~~Confidential~~

Helsinki, 06 September 2021

Addressees
Registrant(s) of JS_112-70-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
27/11/2018

Registered substance subject to this decision ("the Substance")
Substance name: Tridecan-1-ol
EC number: 203-998-8
CAS number: 112-70-9

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 ***13 March 2023***.

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

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

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29)

2. Only if study under section A.1 shows the substance is not poorly water soluble, Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

3. Only if study under section A.1 shows the substance is poorly water soluble, Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

4. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: [EU C.3./OECD TG 201 // EU C.26./OECD TG 221)

Reasons for the request(s) are explained in aappendix 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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa).

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

How to comply with your information requirements

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

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

Appeal

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

Failure to comply

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

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

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

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

1. Water solubility

Water solubility is a standard information requirement in Annex VII to REACH.

Your dossier contains data for this endpoint, which according to the information you provided is an experimental value from a database (IFA GESTIS - Substance Database - Information system on hazardous substances of the Berufsgenossenschaften, 2018). You have reported a water solubility of 100 mg/L and you have concluded that the Substance is "slightly soluble in water". The study report does not provide any further study specifications.

We have assessed this information and identified the following issue(s):

To fulfil the information requirement, a study must comply with OECD TG 105 (Article 13(3) of REACH). Therefore, the following specifications must be met:

- Coverage of the key parameter which is the saturation mass concentration of the test substance in water at 20°C,
- For the column elution and flask method, the following is required to be reported (among others):
  - the individual analytical determinations and the average where more than one value was determined,
  - the pH of each sample,
  - the test temperature,
  - the analytical method employed.

You have not provided any data on study specifications.

Therefore, you have not demonstrated compliance with the above key parameter and the reporting of the study is not sufficient to conduct an independent assessment of its reliability.

Based on the above assessment, the information requirement is not fulfilled.

Study design

Considering the properties of the Substance (the information provided does not exclude solubility < 10 mg/L), the column elution described in EU A.6/OECD TG 105 is the most appropriate method to fulfil the information requirement for the Substance.

In your comments to the draft decision you agree to perform the study with the Substance according to the OECD TG 105.

2. 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.).

Annex VII, section 9.1.1, column 2, requires to perform a long-term toxicity study on aquatic invertebrates instead of an acute test when the substance concerned is poorly water soluble. In that respect, as explained under request A.1, your dossier currently does not include reliable value on the water solubility of the Substance. Therefore, a short-term toxicity testing on aquatic invertebrates must only be conducted if the data generated under request A.1 shows that the Substance is sufficiently soluble in water (i.e. water solubility above 1 mg/L).

You have provided the following information

1) Key OECD TG 202 study performed with the Substance - Daphnia sp. Acute Immobilisation Test, Japan chemicals collaborative knowledge database (J-check), 2017;

2) Supporting OECD TG 202 study performed with the Substance - Daphnia sp. Acute Immobilisation Test, from peer reviewed publication: Toxicity of test material on aquatic invertebrate, Peter R. Fisk et al, Ecotoxicology and Environmental Safety, 2009;

3) Supporting non-guideline short-term toxicity study performed with the Substance on Mysidopsis bahia from peer reviewed publication: Patoczka, J. et al, Water Research, 1990;

4) Supporting non-guideline short-term toxicity study performed with the Substance on aquatic invertebrates from OECD SIDS Initial Assessment Report for SIAM 22, 2006.

We have assessed this information and identified the following issues:

A. Studies 1) and 2)

To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met (among others):

Validity criteria
- the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
- the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;

Technical specifications impacting the sensitivity/reliability of the test
- 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 $CaCO_3$), pH between 6 and 9;

Characterisation of exposure
- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results
- the dissolved oxygen and pH measured at least at the beginning and end of the test is reported;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided.

<u>On studies 1) and 2)</u> the following elements are missing:

- the percentage of immobilised daphnids at the end of the test in the controls;
- the dissolved oxygen concentration in all test vessels at the end of the test;
- the quality of the medium (particulate matter, TOC, hardness, pH);

- no analytical monitoring of exposure was conducted;

Furthermore, under principles of method for studies 1) and 2) you have indicated the basis of effect as "growth of Daphnia magna" which is not the effect investigated under OECD TG 202. In addition, the exposure duration reported for study 1), namely 96 hours is inconsistent with the value indicated under 'Total exposure duration' section of your dossier (48 hours).

