~~Confidential~~

Helsinki, 20 September 2021

Addressees
Registrant(s) of JS_915-656-1 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
25/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of l-Glutamic acid, N-coco acyl derivs., monosodium salts and sodium hydrogen N-(1-oxooctadecyl)-L-glutamate
EC number: 915-656-1
CAS number: NS

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 September 2022***.

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

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

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

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 VIII 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 Annexes VII and VIII to REACH, for registrations 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 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:

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

You have not provided a read-across justification document in the technical dossier.
You read-across between the structurally similar substances, [redacted] (L-Glutamic acid, N-coco acyl derivs., monosodium salts), EC No. 269-087-2 (CAS No. 68187-32-6) as source substance and the Substance as target substance.

You have not provided any reasoning for the prediction of ecotoxicological and biodegradability properties.

Despite above, 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 ecotoxicological and biodegradability properties.

1. *Absence of read-across documentation*

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

[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

justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[4]

You have provided studies conducted with another substance than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In your comments to the initial draft decision, you acknowledge the absence of a RAAF report to properly justify the proposed read-across. You wish to confirm to ECHA that such a RAAF report is currently in preparation and will be provided shortly via a registration update. The RAAF report will include a comparison of the source and target substances as well as justification as to why the proposed read-across is considered valid.

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 documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

2. *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).[5] 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.

In the technical dossier, there is currently no compositional information of the test material for the source substance.

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

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.6.1
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1

3. 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 substance.

As indicated above, 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).

The data set reported in the technical dossier does not include any relevant, reliable and adequate information for the Substance 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.

In your comments to the initial draft decision, you indicate as noted by ECHA the endpoints have each been read-across to the similar substance EC No. 269-087-2 (CAS No. 68187-32-6). You indicate that access to this data has been arranged by you from the data owner. You indicate that the data owner has used the same data in support of their registration of L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) and have received similar comments from ECHA in their draft decision. You therefore indicate you refer ECHA to the responses prepared by the data owner for that substance as the data used is the same. You indicate that your comments to the initial draft decision are essentially those provided by the data owner but you do not have access to the supporting materials that they have provided as attachments in their comments to the initial draft decision on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4).

You indicate that this paragraph applies to all the requests in this decision.

In summary you provided your intentions for future data. No information could be assessed. Therefore ECHA cannot assess from your comments if you have addressed the request(s). It is not for ECHA to develop an adaptation that is not substantiated in the registration dossier or in the comments to the draft decision; in particular if you indicate that you have no access to this information. In any case, the points mentioned in your comments do not address deficiencies identified in this decision.

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)."

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.

4. Further deficiency

Additional endpoint-specific deficiency is addressed under Section A.3.

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. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Annex VII, Section 9.1.1., Column 2 or a general adaptation rule under Annex XI.

You have adapted the standard information requirements mentioned above according to Annex XI, Section 1.5. (grouping of substances and read-across approach) of REACH. In support of your adaptations, you have provided the following sources of information:

i. Key study: OECD TG 202 (2017) with the analogue substance L-Glutamic acid, N-coco acyl derivs., monosodium salts (EC 269-087-2, CAS 68187-32-6).

In your dossier assessed for this decision and based on your comments to the initial draft decision, 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 your comments to the initial draft decision, you indicate that the data owner (registrant of of L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) has reviewed the study report on the read-across substance, EC No. 269-087-2 (CAS No. 68187-32-6) and has made the following comments:

1. "The hardness of the test medium is 250 mg/L as CaCO3 2)
   a. The particulate matter and TOC content were checked to be guideline compliant"
   b. The data owner agrees to update the robust study summary for this endpoint accordingly with the next dossier update.

The data owner agrees to update the robust study summary for this endpoint on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4), with the read-across substance information, EC No. 269-087-2 (CAS No. 68187-32-6) and to provide the relevant read-across justification in their dossier update on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4).

You agree to do the same for your Substance.

No such deficiencies have been raised, in the decision and this point is therefore not relevant. On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the surface active properties (Surface tension= 29.1 mN/m). OECD TG 202 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 202. 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. 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 sources of information:

i. Key study: OECD TG 201 (2018) with the analogue substance substance L-Glutamic acid, N-coco acyl derivs., monosodium salts (EC 269-087-2, CAS 68187-32-6).

In your dossier assessed for this decision and based on your comments to the initial draft decision, 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 your comments to the initial draft decision, you indicate that the data owner (registrant of L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) has reviewed the study report on the read-across substance, EC No. 269-087-2 (CAS No. 68187-32-6) and have made the following comments:

1. By reanalyzing the algae tox test raw data in order to check the fulfilment of the validity criteria we can conclude that all mentioned specifications are met.
2. In addition, it is mentioned that the substance is difficult to test and thus it is required to monitor the test concentration(s) of the substance throughout the exposure duration and report the results.
    1) In the algal test the exposure was verified using TOC analysis. This methodology is considered to be appropriate, since the substance is well soluble in water.
    2) Because of the good analytical recovery of the test substance (91.9 % determined by Total Organic Carbon analysis) the nominal concentrations were taken into account for the calculation of the EC values.
3. The data owner agrees to update the robust study summary for this endpoint accordingly with the next dossier update.
4. In addition in the aquatic testing strategy, the data owner indicates
    1) A respective justification considering the available and valid short-term test with fish and indicating that the algal toxicity test is sufficient to conclude on the accurate acute environmental classification will be provided.

