~~Confidential~~

Helsinki, 20 September 2021

**Addressees**
Registrant(s) of JS_68187-30-4 as listed in the last Appendix of this decision

**Date of submission of the dossier subject to this decision**
04/12/2018

**Registered substance subject to this decision ("the Substance")**
Substance name: L-Glutamic acid, N-coco acyl derivs., disodium salts
EC number: 269-085-1
CAS number: 68187-30-4

**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 ***3 January 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. Justification for an adaptation of short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.) based on the results of the Long-term toxicity testing on aquatic invertebrates requested below (Annex IX, Section 9.1.5.)

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

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

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

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

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

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

**Information required depends on your tonnage band**

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

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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

**How to comply with your information requirements**

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". 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.**

In your dossier assessed for the initial draft decision, 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 ecotoxicological properties**

In your dossier assessed for the initial draft decision, you have provided a read-across justification document in IUCLID Section 13.

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

You have provided the following reasoning for the prediction of toxicological properties: "*the read across to the source substance is considered valid as the target substance and the source substance are structurally very similar (having identical functional groups), which assumes very similar physco-chemical properties resulting in identical environmental behaviour and ecotoxicity".* The source substance (CAS No. 68187-32-6) "*is structurally identical amd solely differ on the degree of deprotonation being a monosodium (source substance) instead of disodium (target substance)*".

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.

[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

ECHA notes the following shortcoming(s) with regards to prediction(s) of aquatic toxicity.

*Adequacy and reliability of source study*

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:

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

In your comments to the initial draft decision on the requests, (addressed under the requests) you have agreed to correct the observed deficiencies under adequacy and reliability of source study for Short-term toxicity testing on aquatic invertebrates and Growth inhibition study aquatic plants. Regarding Ready biodegradability endpoint you agreed to perform the study on the Substance and you agreed to perform a long term toxicity testing on Fish on the Substance and then provide a justification for the short term toxicity testing on Fish (addressed under the requests).

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)."

*Test material identity*

The Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*". Therefore, the unambiguous characterisation of the composition of the test material used to generate the source data is required to assess whether the test material is representative for the source substance as defined in the read-across justification document and thus relevant to the Substance.

In your dossier assessed for the initial draft decision, there is currently no compositional information for the source substance. Furthermore, the information on the composition of the test materials of the source data provided in your dossier is limited in general to the generic name of the test substance. It does not contain information on the chemical identity and quantitative occurrence of its constituents.

Without comprehensive reporting of all constituents present in the test material (including their identity and concentrations), no qualitative or quantitative comparative assessment of the compositions of the source substance and the Substance can be completed.

In you comments to the initial draft decision you submitted your comments and the following attachments:

1. Specification of [redacted] of CAS 68187-32-6 2.
2. Specification of [redacted] of CAS 68187-30-4 3.
3. Acute Daphnia statement TOC
4. Chronic Daphnia statement TOC
5. Re-assessment algae

6. Statement [redacted]

You agreed to revise your read-across justification document and update your dossier with the above listed attachments.

ECHA has assessed all your provided information, found it compliant but the following could be made clearer in particular in relation to cross referencing aspects:

- The Certificate of Analysis (CoA) of your supplier (2001) was of poor quality to read.
- A large number of different trade names/product names were used for the Substance and the source substance.
    - In the hazard sections of the dossier and in the revised read-across justification, all the provided names need to be cross referenced.
- You did not state that the identity and composition of the Substance indicated is identical to the information in the dossier under Section 1.2
- The summary in Table 1 [redacted] (incl. small variations based on the natural origin) :
    - Please include if possible the Substance Identification Profile (attachment 6) to the same document for ease of cross referencing (or cross reference these aspects in another manner).
    - In the attachment 6, the following statement is included:
        - The composition of the Substance and the source substance were almost the same (depending on the actual composition of the [redacted] part) indicated here as [redacted]The significance of this statement should be explained/clarified in light of the CoA of the raw materials in attachment 1 and 2.
- No revised read-across justification integrating all this submitted information in your comments to the initial draft decision.

There are other issues identified in the initial draft decision. So this information does not change the overall 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)."

Due to the above issues in your dossier assessed for the initial draft decision and in your comments to the draft decision, ECHA concludes that it is not possible to assess whether the test material is representative for the source substance and thus relevant to the Substance. Therefore, the studies listed above cannot be considered as adequate for the purpose of classification and labelling and/or risk assessment.