Based on the above, there are critical deficiencies and the reporting of studies 1) and 2) is not sufficient to conduct an independent assessment of their reliability and to verify the validity criteria of the test guideline. Therefore, the requirements of OECD TG 202 are not met for studies 1) and 2).

B. Study 3)

To fulfil the information requirement, a study according to US EPA 40 CFR 797.1930 is an acceptable method (Article 13(3) of REACH; ECHA Guidance R.7, Appendix R.7.8.2). For such a study, the following specifications must be met:

Validity criteria
- test is unacceptable if more than 10 % of the control organisms die or exhibit abnormal behaviour during the 96 hour test period;

Technical specifications impacting the sensitivity/reliability of the test
- The test must be conducted on the mysid life stage (juveniles or young adults) which is most sensitive to the test substance being evaluated;
- the dissolved oxygen concentration, temperature, salinity, and pH must be measured at the beginning and end of the test.

Characterisation of exposure
- the test duration is 96 hours.

Based on the reported data (for example: test organism, type of medium) ECHA understands that the study is a short-term toxicity test on *Mysidopsis bahia* performed in a saltwater in accordance with EPA OPP 72-3 guideline (equivalent to US-EPA: 40 CFR 797.1930).
The study summary for study 3) is missing the following elements:
- the percentage of dead mysids/mysids that exhibited abnormal behavior in the control at the end of the test;
- information on the mysid life stage used for the test;
- dissolved oxygen concentration, salinity and hardness;
- the test duration reported in your dossier is 48 hours.

Based on the above, study 3) does not meet the information requirement as the validity criteria of the test guideline cannot be verified. In addition, there are critical methodological deficiencies such as absence of adequate information on the test design and test procedure resulting in the rejection of the study results. In addition, you have used a saltwater guideline, whereas the recommended guideline is for freshwater.

Finally, you have not provided any information about the test guideline followed, which is itself a critical deficiency as it does not allow an independent assessment of the study.

On this basis, study 3) does not fulfil the information requirement.

C. Study 4)

To the study 4) you have assigned the reliability 4 (not assignable). Based on the reported data ECHA agrees that the results from this study are not reliable. Thus, study 4) does not provide the information required by Annex VII, Section 9.1.1.

In your comments to the draft decision you provided the following adaptation under Annex VII, Section 9.1.1, Column 2):

"By considering the outcomes of long-term studies, and information on reproductive output would be adequate to classify the chemical into chronic category 3."

We have assessed this information and identified the following issue:

This information requirement may be adapted under Annex VII, Section 9.1.1, Column 2, if
- a long-term aquatic toxicity study on invertebrates is available, or
- adequate information for environmental classification and labelling is available.

You have provided the outcomes of three long-term studies (mentioned under Section 3 below) but no details of "information on reproductive output".

As explained in section 3 below, the information provided on long-term toxicity in aquatic invertebrates is rejected and thus you have not demonstrated that it is adequate for classification and labelling.

Therefore, the information requirement is not fulfilled.

As explained above, your dossier currently does not include reliable value on the water solubility of the Substance. Therefore, a short-term toxicity testing on aquatic invertebrates must only be conducted if the data generated under request A.1 shows that the Substance is sufficiently soluble in water (i.e. water solubility above 1 mg/L).

3. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII of REACH. However, pursuant to Annex VII, section 9.1.1, column 2, for poorly water soluble substances (e.g. water solubility below 1 mg/L or below the detection limit of the analytical method of the test substance) long-term toxicity study on aquatic invertebrates (Annex IX, Section 9.1.5) must be considered instead of a short-term test.

As explained under request A.1, your dossier currently does not include reliable data on the water solubility of the substance. More specifically, the studies discussed under request A.1 are not compliant and do not allow the determination of a precise value for water solubility.

Poorly water soluble substances require longer time to reach steady-state conditions. Hence, the short-term tests may not give a true measure of toxicity for this type of substances. Therefore, if the information requested on water solubility (request A.1) confirms that the Substance is poorly water soluble (<1 mg/L), then a long-term toxicity test on aquatic invertebrates will have to be conducted.

