~~Confidential~~

Helsinki, 2 December 2021

Addressees
Registrant(s) of JS_68187-32-6_[redacted] as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
09/04/2020

Registered substance subject to this decision ("the Substance")
Substance name: L-Glutamic acid, N-coco acyl derivs., monosodium salts
EC number: 269-087-2
CAS number: 68187-32-6

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 ***9 March 2023***

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

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. 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)

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

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annexes VII of REACH".

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 Annexes VII and VIII to REACH, for registration at 10-100 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". 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 Mike Rasenberg, 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.**

In your dossier assessed for the initial draft decision, you seek to adapt the following standard information requirement by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- 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.)

In your comments on the initial draft decision you have proposed to apply read-across approach in accordance with Annex XI, Section 1.5., (as part of weight of evidence adaptation under Annex XI, Section 1.2.), to the following standard information requirement:

- Ready biodegradability (Annex VII, Section 9.2.1.1.)

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[2] and related documents[3, 4].

In your dossier assessed for the initial draft decision, you have performed the following read-across and grouping approaches:

Category approaches for the following endpoints:

i) short-term toxicity on invertebrates
ii) growth inhibition of algae
iii) short-term toxicity on fish,

addressed under section A below.

Analogue approach for the following endpoints:

iv) growth inhibition of algae
v) short-term toxicity on fish,

addressed under section B below

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] 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)

[4] 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

In your comments on the initial draft decision, you have performed the following read-across and grouping approaches:

Category approaches for the following endpoint:
vi) Ready biodegradability
addressed under section A below.

Analogue approach for the following endpoints:
vii) growth inhibition of algae
viii) short-term toxicity on fish,
not addressed under section B below, see note below

Please note in your comments on the initial draft decision, you acknowledge that the information requirement for Growth inhibition study aquatic plants is not fulfilled for this endpoint and you agree to perform such a study Growth inhibition study aquatic plants. The endpoint has not been removed from this Appendix, to indicate the initial data gap reasoning. In your comments to the initial draft decision, you have provided no further source studies on this endpoint.

Due to a cease of manufacture, some requests (endpoints indicated in this appendix - short-term toxicity on invertebrates and short-term toxicity on fish) have been removed from this decision, see appendix F for further details. Due to this, your comments to the initial draft decision on Appendix on Reasons common to several requests concerning short-term toxicity on invertebrates and short-term toxicity on fish have not been addressed.

A. Grouping and predictions for ecotoxicological properties with category approach

In your dossier assessed for your initial draft decision, ECHA notes the following shortcomings with regards to prediction of ecotoxicological properties with category approach used for the endpoints i) to iii) listed above.

In your comments to the initial draft decision, ECHA notes the following shortcomings with regards to prediction of ecotoxicological properties with category approach used for the endpoint vi) listed above.

Scope of grouping

Description of the grouping

In your dossier assessed for the initial draft decision and in your comments to the initial draft decision, you have formed groups through identification of source substances using the OECD QSAR Toolbox.

These ESRs using the OECD QSAR Toolbox are flagged as QSARs but the OECD QSAR Toolbox is used in support of a prediction from category members using read-across, as stated in the reports provided. Therefore, ECHA understands that you have submitted a read-across adaptation.

In your dossier assessed for the initial draft decision, you have provided automated reports generated from the OECD QSAR Toolbox software in the respective ESRs in IUCLID Section 6.

In your dossier assessed for the initial draft decision, the selection of category members listed in OECD Toolbox QSAR reports for the endpoints i) to iii) was done on basis of log Kow and selected profilers.

In your comments to the initial draft decision, the selection of category members listed in OECD Toolbox QSAR reports for the endpoint vi) (ready biodegradability) was done on basis of log Kow and selected profilers.

In your dossier assessed for the initial draft decision, you have provided the following attachments:

- Attachment 1: Consolidated comments with brief summaries of details of source substances experimental studies
- Attachment 2: A read-across justification documentation

Predictions for properties

In your dossier assessed for the initial draft decision, you did not provide a read-across justification documentation. However, you have provided a read-across justification document with your comments on the initial draft decision.

