

For the sake of completeness, ECHA has evaluated your adaptation under Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing).

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(a) It can be demonstrated that all the following conditions are met:

i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and

ii. a PNEC can be derived from available data, which:

- must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;

- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.

iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

For the reasons explained under request A.1. and B.1., your dossier does not include reliable information on the hazardous properties of the substance on at least two trophic levels. Currently, you cannot establish which tropic level is the most sensitive. No specific details on your PNEC calculations have been submitted, so no assessment has been made by ECHA.

Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation").

It is in your discretion to generate and provide the necessary supporting information in order to justify any adaptation. If you do so, you are responsible for demonstrating the fulfilment of the specific requirements of Annexes VII-IX and/or the general requirements of Annex XI

to REACH. ECHA will evaluate the latest submission provided after the deadline of this decision.

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 Appendix A.1.

Appendix D: 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[5].

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:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - 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
   - 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.
   - 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.

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[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix E: Procedure

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 9 April 2020.

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

ECHA took into account your comments and did not amend the request(s) but amended the deadline.

> The timeline indicated in the initial draft decision to provide the information requested is 12 months from the date of adoption of the decision.
>
> In your comments on the draft decision, you requested an extension of the timeline to 15 months. You justified your request with the following arguments, which ECHA has evaluated in turn further below:
>
> *The registrants propose a 15 month timescale for the performance of the biodegradability/aquatic toxicity studies to allow time for the necessary coordination by the registrants and for development*
>
> For co-ordination by the registrants no extra time is provided by ECHA for any deadline.
>
> For development, whilst you have not explained what you consider as development, as the Substance is considered as a difficult to test substance, further development is foreseen.
>
> Therefore, the deadline has been amended from 12 months to 15 months.

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: List of references - ECHA Guidance[7] 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)[8]

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

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[9]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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 G: Addressees of this decision and their corresponding information requirements

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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

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