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

In your dossier assessed for the initial draft decision, 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 (2011) with Sodium cocoylglutamate (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

We have assessed this information and identified the following issues:

As explained in Section 1 of the Appendix on Reasons common to several requests in your dossier assessed for the initial draft decision and in your comments to the initial draft decision your adaptation under Annex XI, Section 1.5. is rejected.

In addition, in your dossier assessed for the initial draft decision, the following endpoint-specific deficiencies have been identified in your read-across adaptation:

To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test. Therefore, the following specifications must be met:

- the test medium fulfils the following condition(s): particulate matter ≤ 20 mg/L, total organic carbon (TOC) ≤ 2 mg/L, hardness between 140 and 250 mg/L (as CaCO3).

Your registration dossier provides an OECD TG 202 showing the following:

- You did not report the TOC and hardness of the test medium.

In your comments to the initial draft decision, you provided a signed statement of the TOC content of the dilution water from the laboratory where the OECD TG 202 (2011) was performed (attachment 3). The signed statement indicated that as per SOP (Standard Operating Procedure) deionised water may only be used if the measured TOC is < 1 mg/L. The specification in the aquatic testing guideline of TOC < 2 mg/L in the water used for the medium is therefore fulfilled. The exact TOC measured value of the used batch of water can be made available upon request.

In your comments to the initial draft decision, you indicated that the water hardness of the test medium was 250 mg/L as CaCO3.

You indicated you would update your dossier.

ECHA has assessed the submitted information and found it acceptable to OECD TG 202. However, as stated above, your adaptation under Annex XI, Section 1.5. is rejected.

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)." You must provide this information in your updated dossier by the deadline of this decision.

Based on the above, in your dossier assessed for this decision the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

On this basis, the information requirement is not fulfilled.

The present decision requests the registrant(s) concerned to conduct and submit a long-term toxicity study on aquatic invertebrates (OECD TG 211; see Appendix C.1 for details). According Annex VII, Section 9.1.1., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study on aquatic invertebrates does not need to be provided.

Because you still must comply with the information requirement in Annex VII, Section 9.1.1., you are requested to submit a justification for the adaptation provided in Annex VII, Section 9.1.1., Column 2, second indent.

**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 (2001) with N-cocoylglutaminsäure-Mononatriumsalz (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

We have assessed this information and identified the following issue:

As explained in Section 1 of the Appendix on Reasons common to several requests in your dossier assessed for the initial draft decision and in your comments to the initial draft decision your adaptation under Annex XI, Section 1.5. is rejected.

In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

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

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

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

In your comments to the initial draft decision, you provided the raw data in attachment 5 to confirm the validity criteria were met:

a. You provided the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures

was 20.2% i.e. ≤ 35%;

b. the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 2.3% i.e. ≤ 7% in tests with Desmodesmus subspicatus.

In addition, you also indicated that monitoring of the test concentration(s) of the substance occurred throughout the exposure duration, using TOC analysis. As the analytical recovery of the test substance was between 80-120% of the nominal concentration(s) (91.9% determined by Total Organic Carbon analysis), the nominal concentrations were taken into account for the calculation of the EC values.

You indicated you would update your dossier.

ECHA has assessed the submitted information and found it acceptable to OECD TG 201. However, as stated above, your adaptation under Annex XI, Section 1.5. is rejected.

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)." You must provide this information in your updated dossier by the deadline of this decision.

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

On this basis, the information requirement is not fulfilled.

*Study design*

The Substance is difficult to test due to surface active property ((1) reported surface tension: 61.1mN/m is close to the indicator value (<60mN/m) and (2) You stated in the technical dossier that used as "surface active agents"). 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.

### 3. Ready biodegradability

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

In your dossier assessed for the initial draft decision, you 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 301E (1989) with N-cocoylglutaminsäure-mono-Na-Salz (EC Nr. 269-087-2/ CAS Nr. 68187-32-6).

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

As explained in Section 1 of the Appendix on Reasons common to several requests in your dossier assessed for initial draft decision, your adaptation under Annex XI, Section 1.5. was rejected.

In your comments to the initial draft decision on the requests, you agree to perform the study on the Substance.

In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation.

To fulfil the information requirement, a study must comply with the OECD TG 301 or 310. Therefore, for a study according to OECD TG 301, the following requirements must be met:

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

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

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

In your comments to the initial draft decision, you indicate that the non-adaption of the inoculum, the origin of the inoculum as well as the concrete concentration of the inoculum applied is not specified in the full study report.

Therefore, in your dossier assessed for this decision and in your comments to the initial draft decision, you have not demonstrated that validity criteria were fulfilled. In relation to the other deficiencies, we are not in a position to conduct an independent assessment of the study reliability.