In your read-across justification document, your read-across between the structurally similar substances is the following:

1. Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7)
2. Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5)
3. Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1)
4. Disodium N-(1-oxooctadecyl)-L-glutamate (CAS no. 38079-62-8; EC no. 253-773-3) and
5. Sodium myristate (CAS no. 822-12-8; EC no. 212-487-9).

as source substances and the Substance as target substance.

In your comments to the initial draft decision, in the read-across hypothesis for the environmental properties you note that "The read-across substances have been identified using the OECD QSAR toolbox version 3.4, wherein the target substance profiling has been done in the initial activity, and the read-across substances have been identified based on various criteria of functional groups. The read-across analogues obtained have been further combined with the 'OR' option matching at least one functional group criteria. The findings have been further subcategorized based on mechanistic approach, combined with the 'AND' condition that allows that similar chemicals have all mechanisms matching with the target chemical. Finally, the filter for structural similarity has been used to select the closest read-across substances. The target and read-across analogue Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) are UVCB substances and the other read across analogues i.e., Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7), Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1), Disodium N-(1-oxooctadecyl)-L-glutamate(CAS no. 38079-62-8; EC no. 253-773-3)and Sodium myristate (CAS no. 822-12-8; EC no. 212-487-9) are mono-constituent substances (as defined in the ECHA guidance for the identification and naming of substances under REACH and CLP). The following assessment intends to demonstrate that the target and read-across substances covered in this justification have common properties and present comparable environmental fate, ecotoxicological and toxicological behaviour."

In the dossier assessed for the initial draft decision and in your comments to the initial draft

decision, 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. In the comments to the initial draft decision you clarify that "Properties of the target substance predicted to be quantitatively equal to those of the source substance or prediction based on a worst-case approach."

ECHA notes the following issues with regards to predictions of ecotoxicological properties:

I. Read-across hypothesis

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 source substances. Secondly, it is required that the relevant properties of a substance may be predicted from data for reference substance(s) (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 source substance(s) and your Substance (ECHA Guidance R.6). It should explain why the differences in the chemical structures should not influence the ecotoxicological properties or should do so in a regular pattern.

Your hypothesis is based on structural similarity between the Substance and the selected source substances. In the dossier assessed for the initial draft decision and in your comments to the initial draft decision, you have selected source substances based on similar outcome of selected profilers from the OECD QSAR Toolbox software. QSAR Toolbox results were used for your grouping and the category has been built on the basis of the similarity of one constituent only of the UVCB Substance. However, you did not justify neither why the profilers you selected are the most relevant nor why the single structure selected is representative for the assessment of the whole UVCB. Furthermore, you have not justified why the selection of other profilers as well as structural difference between the Substance and the selected source substances will not impact the prediction for ecotoxicological properties.

In the absence of explanation why the differences in the chemical structure would not influence the ecotoxicological properties or should do so in a regular pattern, you have not provided a well-founded hypothesis to establish a reliable prediction for ecotoxicological properties.

In your dossier assessed for your initial draft decision or in your comments to the initial draft decision, you have not provided a well-founded hypothesis to establish a reliable prediction for ecotoxicological property, based on recognition of the structural differences of the substances (category members), including how these differences would not influence toxicokinetics and toxicodynamics of these substances.

II. 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 structural similarity may be considered as source substance." According to the ECHA Guidance R.6., "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). 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, 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.[5]

In the dossier assessed for your initial draft decision, you have not provided any information on the composition of the selected source substances, including their purity profile and the presence of impurities.

In your comments to the initial draft decision, in your read-across , you provided in Table 1 an overview of the composition of the substances, where you outline that Substance and read-across analogue Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) are UVCB substances and the other read across analogues i.e., Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7), Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1), Disodium N-(1-oxooctadecyl)-L-glutamate (CAS no. 38079-62-8; EC no. 253-773-3)and Sodium myristate (CAS no. 822-12-8; EC no. 212-487-9) are mono-constituent substances (as defined in the ECHA guidance for the identification and naming of substances under REACH and CLP). You provide your representative structures, molecular formula, molecular weight of the Substance and the source substances. You briefly describe the manufacturing process for the Substance. You did not indicate how the manufacturing process (with Aqueous sodium glutamate and coconut fatty acid chloride reacted along with sodium hydroxide) for the Substance is relevant for all the substances in the read-across hypothesis. You did not provide qualitative compositional information of the individual constituents of Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) (a UVCB source substance) or include the quantitative characterisation in the form of information on the concentration of the individual constituents of this source substance.