You have provided the following information:

i. Key OECD TG 211 study performed with the Substance from database: Long-term toxicity to aquatic invertebrates, National Institute of Technology and Evaluation, Japan chemicals collaborative knowledge database (J-check), 2018.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 211 (Article 13(3) of REACH). Therefore, the following specifications must be met (among others):

Validity criteria

- the percentage of mortality of the parent animals (female *Daphnia*) is ≤ 20% at the end of the test;
- the mean number of living offspring produced per parent animal surviving is ≥ 60 at the end of the test;

Technical specifications impacting the sensitivity/reliability of the test

- the test temperature is within 18°C and 22°C and not varying by over ±1°C;
- oxygen concentration, temperature, hardness and pH values are measured at least once a week, in fresh and old media, in the control(s) and in the highest test substance concentration;

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

Reporting of the methodology and results

- water quality monitoring within the test vessels (*i.e.* pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is reported;
- the full record of the daily production of living offspring during the test by each parent animal is provided;
- the number of deaths among the parent animals (if any) and the day on which they occurred is reported;

Your registration dossier is missing the following information:

Validity criteria

- any information about the survival of the parent animals (female Daphnia) and the number of living offspring produced per parent animal surviving at the end of the test.

Technical specifications impacting the sensitivity/reliability of the test

- information on the feeding rate;
- the test temperature is 24 ± 1° C, i.e. higher than the range required by OECD TG 211 (18-22°C and not varying by over ±1°C);

Characterisation of exposure

- you have specified gas chromatography with mass spectrometry (GC/MS) as analytical method, however you have not provided the performance parameters of the analytical method such as recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range;

Reporting of the methodology and results

- the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;
- the full record of the daily production of living offspring during the test by each parent animal is not provided;
- water quality monitoring within the test vessels (pH, dissolved oxygen concentration,

hardness) is not reported;

In your comments to the draft decision you refer to the key study and indicate: "(…) *we have reviewed the details and the study was carried out as per the OECD Guideline 211 (Daphnia magna Reproduction Test) method. Although details are not reported in depth in the study, since it is a published information, it was expected to follow the principles of the reported test method thereby fulfilling the validity criteria of the same.*"

You have not provided specific information addressing the issues identified above.

Based on the above, the key parameters of OECD TG 211 are not reported, the validity criteria of OECD TG 211 cannot be verified, and the reporting of the study is not sufficient to conduct an independent assessment of its reliability. The information provided in your comments do not change this assessment.

In your comments you provided an adaptation which ECHA understands is based on Annex XI, Section 1.2 (weight of evidence).

To justify your adaptation you indicate*: "(…) the information requirement for the long term toxicity to aquatic invertebrates is fulfilled from the (…) data of read across analogues which shall be updated within the dossier submitted on REACH-IT system shortly."*

ECHA understands that you propose to fulfil the information requirement by applying a weight of evidence approach according to Annex XI, Section 1.2. of REACH. In support of your adaptation, you refer to the following sources of information:

A. the existing key study performed with the Substance according to OECD TG 211: Long-term toxicity to aquatic invertebrates, National Institute of Technology and Evaluation, Japan chemicals collaborative knowledge database (J-check), 2018,

and you provide in your comments to the draft decision the following data:

B. Outlines of the three studies performed with analogue substances:
    1. OECD 211 study with Dodecanol, EC 203-982-0;
    2. OECD 202 study – Daphnia sp. Acute immobilization test, Part 2 method, with Dodecanol, EC 203-982-0;
    3. OECD 211 study with Octanol, EC 203-917-6;

Based on the above sources of information you argue that the available data gives sufficient information to conclude on long-term toxicity to aquatic invertebrates.

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

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, 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 adaptation.

ECHA has assessed the validity of your adaptation and identified the following shortcomings with regards to prediction of (eco)toxicological properties:

To fulfil the information requirement, normally a study according to OECD TG 211 must be provided. The key investigations of this test are the concentrations of the test material leading to no observed effect (NOECs) estimated on the following parameters:

i) the reproductive output of *Daphnia* sp. expressed as the total number of living offspring produced at the end of the test,
ii) the survival of the parent animals during the test, and
iii) the time to production of the first brood.

i) Reproductive output

Only source A. provides a NOEC (21-day). For studies within the source B you indicate:*"the number of juvenile organisms is determined"* (study 2) and *"Effect parameter measured: (…) reproduction rate and appearance of offspring, daily."* (study 3). For study 1 you indicate: *"For each endpoint, the NOEC, LOEC, and, if possible, the EC50, EC20 and EC10 were determined"* and *"reproduction data of the test daphnids during the exposure period is reported in technical dossier".* We understand that such data are reported in the respective technical dossiers for those source substances, however this information is currently not available in your registration dossier. Therefore, source A contributes to the key investigation but it is unclear, you have not demonstrated, that source B does.

