EUROPEAN CHEMICALS AGENCY

Helsinki, 17 March 2021

Addressees
Registrant(s) of Triamine_C16-18_C18-unsat. as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
20/12/2013

Registered substance subject to this decision ("the Substance")
Substance name: N-(3-aminopropyl)-N'-C16-18 (evennumbered), C18 unsaturated alkyl - propane-1,3-diamine
EC number: 628-863-4
CAS number: 1219458-14-6

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***24 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. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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

B. Information required from all the Registrants subject to Annex VIII of REACH

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

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, 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.

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach 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.)
- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach 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 (addressed under 'Scope of the grouping'). 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.

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have formed a group (category) of 'polyamines'. You have provided a read-across justification document in IUCLID Section 13 and relevant endpoint summary.

For the purpose of this decision, the following abbreviations are used for the group members:

- Substance A (EC No. 266-613-2) N-oleyl tripropylenetetraamine;
- Substance B (EC No. 628-863-4) Tallow dipropylene triamine;
- Substance C (EC No. 249-276-6) Oleyl dipropylene triamine;
- Substance D (EC No. 294-908-6) Coco dipropylene triamine; and
- Substance E (EC No. 628-862-9) N-tallow alkyltripropylene tetraamine.

You provide the following reasoning for the grouping the substances: *"Polyamines are substances that contain multiple (2 or more(1,3-diamine propane (DP) groups linked to a fatty amine. These can be linearly linked based on two DP and fatty amine (triamine structure: alkyl dipropylenetriamine) or 3 DP with a fatty amine (tetramine structure: alkyl tripropylenetetramine) or, in a branched form or two DP and a fatty amine. This category is only restricted to the linear polyamines".*

You define the applicability domain of the category as follows: " *The category applies to linear triamines and linear tetramines"* with structural formulae as provided in the justification document, and with *"alkyl chain length ranging from 10 (dodecane) to 18 (Octadecane), depending on the source of the fatty amine"*.

ECHA understands that this is the applicability domain of the grouping and will assess your predictions on this basis.

B. Predictions for environmental fate / behaviour and ecotoxicological properties

I. Predictions within the category

You have provided the following reasoning for the prediction of environmental fate / behaviour and ecotoxicity:

- *"structurally, the linera tri- and tetramines are very similar (...). Consequently, they share the same chemical reactivity and their physico-chemical properties are very similar from which a comparable toxicological profile can be expected."*
- *"alkyl polypropylene polyamines are completely biodegradable and are protonated under environmental conditions".*
- "(...) *It is unlikely that the biodegradability of these surfactants differ significantly with varying alkyl chain length."*

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 based on an identified trend within the group.

ECHA notes that with regards to prediction(s) of environmental fate / behaviour and ecotoxicological properties there are shortcoming(s) that are common to all aquatic toxicity, as well as, ready biodegradability information requirements under consideration and also shortcoming(s) that are specific for these information requirements individually. Altogether they result in a failure to meet the requirement of Annex XI, 1.5. The common shortcoming(s) are set out here, while the specific shortcomings are set out under the information requirement concerned in the Appendices below.

I.1. Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for environmental fate / behaviour and ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance(s) and your Substance[2]. It should explain why the differences in the chemical structures should not influence the environmental fate / behaviour and ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structure and in some of the physicochemical/ ecotoxicological/ toxicological properties between the category members is

[2] ECHA Guidance R.6

a sufficient basis for predicting the properties of the Substance for other endpoints.

Similarity in chemical structure and similarity of some of the physicochemical/ ecotoxicological/ toxicological properties does not necessarily lead to predictable or similar environmental fate / behaviour and ecotoxicological properties in other endpoints. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the category members.

I.2. Missing information to support the hypothesis

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[3]. 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 other category members.

Supporting information must include for example bridging studies of comparable design and duration for the Substance and the source substances.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

In the technical dossier you have provided aquatic toxicity studies for the category members, as listed under the relevant information requirement section(s) A.1, A.2. B.1 and C.1 below.

In your technical dossier you have provided ready biodegradability studies on the category members, as listed under the relevant information requirement section A.3 below.

However, these aquatic toxicity studies and ready biodegradability studies provided in the dossier for the category members are considered as not adequate, for the reasons explained in section '*I.3. Adequacy and reliability of source studies*' and under the relevant information requirements in the Appendices below.

Furthermore, in your technical dossier, you have not provided any reliable studies on the Substance for any of the endpoints. Hence it is not possible to compare the properties of the category members and the Substance.

In your comments to the draft decision, you indicated your intention to first address the shortcomings of the existing studies and if the shortcomings cannot be fully addressed, you further proposed to perform new studies. You indicated your intention to have short-term toxicity to *Daphnia* and algae growth inhibition data for all category members as supporting studies and to update the read-across approach. If these supporting studies will confirm the hypothesis of same of type of effects, you proposed to have data for other aquatic toxicity endpoints on few category members that would cover the data gap on short-term toxicity to fish, long-term toxicity to Daphnia and fish.