The data owner agrees to update the robust study summary for this endpoint on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4), with the read-across substance information, EC No. 269-087-2 (CAS No. 68187-32-6) and to provide the relevant read-across justification in their dossier update on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4).

You agree to do the same for your Substance.

No such deficiencies have been raised in the decision and this point is therefore not relevant. On this basis, the information requirement is not fulfilled.

Study design
OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above in A.1., the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

3. Ready biodegradability

Ready biodegradability is an information requirement under 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 adaptations, you have provided the following sources of information:

i. Key study: OECD TG 301D (2016) with the analogue substance L-Glutamic acid, N-coco acyl derivs., monosodium salts (EC 269-087-2, CAS 68187-32-6).

In your dossier assessed for this decision and based on your comments to the initial draft decision, 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:

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should, among others
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 301 or 310. For that purpose, the following specifications of OECD TG 301 must be met in this case;

- The inoculum is not pre-adapted to the test material;
- The concentration of the inoculum is set to reach a bacterial cell density of 10^4 to 10^6 cells/L in the test vessel;

In the technical dossier which was assessed for the initial draft decision, you indicated the inoculum as '*activated sludge, domestic (adaptation not specified)*' with the source of inoculum/activated sludge being '*secondary effluent, microorganisms from a domestic waste water treatment plant in* [redacted] *- Concentration of sludge: 0.5 mL/L'*.

You did not specify whether the inoculum is pre-adapted to the test material nor reported on the setting of the concentration of the inoculum to reach the test guideline's bacterial cell density.

In your comments to the initial draft decision, you indicate that the data owner (registrant of of L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) has reviewed the study report on the read-across substance, EC No. 269-087-2 (CAS No. 68187-32-6) and have made the following comments:

- By reanalyzing the algae tox test raw data in order to check the fulfilment of the validity criteria we can conclude that all mentioned specifications are met.
- In addition, it is mentioned that the substance is difficult to test and thus it is required to monitor the test concentration(s) of the substance throughout the exposure duration and report the results.
- In the algal test the exposure was verified using TOC analysis. This methodology is

considered to be appropriate, since the substance is well soluble in water.
- Because of the good analytical recovery of the test substance (91.9 % determined by Total Organic Carbon analysis) the nominal concentrations were taken into account for the calculation of the EC values.
- The data owner agrees to update the robust study summary for this endpoint accordingly with the next dossier update.
- In addition in the aquatic testing strategy, the data owner indicates
- A respective justification considering the available and valid short-term test with fish and indicating that the algal toxicity test is sufficient to conclude on the accurate acute environmental classification will be provided.

The data owner agrees to update the robust study summary for this endpoint on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4), with the read-across substance information, EC No. 269-087-2 (CAS No. 68187-32-6) and to provide the relevant read-across justification in their dossier update on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4).

You agree to do the same for your Substance.

In summary you provided your intentions for future data. No information could be assessed. Therefore ECHA cannot assess from your comments if you have addressed the request(s). Regarding the request to look into comments from another registrant and a different draft decision, it is not for ECHA to develop an adaptation that is not substantiated in the registration dossier or in the comments to the draft decision. In any case, this information does not address the deficiencies addressed above.

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)."

Based on the above,
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Therefore, the requirements of OECD TG 301 are not met.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 301 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, in A.1. the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

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

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

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 sources of information:

i. Key study: OECD TG 203 (2018) with the analogue substance L-Glutamic acid, N-coco acyl derivs., monosodium salts (EC 269-087-2, CAS 68187-32-6).

In your dossier assessed for this decision and based on your comments to the initial draft decision, 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 your comments to the initial draft decision, you indicate that the data owner (registrant of L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) has reviewed the study report on the read-across substance, EC No. 269-087-2 (CAS No. 68187-32-6) and have made the following comments:

1. "We confirm that analytical measurements are a standard requirement of current standard ecotox tests and that exposure control analytics was not performed in this test.
    1) However, based on the high-water solubility of the test substance exposure of the test animals to the respective nominal concentrations can safely be assumed. This is confirmed by TOC analysis in other ecotox tests provided in the dossier.
    2) Nevertheless, as mentioned in the draft decision, according to 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, as we propose to perform the long-term toxicity test with fish.
    3) A respective justification considering the available and valid short-term test with fish and indicating that the algal toxicity test is sufficient to conclude on the accurate acute environmental classification will be provided."
    4) The data owner notes that the data owner is proposing to complete a chronic fish study on the read-across substance and is proposing not to repeat the acute fish study.
    5) A decision on how to address this endpoint will be made once the final ECHA decisions are received.

You outline a proposed testing strategy of the data owner, which will be finalised once they receive the adopted decision. They propose to undertake a long term toxicity fish on EC No. 269-087-2 (CAS No. 68187-32-6) and to provide the relevant robust study summary and read-across justification in their dossier update on L-Glutamic acid, N-coco acyl derivs., disodium (EC 269-085-1, CAS 68187-30-4) and provide a validated justification for the short term toxicity in fish to conclude on the accurate acute environmental classification. None of these statements/adaptations are substantiated.

You agree to do the same for your Substance.

First, no analytical measurement deficiency has been raised in the decision and this point is therefore not relevant.

Second, in your comments to the initial draft you also state that the data owner invokes 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.

Third, the present decision requests a short term toxicity testing on fish, only.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 203 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, in A.1. the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

Appendix C: 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[6].

B. Test material

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 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
   - 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

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

Appendix D: 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 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).

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[8] 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)[9]

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[10]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] 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]

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.