In your comments to the initial draft decision, you did not provide any information on purity profile and the presence of impurities on the selected source substances.

Therefore, in your comments to the initial draft decision, whilst you provided some limited information for certain properties, a complete qualitative, or a quantitative comparative assessment of the compositions of the Substance and of the source substances cannot be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substances.

III. Adequacy and reliability of source studies for ready biodegradability

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);

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

The three experimental ready biodegradability studies with source substances that you have provided in your comments to the initial draft decision and used in your read-across approach for ready biodegradability are as following:

- OECD TG 301E with analogue Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7)(28 day reported)
- Test Method Relating New Chemical Substances (Kanpogyo No. 5, Yakuhatsu No. 615, 49 Kikyoku No. 392, 1974) with analogue Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) (28 day duration reported)
- No test method stated with analogue Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1) (14 day duration reported);

According to the provisions of Annex VII, Section 9.2.1.1.; information on Ready biodegradability as specified in the OECD TGs 301/ 310 shall be provided. Ready biodegradability studies provided in the comments on the initial draft decision do not provide an adequate coverage of some key parameters expected to be investigated in a study performed according to the OECD TGs 301 / 310 (and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test). This means meeting the following specifications:

- The methods of preparation of test solutions/suspensions is reported;
- The raw results of measurements at each sampling point in each replicate is reported in a tabular form in order to establish the validity criteria for the study;
- Any observed inhibition phenomena is reported.

In your comment to the initial draft decision you have provided three experimental ready biodegradability studies with three different source substances, without information reported as specified above. None of the data provided enables the confirmation of fulfilment of the validity criteria for reported studies with the three different source substances.

Thus, the reporting of the studies is not sufficient to conduct an independent assessment of its reliability and is not sufficient to conclude if they are adequate for the purpose of classification and labelling and/or risk assessment.

IV. Missing relevant, reliable, adequate supporting information to compare properties of the substances

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including, among others, robust study summary(ies) of the source study(ies).[6]

A robust study summary must cover sufficient information to make an independent assessment of the study.[7]

In your dossier assessed to the initial draft decision, to support your predictions, you have provided automated reports generated from the OECD QSAR Toolbox software. These reports contain EC/LC_{50} values for category members only. However, you have not provided robust study summaries of the source studies.

In your comments to the initial draft decision, regarding endpoint vi) ready biodegradability, you outline your predictions results generated from the OECD QSAR Toolbox software, in tabular format:

[6] ECHA Guidance R.6, Section R.6.2.6.2
[7] How to report robust study summaries Practical Guide 3, Version 2.0 – November 2012

Table 2: Different alerts extracted using OECD QSAR toolbox v.3.4 of the target substance and read-across analogues for ecotoxicological endpoints:

- Biodegradation fragments (BioWIN MITI) for each substance

Table 5 Prediction of abiotic and biotic degradation for the representative constituents of the Substance and analogue group of chemicals:

- Hydrowin v2 – Half - life at pH 7 using OECD QSAR toolbox v. 3.4. (info included on source substances, CAS 56-86-0; CAS 90387-74-9, only)
- BioWinprogram using OECD QSAR toolbox v. 3.4. – info on all substances indicating Ready Biodegradability Prediction of Yes.

In your comments to the initial draft decision, regarding endpoint vi) ready biodegradability, you have provided very brief summaries of three experimental source study(ies). The lack of reporting on these very brief summaries, is insufficient to make an independent assessment of them (this aspect has been addressed under A. III, above).

In the absence of such documentation, ECHA cannot verify that the results to be read-across meet the criteria above.

a. *Missing supporting information* to compare properties of the category members

1. Bridging studies to compare properties of the Substance and source substances;

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*"[8]. 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 category members cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

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).