[3] ECHA Guidance R.6, Section R.6.2.2.1.f

ECHA notes the following with regard to your intention of addressing shortcomings and plans for future testing:

- Currently you have not provided information that would remove the deficiencies of the existing studies as described in sections I.3. and II.2 below ('Adequacy and reliability of source studies');
- Lacking the above information or any further data generated on the target and source substances, currently there is no information that could be used to support your hypothesis. Also, the results of any future testing may or may not confirm your hypothesis. Hence, results of any such future testing cannot be taken into account at this stage.

Consequently, since there are no adequate and reliable studies provided for the aquatic toxicity and ready biodegradability studies across the category, no comparison of environmental fate / behaviour and ecotoxicological properties can be made.

As explained above, the data set reported in the technical dossier does not include relevant, reliable and adequate information to support your read-across hypothesis.

In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

I.3. Adequacy and reliability of source studies

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

- 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).

I.3.1. 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.

Your read-across justification document does not contain compositional information for the members of your category, but it states that "*tetramines also contain for a large part triamines and some diamine, and the triamines can contain a considerable amount of diamines and some tetramines*". However, 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 and/or trade name of the the test substance and/or numerical identifier. It does not contain the chemical identity and quantitative occurrence of its constituents.

This issue concerns the following studies (studies listed under the relevant request in the Appendices below):

i. Key study (1997) used to cover the requirement for short-term daphnia (with substance A);
ii. the key study (2009) used to cover the requirement for growth inhibition aquatic plants

(With the substance C);

iii. Key study (2009) used to cover the requirement for Ready biodegradability (with substance D);

iv. Key study (1997) used to cover the requirement for short-term fish (with the substance A);

v. Key study (2010) used to cover the requirement for long-term invertebrates (with substance C);

Due to the above deficiency, 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.

In your comments to the draft decision, you indicated your intention to review and provide data on the test material identity for the studies listed above. You also indicated that you will reposition some of the studies as supporting study and/or lower the Klimisch score if sufficient information is not available for these studies. Since you did not provide any such data in your comments, you have not demonstrated that test material is representative for the source substance(s).

I.3.2. Further deficiencies

For aquatic toxicity only

According to Annex XI, Section 1.5., if the grouping concept is applied then a source study must have adequate and reliable coverage of the key parameters of the corresponding test method, in this case OECD TG 201/202/203/211. Therefore, the following requirements must be met:

1. The analytical measurement of test concentrations is conducted (validity criterion OECD TG 203);

2. 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;

3. Analytical monitoring of test concentrations were not conducted for short-term daphnia and short-term fish studies performed with analogue substances listed above.

4. For growth inhibition aquatic plants and long-term invertebrates studies, analytical monitoring was performed and reported measured concentrations were significantly lower than the nominal concentrations in both fresh and old medium for algae study, and in old medium for long-term daphnia study. However, effect concentrations are reported based on nominal concentrations. Furthermore, you have stated that because you have used the 'bulk' approach, "the residual sorption to glassware will be negligible". However, in the long-term daphnia study, you have reported 15% adsorption to glassware in old medium at test concentration of 270 µg/L.

5. For growth inhibition aquatic plants and long-term invertebrates studies, you have not provided information on preparation of the sample for analytical monitoring.

In all the aquatic toxicity studies mentioned above, you have not demonstrated that the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test.

In your comments to the draft decision, you indicate that short-term fish and daphnia are old studies and analytical monitoring was not performed due to the absence of suitable analytical methods at the time these studies were performed. However, you have not provided any evidence of maintenance of exposure concentrations nor any justification for the absence of suitable analytical monitoring.

Despite this, you reported the result based on the nominal concentration. In addition, you did not account for the observed adsorption to the glassware for the long-term daphnia study.

In the absence of such information nor information on sample preparations, ECHA cannot determine if the used analytical procedure determines the truly dissolved concentrations of the test substances.

In the absence of justification despite the importance of analytical monitoring to account for the potential of loss (adsorption to the glassware), the alleged absence of suitable analytical methods is not demonstrated.

Finally, the fact that studies are old is not a justification for accepting them; a registrant must demonstrate "adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3)", which is not demonstrated in this case.

Therefore, the validity criterion of OECD TG 203 is not met for the short-term fish study (key study, 1997), and there are critical methodological deficiencies affecting the reliability of the test results for short-term and long-term daphnia and algae studies.

A. Endpoint specific issues

None of the studies listed above in section I.3.1 were performed according to the testing specifications set out in the corresponding OECD TGs. Therefore, these studies are not adequate for the purpose of classification and labelling and/or risk assessment. There are additional endpoint specific reasons which are explained further below under the relevant information requirement section(s) A.1, A.2, B.1. and C.1.

For the reasons listed above, the predictions within the category fail.