The reliability of both sources of information is also significantly affected by the following deficiencies:

A. Reliability of the existing key study

As explained above, the reporting of the key study is not sufficient to conduct an independent assessment of its reliability. Therefore the study cannot be regarded as reliable.

B. Reliability of the read-across approach

You have provided the outlines of the three studies performed with analogue substances:

1. OECD 211 with Dodecanol, EC 203-982-0;
2. OECD 202 – Daphnia sp. Acute immobilization test, Part 2 with Dodecanol, EC 203-982-0;
3. OECD 211 with Octanol, EC 203-917-6;

We have assessed this information and identified the following issues:

According to Annex XI, Section 1.5., two conditions must 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).

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

Read-across hypothesis contradicted by existing data

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 ECHA Guidance[4] 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 substances. The observation of differences in the toxicological properties among some members of a category is a warning sign. An explanation for such a difference resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties needs to be provided and supported by scientific evidence.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar target and source substances cause the same type of effect(s).

Based on the read-across justification attached to your comments ECHA understands that you estimate the toxicity for the Substance using measured toxicity values of two source substances. As such you assume that the toxicity of tridecanol (C13) will be equivalent to the toxicity of two category members – octanol (C8) and dodecanol (C12).

You conclude: *"(…) based on shared structures, structural and functional similarities as well as similarities in predicted chemical (or biochemical) reactivity (mechanistic profilers), common alerts in general mechanistic which includes OECD HPV chemical categories, US-EPA new chemical categories, protein, and DNA binding alerts as well as in endpoint specific mechanisms like acute aquatic toxicity classification by Verhaar (Modified), acute aquatic toxicity MOA by OASIS and acute aquatic toxicity by ECOSAR, respectively, by using OECD QSAR toolbox v.3.4., the analogue members results are in line. They are not expected to exert different ecotoxicity."*

However, the attached read-across justification and OECD HPV category (Long-chain primary aliphatic alcohols C6-C22) indicate a trend of increasing lipophilicity and aquatic toxicity associated with an increase of the alkyl chain length. This trend continues beyond dodecanol (C12) and contradicts your read-across hypothesis of similar aquatic toxicity of the target and the source substances. However, you have not provided an explanation for this difference of toxicity, in particular its impact on your read-across hypothesis; you have for example not demonstrated that dodecanol (C12) is the worse case consideration or that your Substance (C13) is a turning point in the trend and that it would not be more toxic for aquatic organisms than dodecanol (C12).

Therefore you have not demonstrated and justified that the properties of the category members are likely to be similar despite the observation of these differences.

Adequacy and reliability of source studies

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, May 2008, ECHA.
[3] Read-across Assessment Framework (RAAF) March 2017, ECHA.
[4] Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.6, Section R.6.2.2.1.f

Annex XI, Section 1.5 requires that whenever read-across is used, there must be adequate and reliable coverage of the key parameters of the corresponding test methods, in this case OECD TG 211. On that basis, the following validity criteria apply:

iv) the percentage of mortality of the parent animals (female *Daphnia*) is ≤ 20% at the end of the test;
v) the mean number of living offspring produced per parent animal surviving at the end of the test is > 60.

In your comments to the draft decision you indicate that the validity criteria for studies performed according to OECD 211 are met for study 1 and 3. However, none of the study outlines provided in your comments lists the above validity criteria.

Therefore you have not demonstrated that the information provided has adequate and reliable coverage of the key parameters.

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 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 potential source substances, including test materials.[5] Therefore, qualitative and quantitative information on the compositions of the test materials should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

The provided 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 source substances.