In your dossier and comments on the initial draft decision does not contain studies that were conducted with the Substance; only studies with source substances. In your comments to the initial draft decision, you indicate that "Read across analogue, i.e., CAS no. 142-47-2; EC no.

[8] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

205-538-1 is one of the constituent of the Substance and that the analogues contain carboxylic acid, aliphatic carbon chain and amine group and sodium as a common cation, respectively".

More specifically, for example, regarding ready biodegradability, three studies (one with OECD TG 301E; one with (CAS no. 56-86-0; EC no. 200-293-7)/ one with Test Method Relating New Chemical Substances (CAS no. 90387-74-9; EC no. 291-350-5)/ one where the method was not stated (CAS no. 142-47-2; EC no. 205-538-1). Thus you have one study which was conducted with CAS no. 142-47-2 that corresponds to a constituent of your Substance. The Substance is an UVCB of which the source substance, CAS No. 142-47-2) is a [redacted] constituent. However, in this study property of only one constituent was tested and the properties of the remaining constituents of the Substance are not addressed/unaccounted for.

Overall, this information indicates the lack of relevant, reliable and adequate information which could allow, a comparison of the properties of the category members to confirm that the substances cause the same type of effects(s), and thus, cannot support the applied read-across for the ecotoxicological properties.

Therefore the data set reported in the dossier or in your comments to the draft decision does not include relevant, reliable and adequate information for the Substance and of the source substances to support your read-across hypothesis.

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.

B. Predictions for ecotoxicological properties with analogue approach

ECHA notes the following shortcomings in your dossier assessed for the initial draft decision with regards to prediction of ecotoxicological properties with analogue approaches used for the endpoints iv) (Algae) and v (Fish)).

In your dossier assessed for the initial draft decision, you have provided prediction on analogue substance using Danish EPA QSAR.

You read-across between the structurally similar substances, sodium hydrogen 2-aminopentanedioate, EC No. 205-538-1 (CAS No. 142-47-2) as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of ecotoxicological properties: "*This source substance is a structural analog to the target chemical and have more than 92 % structural similarity*".

Attached to your comments on the initial draft decision you submitted a read-across justification document. In your justification document you have indicated that 'Scenario 2' was selected for the analogue approach. You provided the following reasoning for the prediction of (eco)toxicological properties: "read-across of environmental fate, ecotoxicological and toxicological data from an analogue may be justified on the basis of:

1. Identifying the read across substances based on common functional groups and further filled with relate mechanistic approaches and finally fine-tuned with structural similarity using the QSAR Toolbox Version 3.4
2. Common structural alerts or reactivity
3. Common physico-chemical properties
4. Likelihood of common breakdown products via biological/degradation processes"

You conclude that "the descriptors, various alerts and scenario (for analogue approach) which were taken into consideration for ecotoxicological and toxicological assessment as reported in this RA justification document obtained by using OECD QSAR toolbox v.3.4 of the target substance and source substances (i.e., read across analogues) were evaluated to be similar and therefore justified and appropriate".

As the analogues are used as source substances to predict the property of the Substance, we understand that you have adapted the standard information requirements under Annex XI, Section 1.5 to REACH (grouping and read-across). Based on the above, you used the QSAR Toolbox for the identification of analogues and use information on these analogues to 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(s).

In the dossier assessed for the initial draft decision 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.

In the comments to the initial draft decision you clarify that "Properties of the target substance predicted to be quantitatively equal to those of the source substance or prediction based on a worst-case approach."

In the dossier assessed for the initial draft decision, ECHA notes the following shortcoming(s) with regards to prediction(s) of ecotoxicological properties with analogue approach.

I. Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 substances[9]. 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 structural similarity between the source substance and your Substance is a sufficient basis for predicting the properties of your Substance.

In the absence of explanation why the differences in the chemical structure would not influence the ecotoxicological properties or should do so in a regular pattern, you have not provided a well-founded hypothesis to establish a reliable prediction for ecotoxicological properties.

In your dossier assessed for your initial draft decision or in your comments to the initial draft decision, you have not provided a well-founded hypothesis to establish a reliable prediction

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

for ecotoxicological property, based on recognition of the structural differences of the source substances, including how these differences would not influence toxicokinetics and toxicodynamics of these substances.

