~~Confidential~~

Helsinki, 09 February 2022

Addressee
Registrant of DAM_diC12-18 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
07/11/2011

Registered substance subject to this decision ("the Substance")
Substance name: Amines, di-C12-18-alkylmethyl
EC number: 270-418-8
CAS number: 68439-75-8

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 ***16 February 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. Skin sensitisation (Annex VII, Section 8.3.):

    i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

    ii. Only if the *in vitro/in chemico* test methods specified under point 1.i. are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429)

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

3. 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)

5. Ready biodegrability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301 B/C/D/F or OECD TG 310)

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

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

REACH".

Information required depends on your tonnage band

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 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 Mike Rasenberg, Director of Hazard Assessment

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

Appendix on Reasons common to several requests

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

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

- Skin sensitisation (Annex VII, Section 8.3)
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

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.

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 toxicological and ecotoxicological properties

You have not provided any read-across justification document in your registration dossier.

You read-across between the following substances:

- N-decyl-N-methyldecan-1-amine, EC No. 230-990-1 (CAS No. 7396-58-9)
- Amines, bis(hydrogenated tallow alky)methyl [redacted], EC No. 262-991-8 (CAS No. 61788-63-4)
- N-hexadecyl-N-methylhexadecan-1-amine [redacted], EC No. 266-923-8 (CAS No. 67700-99-6)

as source substances and the Substance as target substance.

In your registration dossier, you have not provided any reasoning for the prediction of (eco)toxicological properties.

In the absence of supporting justification, ECHA presumes that you intend to predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

In your comments on the draft decision, you provide the following statements regarding skin sensitisation and *in vitro* gene mutation in bacteria:

- "*The basis of the read-across is based on structural similarity, consisting of an amine to which two (linear, saturated) alkyl-chains connected and one methyl.*"

[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

- "*The hypothesis is that chemical reactivity is comparable, and properties determining biological availability will be gradually varying with chain-length -decreasing with increasing length of the alkyl chains.*"

ECHA notes the following shortcomings with regards to predictions of (eco)toxicological properties.

A. 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 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) (ECHA Guidance R.6.2.6.1).

You have provided studies conducted with other substances 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 on the draft decision, you agree that you have neither provided a separate read-across support document nor adequately provided support for read-across in the study summaries. You indicate your intention to "*prepare appropriate support to the applied read-across according to the RAAF requirements*".

In the absence of such documentation in your registration dossier, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substances.

B. Inadequate read-cross hypothesis

A read-across hypothesis must be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. Firstly, this hypothesis should be based on recognition of the structural similarities and differences between the substances (Guidance on IRs and CSA, Section R.6.). Secondly, it should also explain why the differences in the chemical structures should not influence the toxicological or ecotoxicological properties or should do so in a regular pattern, taking into account that variations in chemical structure can affect both toxicokinetics (uptake and bioavailability) and toxicodynamics (e.g. interactions with receptors and enzymes) of substances (Guidance on IRs and CSA, Section R.6.2.1.3).

In your comments on the draft decision, you provide a read-across hypothesis regarding information requirements for skin sensitisation and *in vitro* gene mutation in bacteria but not for ecotoxicological properties. Your read-across hypothesis is only based on the structural similarity between the source substance(s) and the Substance, which you consider a sufficient basis for predicting the properties of the Substance. However, your hypothesis does not explain why the structural differences between the substances do not influence the toxicological or ecotoxicological properties or do so in a regular pattern.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar human health or ecotoxicological properties. You have not provided a well-founded hypothesis in your comments on the draft decision or registration dossier to establish a reliable prediction for a toxicological or ecotoxicological property, explaining why the structural

differences do not influence toxicodynamics of the substances. You only claim "*properties determining biological availability will be gradually varying with chain-length -decreasing with increasing length of the alkyl chains*".

C. Adequacy and reliability of source study

We have identified deficiencies with one of the source studies provided on one of the selected analogue substances. These deficiencies are addressed under the corresponding Appendix A.1.