In the read-across justification document attached to your comments you only refer to: *"the same group of chemicals that are mostly used as antifoam agent and to make detergents".* You also indicate that *"The source and target substance identities are unambiguous and identified by name and CAS and/or EC numbers."* You specify the type of the source substances as *"predominantly mono-constituent"* without further characterisation of purity profile and the presence of impurities (their typical concentrations and concentration ranges).

Therefore, it is not possible to assess whether the attempted prediction is compromised by the composition of the source substance.

Conclusion

Therefore these study cannot be regarded as reliable.

ii) Survival of the parent animals during the test

Source A does not contain any relevant information to cover this key investigation.

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

For study 1 within the source B you indicate that *"the result of survival (…) of the test daphnids during the exposure period is reported in technical dossier"*. However, this information is currently not available in your registration dossier. The outlines of study 2 and 3 do not contain the information about this key investigation.

iii) Time to production of the first brood

You have not provided any relevant information to cover this key investigation.

C. Conclusion on the weight of evidence approach

Taken together, source of information A provides the information on i): the reproductive output of *Daphnia* sp., while source of information B provides partial information on ii) the survival of the parent animals during the test. None of the sources provide the information on iii): the time to production of the first brood.

Furthermore, the reliability of both sources 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 hazardous property foreseen to be investigated by OECD TG 211 study. Therefore, your adaptation 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").

Therefore, the information provided does not comply with OECD TG 211 and the information requirement is not fulfilled.

Study design

Depending on the results of request A.1., the Substance may be difficult to test if it is poorly water soluble (below < 1 mg/L). OECD TG 211 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. In particular, 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 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

4. Growth inhibition study aquatic plants

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

You have provided the following information:

1) Key non-guideline study from database: Toxicity to aquatic algae and cyanobacteria,

National Institute of Technology and Evaluation, Japan chemicals collaborative knowledge database (J-check), 2017;
2) Supporting non-guideline study from secondary source: Toxicity to aquatic algae and cyanobacteria, OECD SIDS Initial Assessment Report for SIAM 22, 2006;
3) Supporting OECD TG 201 study from database: Toxicity to aquatic algae and cyanobacteria, National Institute of Technology and Evaluation, Japan chemicals collaborative knowledge database (J-check), 2017.

We have assessed this information and identified the following issues:

A. Studies 1) and 3)

To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met (among others):

- Analytical monitoring to verify initial concentrations and maintenance of these concentrations throughout the test as required in guideline,
- If the test concentrations are not maintained within the required 20% of the measured initial concentrations throughout testing, the effect concentrations based on the measured values must be reported (see ECHA Guidance R7b (section R.7.8.4.1)
- The test organisms in the control must be exponentially growing over the duration of the test;
- The biomass in the control cultures must increase by at least 16-fold within the exposure period;
- 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 must be < 35%;
- The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must be < 7% in tests with *Pseudokirchneriella subcapitata* and *Desmodesmus subspicatus*. For other less frequently tested species, the value must be < 10%;

On studies 1) and 3) you have not indicated if the analytical monitoring was performed. For both studies 1) and 3) you have based the effect values on nominal concentrations without demonstrating that the test substance concentration during the tests was maintained within 20% of the measured initial concentrations.

Furthermore, for study 1) you have not specified any validity criteria or the guideline followed. For both studies 1) and 3), information is missing on the exponential growth of the control over the duration of the test, biomass and the mean coefficient of variation for section-by-section specific growth rates in the control cultures, and the coefficient of variation of average specific growth rates.

Therefore, it is not possible for ECHA to verify whether all the validity criteria were fulfilled for studies 1) and 3). Therefore, the aforementioned conditions of the OECD 201 guideline are not met, and studies 1) and 3) do not fulfil the information requirement.

B. Study 2)

To study 2) you have assigned reliability 4 (not assignable). Based on the reported information ECHA agrees that the results from this study are not reliable. Thus, study 2) does not provide the information required by Annex VII, Section 9.1.2.

Therefore, the information requirement is not fulfilled.

Study design

Depending on the results of request A.1., the Substance may be difficult to test if it is poorly water soluble (below < 1 mg/L). OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed.

In your comments to the draft decision you agree to perform the study with the Substance according to the OECD TG 201.

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[6].

B. Test material

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

1. Selection of the Test material(s)

   The Test Material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

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

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

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

Appendix C: 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 8 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 requests.

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 D: 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 E: 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.