II. 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:

- 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);
  - cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

In the dossier assessed for the initial draft decision, there are deficiencies with the studies for algae and fish provided identified in the corresponding Appendices of the initial draft decision.

Also in your comments to the initial draft decision, the deficiencies with the studies for ready biodegradability are provided above in A. III, above.

III Characterisation of the source substance(s)

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 structural 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).[10] 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 substance are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the substances 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.[11]

In your dossier assessed for the initial draft decision, your read-across justification document contained no compositional information for the source substance (sodium hydrogen 2-aminopentanedioate, EC No. 205-538-1 (CAS No. 142-47-2). The Substance is an UVCB of which the source substance is a [redacted] constituent.

In your dossier assessed for the initial draft decision, you did not provide any description of the source substance identified in read-across justification document for the predictions iv

[10] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1
[11] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

(algae) and v (fish)). Furthermore, for all the studies provided in the dossier, no information on the composition of the test material used to generate the source data was provided.

In your comments to the initial draft decision, in your read-across , you provided in Table 1 an overview of the composition of the substances, where you outline that Substance and read-across analogue Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) are UVCB substances and the other read across analogues i.e., Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7), Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1), Disodium N-(1-oxooctadecyl)-L-glutamate (CAS no. 38079-62-8; EC no. 253-773-3)and Sodium myristate (CAS no. 822-12-8; EC no. 212-487-9) are mono-constituent substances (as defined in the ECHA guidance for the identification and naming of substances under REACH and CLP). You provide your representative structures, molecular formula, molecular weight of the Substance and the source substances. You briefly describe the manufacturing process for the Substance. You did not indicate how the manufacturing process (with Aqueous sodium glutamate and coconut fatty acid chloride reacted along with sodium hydroxide) for the Substance is relevant for all the substances in the read-across hypothesis. You did not provide qualitative compositional information of the individual constituents of Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) (a UVCB source substance) or include the quantitative characterisation in the form of information on the concentration of the individual constituents of this source substance.

You did not provide any information on purity profile and the presence of impurities on the selected source substances.

Some aspects to note, [redacted] constituent of the Substance is Sodium hydrogen N-(1-oxododecyl)-L-glutamate (CAS 29923-31-7) according to your dossier. The structure of [redacted] constituent in the dossier does not match the structure given for the Substance "representative" structure in your comments to the initial draft decision. The structure does not match with any of the reported constituent(s) in the composition. No explanation is provided for this. In Table 1 - Identity details of the target substance and read-across analogues, you indicate that when using your representative Substance structure, the QSAR Toolbox Version 3.4, Percentage of similarity with the analogue substances, range from 30 – 90%. This very wide range is not explained nor substantiated.

Therefore, in your comments to the initial draft decision, whilst you provided some limited information for certain properties, a complete qualitative , or or a quantitative comparative assessment of the compositions of the Substance and of the analogue source substances cannot be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substances.

IV. Existing data contradicts with the hypothesis

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". The Guidance on IRs and CSA, Section R.6.2.2.1.f., indicates that "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)/category members.

The observation of differences in the eco-toxicological properties between the source substance(s) and the Substance would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substances/category members. An

explanation why such differences do not affect the read-across hypothesis must be provided and supported by scientific evidence.

In your comments to the initial draft decision, you provided a read-across hypothesis based on the assumption that the structurally similar category members cause the same type of effect(s). You used the QSAR Toolbox (version 3.4) for the identification of analogues and use information on these analogues to 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(s).

Regarding your reasoning for the prediction of (eco)toxicological properties: "read-across of environmental fate, ecotoxicological and toxicological data from an analogue may be justified on the basis of:

1. Identifying the read across substances based on common functional groups and further filled with relate mechanistic approaches and finally fine-tuned with structural similarity using the QSAR Toolbox Version 3.4:
2. Common structural alerts or reactivity
3. Common physico-chemical properties
4. Likelihood of common breakdown products via biological/degradation processes"

Regarding point 2., common structural alerts or reactivity, you have provided a list of "*alerts extracted using OECD QSAR toolbox v.3.4 of the target substance and read-across analogues*" Table 2 - Common structural alerts or reactivity. You indicate that as the target and read-across analogues show the presence of nearly similar functional groups, different structural activity amongst the various read-across substances is not expected. As per the analysis conducted with the OECD (Q)SAR Toolbox v.3.4, it is indicated that the Substance target and the source substances share similar structural alerts. ECHA understands that you consider this as supporting information for the read-across applied for ecotoxicological properties.