B. Conclusions on the read-across approach

As explained above, you have not established in your registration dossier or in your comments on the draft decision 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. Skin sensitisation

Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Under Section 8.3., Column 1, the registrants must submit information allowing (1) A) a conclusion whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and (2) risk assessment, where required.

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across approach'). In support of your adaptation, you have provided the following information:

i. a key study according to OECD 406 with an analogue substance N-decyl-N-methyldecan-1-amine (EC No. 230-990-1) ([redacted] 2010c)
ii. a key study according to OECD 406 with an analogue substance Amines, bis(hydrogenated tallow alky)methyl (EC No. 262-991-8) ([redacted] 1991)

We have assessed this information and identified the following issues:

A) Assessment whether the Substance causes skin sensitisation

a) Read-across rejection

As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected for the studies (i) and (ii).

Therefore studies (i) and (ii) cannot be taken into account in the assessment of whether the Substance causes skin sensitisation.

b) Non-compliant study

To be considered compliant and enable concluding whether the Substance causes skin sensitisation, a study has to meet the requirements of the EU Method B.6/OECD TG 406. The following key parameter(s) of this test guideline include:

- Positive control to establish the sensitivity and reliability of the experimental technique (OECD TG 406, paragraph 11)

However, in the provided study (ii), no information on positive control group is provided.

Therefore the study (ii) does not fulfil on of the key parameters set in the EU method B.6./OECD TG 406 and cannot be taken into account in the assessment of whether the Substance causes skin sensitisation.

In your comments on the draft decision, you agree that no information is included on the performance of a positive control in the study (ii). You also submit information on two reliability checks performed with dinitrochlorobenzene in guinea-pigs in the same testing facility as the study (ii). Both reliability checks indicate adequate performance of the positive control. You state your intention to "*update the current IUCLID summaries with the additional information on results on positive controls*".

The information you have provided in your comments addresses the issue identified above for the study (ii). However, as the information is currently not available in your registration dossier, the incompliance remains for the source study (ii). You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

Furthermore, ECHA notes that the information provided in your comments does not change the assessment as the read-across adaptation is rejected as described above.

Based on the above, the information submitted does not enable to conclude whether the Substance causes skin sensitisation.

B) Assessment whether the Substance can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A)

No assessment of potency

To be considered compliant and enable concluding whether the Substance causes skin sensitisation, in case the substance is considered to cause skin sensitisation the information provided must allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

In your comments on the draft decision, you indicate your intention to update the information for this endpoint.

While ECHA takes note of your intention, currently you have not provided any new information in the registration dossier on this endpoint. The information provided in your comments does not change the assessment as the read-across adaptation is rejected as described above.

As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section A. above), this condition cannot be assessed.

On this basis, the information requirement is not fulfilled.
Study design

To fulfil the information requirement for the Substance for skin sensitisation, *in vitro/in chemico* studies (OECD TG 442C, OECD TG 442D and EU Method B.71/OECD TG 442E) are considered suitable. In case *in vitro/in chemico* methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (EU Method B.42/OEDC TG 429) is considered as the appropriate study.

2. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across approach'). In support of your adaptation, you have provided the following information:

i. a key study according to OECD 471 with an analogue substance N-decyl-N-methyldecan-1-amine (EC No. 230-990-1) in *S. typhimurim* strains TA1535, TA1537, TA98, TA100 and TA102, which all gave negative results ([redacted] 2010)

ii. a key study according to OECD 471 with an analogue substance N-hexadecyl-N-methylhexadecan-1-amine (EC No. 266-923-8) in *S. typhimurim* strains TA1535, TA1537, TA1538, TA98 and TA100, and *E. coli* WP2 uvr A, which all gave negative results ([redacted] 1988)

We have assessed this information and identified the following issue:

As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected.

In your comments on the draft decision, you indicate your intention to further evaluate genotoxic properties.