On this basis, in your dossier assessed for this decision and in the comments to the initial draft decision, the information requirement is not fulfilled.

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

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

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

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. of REACH. In support of your adaptations, you have provided the following source of information:

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

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

As explained in Section 1 of the Appendix on Reasons common to several requests in the dossier assessed for initial draft decision and in your comments to the initial draft decision, your adaptation under Annex XI, Section 1.5. is rejected.

In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

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

- the analytical measurement of test concentrations is conducted;

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

- no analytical measurement of test concentrations was conducted;

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

In your comments to the initial draft decision, whilst you confirm that no analytical measurement of test concentrations were conducted, you outline that based on the high water solubility of the test substance exposure of the test organisms to the respective nominal concentrations and the TOC analysis in other ecotox tests, similar results could be expected for the fish.

There are a number of uncontrolled aspects in the laboratory based ecotox testing like for example the behaviour of the organisms during the duration of the tests can be very different; whilst the test mediums for Fish and Daphnia are the most similar of the ecotox testing, the duration of these two ecotox tests are very different, 96 hrs and 48 hrs, respectively. In order to reduce the number of different variables, one of the most important aspects for an OECD TG 203 is to use a validated analytical method during the exposure of the test material to the organisms. You have not demonstrated, nor substantiated, your claim that the high water solubility of the Substance and TOC analysis in other ecotox tests would equally serve the purpose of a validated analytical method. As you did not undertake the analytical measurement of test concentrations or provide a valid justification, this validity criterion of OECD TG 203 is still not met.

On this basis, the information requirement is not fulfilled.

In your comments to the initial draft decision on the requests, you proposed to provide a justification for this endpoint, based on the long term aquatic fish testing with the Substance. You indicated you will update your dossier.

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)."

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

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

### 1. Long-term toxicity testing on aquatic invertebrates

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

You have provided OECD TG 211 Key study (2016) with the Substance.

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

To fulfil the information requirement, a study must comply with the OECD TG 211 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

- young female *Daphnia*, aged less than 24 hours at the start of the test, are used;
- the test temperature is within 18°C and 22°C and not varying by over ±2°C;
- the test medium fulfils the following condition: total organic carbon (TOC) ≤ 2 mg/L.

Your registration dossier provides an OECD TG 211 showing the following:

- you did not specify the age of the test organisms at the start of the test.
- you reported that test temperature was 17.8-21.6°C, hence it varied over 2°C.
- You did not report TOC of the test medium.

Based on the above, in the dossier assessed for the initial draft decision, the reporting of the study is not sufficient to conduct an independent assessment of its reliability and there is critical methodological deficiency resulting in the rejection of the study results. More, specifically test temperature deviates from what is specified in the TG.

On this basis, in your dossier assessed for the initial draft decision the information requirement is not fulfilled.

In your comments to the initial draft decision, you indicated you had reviewed the full study report and you confirmed the following:

2. The age of the organisms at the start of the test was < 24h.
3. The temperature for the main test was slightly out of the demanded range (17.8 to 21.6°C instead of 18 to 22 °C). It was observed and justified as acceptable by the study director on March 03, 2016, taking into account the mean of 19.7 °C the values are not varying more than ± 2°C and no significant effects on reproductive output occurred during the test.
4. TOC of the test medium:
    a. You provided a signed statement of the TOC content of the dilution water from the laboratory where the OECD TG 211 (2016) was performed (attachment 4). The signed statement indicated that as per SOP (Standard Operating Procedure) deionised water may only be used if the measured TOC is < 1 mg/L. The specification in the aquatic testing guideline of TOC < 2 mg/L in the water used for the medium is therefore fulfilled. The exact TOC measured value of the used batch of water can be made available upon request.
5. You indicated you would update your dossier.

ECHA has assessed the information against the requirement in OECD TG 211. The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

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

**2. Long-term toxicity testing on fish**

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

You have provided the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: The hazard assessment of the Substance reveals that fish is not the most sensitive organisms and for the reasons of animal welfare, a long-term test in fish is not provided.

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

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

Your adaptation is therefore rejected.

In the comments to the initial draft decision, you agree that a long-term toxicity test with fish would provide valuable new information for the hazard assessment of the Substance and therefore you agree to perform the test.

On this basis, the information requirement is not fulfilled.

*Study design*

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

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

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

### A. Test methods, GLP requirements and reporting

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

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

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

### 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[5].

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

## Appendix E: 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 F: Procedure

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

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 09 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 G: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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

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

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

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

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

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

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

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

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

OECD Guidance documents[9]

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

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

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

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

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

## Appendix H: 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] |
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| [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.