However, whilst some results of individual alert(s) for the Substance might be the same as the result of that specific alert for a source substance, however for each source substance there are some alerts giving different results from that of the Substance, e.g.

- Prediction for Protein binding by OASIS v.1.4 is different for the Substance and for the source substances, CAS 38079-62-8 and CAS 90387-74-9; and
- Prediction for Biodegradation fragments (BioWIN MITI) is different the Substance and for the source substances CAS 56-86-0, CAS 38079-62-8, CAS 90387-74-9, CAS 142-47-2 and CAS 822-12-8
- The selection of these specific stated profilers.

Regarding point 3., Common physico-chemical properties:
You provide partition coefficients in Table 4 (attachment 2). We observe that the range is very wide, log Kow values range is <– 4.0 – 2.17. The Substance has a logKow of -1.19. The relevance of these differences between the substances is not considered or substantiated.

Regarding point 4., Likelihood of common breakdown products via biological/degradation processes":
You have not explained or substantiated how biodegradation fragments (BioWIN MITI) would address the biodegradation, degradation pathways or degradation products. It only reflects some of the structural similarities e.g. that some of the source substances contain an amine group, whereas others contain amide functional groups, and one lacks nitrogen containing groups.

In Table 5, you provide hydrolysis predictions (Hydrowin (v.2) and BIOWIN ready

biodegradability predictions (Biowin 2, 3 and 6) from the QSAR Toolbox v.3.4 to compare the group of substances regarding their degradability. However, for abiotic degradation results for two source substances are reported, only which indicate a difference, source substance CAS 56-86-0 is predicted to be hydrolytically stable with a DT50 of > 96 hrs and source substance CAS 90387-74-9 is predicted to be hydrolytically stable with a DT50 of > 28 days. However as information on the Substance and the other source substances are not present, we cannot make a comparison.

You have not explained nor substantiated how the identification and nature of possible degradation products can be interpreted from the hydrolyses predictions, nor from the Biowin predictions. The Biowin predictions generated with the QSAR Toolbox can only be used to indicate at a high level insufficient for conclusion that the whole group, not individual substances (or individual constituents), is predicted to be ready biodegradation.

The available set of data on the Substance and on the category members indicates differences in the (eco)toxicological properties of the substances. This contradicts your read-across hypothesis whereby the Substance and source substances cause the same type of effect(s). Therefore you have not demonstrated and justified that the properties of the source substances are likely to be similar despite the observation of these differences.

In addition, under A.III. above, outlines missing relevant, reliable, adequate and reliability of supporting information to compare properties of the Substance and the source substances

C. Conclusions on the read-across approaches

As explained above, in your dossier assessed for the initial draft decision or in your comments to the initial draft decision, you have not established that relevant properties of the Substance can be predicted from data on the source substances. 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.

2. Assessment of your QSAR adaptation under Annex XI, Section 1.3

In your dossier assessed for the initial draft decision, you seek to adapt the following standard information requirement by applying Qualitative or quantitative structure-activity relationship (QSAR) in accordance with Annex XI, Section 1.3:

- Ready biodegradability (Annex VII, Section 9.2.1.1.)

Rule for Annex XI, Section 1.3 adaptation

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

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;
3. adequate and reliable documentation of the applied method is provided; and
4. the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Prediction Reporting Format (QPRF) is required.

I. lack of QMRF and/or QPRF

ECHA Guidance R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the model prediction(s), including the endpoint,
- a precise identification of the substance modelled,
- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues

In your dossier assessed for the initial draft decision, you have provided a QSAR predictions on the Substance for endpoint(s) listed above.

You have not provided a QPRF or equivalent information. Without such information, the adequacy of the predictions cannot be established.