While ECHA takes note of your intention, currently you have not provided any new information in the registration dossier on this endpoint. The information provided in your comments does not change the assessment.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

3. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2)

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided the following studies conducted on analogue substance but no information on long-term toxicity on aquatic invertebrates for the Substance.

i. an OECD TG 202 key study on the analogue N-decyl-N-methyldecan-1-amine, EC No 230-990-1), [redacted] 2010;

We have assessed this information and identified the following issues:

A. Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

   You have provided information which indicates that the Substance includes constituents that are poorly water soluble with your water solubility estimation of 0.000044446 mg/L using EPI Suite/WATERNT model.

   Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

B. As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected.

On this basis, the information requirement is not fulfilled.

In your comments, you agree to perform the requested test and ask for an extension of the deadline (see Appendix D.)

Study design

The Substance is difficult to test due to the low water solubility (4,44 10-6 mg/L) and adsorptive properties (estimated log kow 11,7). 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. 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 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.

Furthermore, for multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

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:

i. an OECD TG 201 key study with the Substance, [redacted], 2008;

We have assessed this information and identified the following issue:

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 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Requirements applicable to difficult to test substances

- if the test material is poorly water soluble, the maximum dissolved concentration that can be achieved in the specific test solution under the test conditions is determined;
- if the test material is forming dispersion or emulsions (*e.g.* certain surfactants, aliphatic amines), the dispersibility limit or the critical micelle concentration of the test material in the specific test solution under the test conditions is determined;
- for adsorbing test chemical, dissolved total organic carbon concentrations (other than that due to the test chemical) must be maintained in all test solutions at or below 2 mg/L;
- demonstration that the stock solution preparation method:
  1) is of adequate quality (*e.g.* water solubility limit is reached when targeted), and
  2) allows to produce reproducible stock solutions (*i.e.* acceptable variation between preparations);
- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
  1) an analytical method validation report demonstrating that the analytical method is appropriate, and
  2) information on the saturation concentrations of the test material in water and in the test solution, and
  3) a description of the method used to prepare the test solution, and
  4) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;
- if water-accommodated fractions (WAFs) are used, a preliminary study must be conducted to determine that saturation has been achieved;
- for UVCBs, it must be demonstrated that concentrations were consistently maintained within 80-120% of the initial or mean measured values over the exposure duration based on a comparison of the mass spectral full-scan GC or HPLC chromatogram peak area;
- a semi-static or flow through exposure system is used if exposure concentrations cannot be maintained within 80-120% of nominal in a static exposure system;

However, while you provided information on the test methods used to prepare stock and test solutions are reported, no information on the preliminary test study solubility was provided and therefore they do not meet the requirement of the OECD GD 23;
Furthermore, you did not provide data on TOC, while the substance is adsorptive or potentially very adsorptive; neither did you provide information on saturation concentrations of the test material in water and in the test solution during preliminary test study preparation using WAF and during test study.

Characterisation of exposure

- for some substances (*e.g.* adsorbing substances), the results may only be expressed based on nominal concentrations if the decrease in measured concentrations of the test substance during the test is not accompanied by a decrease in growth inhibition. If a reduction in growth inhibition is observed, a suitable model describing the decline of the concentration of the test material must be used;
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

However, no reporting on the analytical monitoring of exposure was reported. You only reported one measurement result stating that all concentrations were found to be below

detection limit without reference to sampling time. You therefore you did not demonstrate that the exposure concentrations can be maintained within 80-120% of nominal concentrations in a static system and that the results can reliably be expressed based on nominal concentrations.

Reporting of the methodology and results

- the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported;
- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the 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 is provided;

However concerning the reporting of test methodology and results, the robust study summary provided in the dossier does not meet the information requirement as:

- tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
- microscopic observation of the algae culture at initiation and end of the test was not reported;
- the composition of the test medium was not reported which leads to the absence of adequate information on the test procedure;
- Consequently without these data it is not possible to verify that the validity criteria of the test guideline were met and that the interpretation of the study results is appropriate.