Therefore, ECHA cannot establish whether the model is scientifically valid, whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment.

II. Selection of the representative structure(s) and coverage of all constituents of the Substance

Under ECHA Guidance R.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following cumulative conditions is/are met:

- representative structure(s) for the assessment are selected.
- different constituents of the same substance are predicted individually.

Your dossier assessed for the initial draft decision provides the following information:

- In Section 1.1 of your technical dossier, you define the Substance as UVCB;
- In the assessment, you do not specify the SMILES (i.e. structure) used for the assessment in all records. However, when the SMILES is provided, this points to a single structure. When the SMILES is not provided, a single predicted value is given, suggesting that only one SMILES was subject to the prediction.

In the dossier assessed for the initial draft decision, you have not demonstrated that you predicted separately different constituents of the Substance nor justify why the single structure selected is representative for the assessment of the whole UVCB.

Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

The adaptation you provided does not fulfil the criteria specified in Annex XI, Section 1.3. and it is therefore rejected.

3. Assessment of your weight of evidence adaptation under Annex XI, Section 1.2.

In your dossier assessed for the initial draft decision, ECHA understands that you have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2:

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

In your comments on the initial draft decision you have proposed to apply weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2:

- Ready biodegradability (Annex VII, Section 9.2.1.1.)

In your dossier assessed for the initial draft decision, or in your comments on the initial draft decision, your weight of evidence adaptation raises the same deficiencies irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed these deficiencies in the present Appendix, before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, Section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation.

Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

The common deficiencies identified below are essential for all the information requirement(s) in which you invoked a weight of evidence, while the specific ones are set out under the information requirement concerned in the Appendices, below.

Reliability of the read across approach

Information from source substance(s) can be used as part of weight of evidence adaptation if the read-across is accepted.

All studies are performed with source substances. Section 1. of the present Appendix identifies deficiencies of the grouping and read across approach used in your dossier. These findings apply equally to the sources of information relating to analogue substances submitted under your weight of evidence adaptations. The information on the source substance(s) does not provide reliable information for weight-of-evidence.

Reliability of the QSAR approach

Section 2. of the present Appendix identifies deficiencies of QSAR approach used in your dossier. These findings apply equally to the sources of information relating to source substances submitted under your weight of evidence adaptations.

In your dossier assessed for the initial draft decision, additional issues related to weight of evidence are addressed under the corresponding Endpoint(s).

Relevance of the different pieces of information

The sources of information need to provide sufficient weight of evidence to conclude that the information requirement for OECD TG 301/310 are fulfilled for the property(ies) ready biodegradability.

ECHA has assessed to what extent the sources of information submitted enables a conclusion on these properties as investigated in the information requirements proposed to be adapted and identified deficiencies in the endpoint sections A.2.

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).

In your dossier assessed for the initial draft decision, you have adapted this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. and Weight of Evidence under Annex XI, Section 1.2. of REACH. In support of your adaptations, you have provided the following sources of information:

i) Weight-of-evidence (2013): QSAR toolbox (version 3.1) prediction for the Substance
ii) Weight-of evidence (2012): Danish EPA (Q)SAR database on analogue substance sodium hydrogen 2-aminopentanedioate (EC 205-538-1).

In your dossier assessed for the initial draft decision, as explained in Sections 1 and 3 of the Appendix on Reasons common to several requests, the read-across adaptations are rejected and the weight of evidence must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

In your dossier assessed for the initial draft decision, we have assessed this information and identified the following issues:

Weight-of-evidence

To fulfil the information requirement, normally a study according to OECD TG 201 must be provided. The key parameter investigated by this test is growth rate of algal cultures or of Lemna sp.

In your dossier assessed for the initial draft decision, all the sources of information you provided investigate the above mentioned key element. Therefore, they provide information that would contribute to the conclusion on this key parameter.

However, the reliability of these sources of information is significantly affected by the deficiencies identified in Section 3 of the Appendix on Reasons common to several requests.

Taken together, even if these sources of information provide information on the key parameters, their reliability is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated by the required study. Therefore, in your dossier assessed for the initial draft decision, your adaptation is rejected and the information requirement is not fulfilled.