In your comments on the draft decision, you submitted supporting information on tabulated data on the algal biomass microscopic observation composition of the test medium, within the commenting document. The information you have provided in your comments addresses partially the deficiencies identified for this reporting on test methodlogy and results. However, you did not report information on the preliminary test study nor on the analytical monitoring of exposure. In addition the information you provided in your comment is currently not available in your registration dossier, therefore the incompliance remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision and resolve all the other deficiencies identified above or perform a new test fulfilling the specifications of OECD TG 201.

In the meantime, the requirements of OECD TG 201 are not met.

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, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.3.

5. Ready biodegradability

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

You have provided two robust study summaries on the same study:

i. OECD TG 301 D key study, performed with the Substance, [redacted] (1992)

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirements must be met:

Technical specifications impacting the sensitivity/reliability of the test

- The dilution water does not contain more than 10% of the organic carbon content introduced by the test material;
- The inoculum is not be pre-adapted to the test material;
- When an abiotic control needs to be included to check for possible abiotic degradation, sterilization is conducted by filtration through a membrane (0.2-0.45 µm) or by the addition of a suitable toxic substance at an appropriate concentration;
- A dilute inoculum without sludge flocs is used. The inoculum is normally derived from the secondary effluent of a treatment plant or laboratory-scale unit receiving predominantly domestic sewage. An alternative source for the inoculum is surface water;
- 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. The concentration of added inoculum is ≤ 5 mg/L;
- The test temperature is 22°C ± 1°C;
- The pH is adjusted to 7.4 ± 0.2;
- Measurements of O_2 uptake in the test suspensions and inoculum blanks are done in parallel;

However, specifically for this study, you have used an activated sludge plant extract for the test that was then diluted. However such use is not accepted for OECD TG 301 D.

Reporting of the methodology and results

- The source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
- The test temperature is reported;
- The methods of preparation of test solutions/suspensions is reported;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;
- Any observed inhibition phenomena and/or abiotic degradation are reported;
- The calculation of the ThOD is described and justified;
- For nitrogen-containing test materials, correction for nitrification is applied on the theoretical oxygen demand (*i.e.* $ThOD_{NO3}$) unless it can be demonstrated that nitrification did not occur (*e.g.* by monitoring changes in concentrations in nitrite and nitrate);

However, for both robust study summaries on the study with regard to technical specifications and reporting on the methodology and test results:

- You have not reported the concentration of the inoculum in the test (in Cells/mL) ;
- The test temperature is not reported;
- The pH reported is lower than the one prescribed in the test guideline;
- The results of measurements at each sampling point in each replicate is not reported in a tabular form;
- The use of toxicity control and/or abiotic control is not reported nor their potential results;

- The calculation of the ThOD is not described nor justified;
- You have reported that ammonium choride was removed but you have not reported whether a correction for nitrification on the theoretical oxygen demand (*i.e.* $ThOD_{NO3}$) was applied and you have not provided any justification or supporting evidence that nitrification did not occur;

Therefore, due to the deviations to the technical specifications of OECD TG 301 and in the absence of justification if $ThOD_{NO3}$ was calculated and why no controls were done, this study does not meet the validity criteria of OECD TG 301. Furthermore, as you have not provided adequate reporting for the study, we are not in a position to further assess the study reliability.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision, you agree with the request.

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[4].

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
   - 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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that information, ECHA can confirm 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[5].

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

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

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix D: Procedure

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 18 November 2020.

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

In your comments on the draft decision, you requested an extension of the deadline to provide information from 9 to 12 months from the date of adoption of the decision. You considered that an extension of 3 months is needed to refine the testing procedures for your difficult to test Substance (high sorption potential and very low water solubility).

ECHA acknowledges the difficulties in conducting the test with your difficult to test Substance.

On this basis, ECHA has granted the request and extended the deadline to 12 months.

ECHA took into account your other 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 E: 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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[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 F: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

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.