In your comments to the initial draft decision, you have provided no further source studies on this endpoint. You acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study.

Study design

The Substance is difficult to test due to the surface active properties of the Substance (although in the dossier, you state that "surface activity is not a desired property of the material", based on the structure of the Substance, surface activity is expected, because the Substance has hydrophilic and lipophilic moieties). 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 under Annex VII to REACH (Section 9.2.1.1.).

In your dossier assessed for the initial draft decision, you have adapted this information requirement by using Qualitative or quantitative structure-activity relationship (QSAR) under Annex XI, Section 1.3. In support of your adaptation, you have provided the following information for this endpoint:

i) Key study (2013): QSAR PBT profiler (version 1.301) prediction for the Substance

In your dossier assessed for the initial draft decision, we have assessed this information and identified the following issue:

As explained in Section 2 of the Appendix common to several requests, your adaptation under Annex XI, Sections 1.3. is rejected.

In your comments to the initial draft decision, you have adapted this information requirement by using Grouping of substances and read-across approaches under Annex XI, Section 1.5. and Weight of Evidence under Annex XI, Section 1.2. of REACH. In support of your adaptations, you have provided the following sources of information:

i) Part of supporting the Weight-of evidence (2021)
   (1) Supporting experimental study 301E with the analogue substance Glutamic acid (CAS no. 56-86-0; EC no. 200-293-7)
   (2) Supporting experimental study with the analogue Glycine, N-coco acyl derivs., sodium salts (CAS no. 90387-74-9; EC no. 291-350-5) in accordance to 'Test Method Relating New Chemical Substances (Kanpogyo No. 5, Yakuhatsu No. 615, 49 Kikyoku No. 392, 1974)
   (3) Supporting experimental study with the analogue Glutamic acid, monosodium salt (CAS no. 142-47-2; EC no. 205-538-1);
   (4) Read-across based on grouping of substances
      (a) QSAR toolbox (version 3.4) prediction(s) for the Substance

All studies and prediction(s) indicate the substances are readily biodegradable.

As explained in Sections 1. A. and 3 of the Appendix on Reasons common to several requests, the read-across adaptation are rejected and the weight of evidence must fulfil the information

requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

In your dossier assessed for the initial draft decision, we have assessed this information and identified the following issues:

Weight-of-evidence

To fulfil the information requirement, normally a study according to OECD TG 301A/B/C/D/E/F or 310 must be provided. The key parameter investigated by this test is the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation.

All the sources of information you provided investigate this key parameter. Therefore, they provide information that would contribute to the conclusion on this key parameter.

However, the reliability of these sources of information is significantly affected by the deficiencies identified in Section 3 of the Appendix on Reasons common to several requests. Taken together, even if these sources of information provide information on the key parameter, their reliability is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous property foreseen to be investigated by the required study. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

On this basis, the information requirement is not fulfilled.

In addition, in your comments to the initial draft decision, you state that if ECHA is not satisfied with the above weight of evidence argument, you would consider testing of Ready biodegradability which would be performed in accordance with an internationally accepted standard test guideline, to support the classification of the Substance .

Appendix B: 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[12].

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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.
   - The reported composition must also include 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[13].

[12] https://echa.europa.eu/practical-guides
[13] https://echa.europa.eu/manuals

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

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents 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 synthesize its relevant constituents and/or fractions.

Appendix D: Procedure

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

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 21 April 2020.

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

ECHA took into account your comments and did amend the request(s) and did amend the deadline(s).

More specifically, due to a cease of manufacture, the following requests have been removed from this draft decision:

- Justification for an adaptation of short-term toxicity testing on aquatic invertebrates based on the results of the Long-term toxicity testing on aquatic invertebrates
- Justification for an adaptation of short-term toxicity testing on fish based on the results of the Long-term toxicity testing on fish
- Long-term toxicity testing on aquatic invertebrates
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)
- Simulation testing on ultimate degradation in surface water at a temperature of 12 °C
- Identification of degradation products

In addition, the removal of the above requests, has resulted in the amending of the deadline, from 18 to 12 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 E: List of references - ECHA Guidance[14] 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)[15]

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[16]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

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.