II. Predictions outside of the category

ECHA notes that the following analogue substances are not listed as category members in your read-across justification document. Furthermore, information on the test material with its composition, as well as purity/impurity are not available. Therefore it is not possible for ECHA to assess whether these substances can be included in the "polyamine" category. Such substances are thus treated to be outside of the category. Furthermore, ECHA notes that although you mention diamines as a constituent of tri- and tetramines (containing "respectively about [redacted] and [redacted] diamines") and test materials of some source studies, you do not include diamine in the polyamine category members. Therefore the diamines are considered outside of the polyamine category.

The source studies performed with these substances are included in the technical dossier for the following ecotoxicological endpoints:

Short-term aquatic invertebrates (Annex VII, Section 9.1.1.):

- EC No 288-048-0, CAS No 85632-63-9
- EC No 230-528-9, CAS No 7173-62-8

- EC No 219-145-8, CAS No 2372-82-9
- EC No 266-613-2, CAS No 67228-83-5

Ready biodegradability (Annex VII, Section 9.2.1.1):

- EC No 272-787-0, CAS No 68911-79-5
- hexadecyltrimethylammonium bromide (Raymond & Alexander, (1977);
- N-Tallow-l,3-diaminopropane (van Ginkel; 1995);
- Surfactants (van Ginkel, 1996);
- several types of surfactants (van Ginkel, 2007);
- Triameen C ([redacted] 2009);
- Spermidine and apermine (Rothkopf and Bartha, 1984);
- Spermidine and putrescine (Large, 1992) and
- Test material not reported (Kluver and Donker, 1926).

Short-term fish (Annex VIII, Section 9.1.3.):

- EC No 219-145-8, CAS No 2372-82-9
- EC No 271-699-9, CAS No 68603-64-5
- EC No 230-528-9, CAS No 7173-62-8
- EC No 263-189-0, CAS No 6179-55-7

Concerning the predictions of ecotoxicological properties based on these substances, ECHA notes the following shortcomings.

You have provided the following reasoning for the prediction of aquatic toxicity with the substances which are not listed as category members in the read-across justification document:

- *"Only limited number of acute fish and daphnia studies were available for the substances under consideration. Therefore the test results of a number of alkyl-1,3-diaminopropanes and for dodecyl triamine Y were added to the dossier. Tri- and tetramines contain respectively about [redacted] diamines and for this reason the data for the diamines was added to the dossier";*
- *"Dodecyltriamine Y (a branched triamine) was used a worse-case as this substance is similar as the liner triamine and considered a the most toxic triamione". "This substance is used as [redacted] and this substance is considered the most ecotoxici substance for the alkyltriamines (3N)". "the observed LC 50 for this substance of 0.43 mg/L (for short-term fish; and 0.0775 mg/L for short-term daphnia), suggests that the alkyl-1,3-diaminopropanes (2N) are more ecotoxic than the alkyl polyamines (>2)".*

You did not provide the substance specific justification for the prediction of biodegradation with the substances which are not listed as category members. However, in the endpoint summary for the environmental fate and pathway (Section 5 in IUCLID) and biodegradation (Section 5.2 in IUCLID), you have provided general justification on the use of read-across for biodegradability, which include the following:

- *"Based on the broad substrate specificity of microorganisms degrading fatty amine derivatives with respect to the alkyl chain length is unlikely that the biodegradability of these substances differ significantly with varying alkyl chain length".*
- *"all N-alkyl dipropylene triamines are readily biodegradable".*

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 based on a worst-case approach for the ecotoxicological properties (aquatic toxicity), and based on an identified trend within the

group for environmental fate/behaviour (ready biodegradability).

ECHA notes that with regards to prediction(s) of environmental fate / behaviour and ecotoxicological properties there are shortcoming(s) that are common to all information requirements under consideration and also shortcoming(s) that are specific for these information requirements individually. Altogether they result in a failure to meet the requirement of Annex XI, 1.5. The common shortcoming(s) are set out here, while the specific shortcomings are set out under the information requirement concerned in the Appendices below.

II.1. Characterisation of the analogue (source) substances

According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[4] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, whenever the Substance and/or the source substance(s) are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the category members needs to be provided; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[5]

Your do not provide any description of the source substances. Furthermore, for all the studies provided in the technical dossier that were conducted with these substances, as listed above, no information on the composition of the test material used to generate the source data is provided (see Section *II.2.1* below).

In your comments to the draft decision, you indicated that you will update the information on the identity of the analogue substances that are not referred as category members in your current read-across justification document. You claim that the analogue substances listed above refer to the following category members:

- EC No 272-787-0, CAS No 68911-79-5 corresponds to Substance [E]
- Triameen C corresponds to Substance [D]

In addition, you stated that following substances are outside of the category:

- hexadecyltrimethylammonium bromide (Raymond & Alexander, (1977);
- Surfactants (van Ginkel, 1996);
- several types of surfactants (van Ginkel, 2007);
- Spermidine and apermine (Rothkopf and Bartha, 1984);
- Spermidine and putrescine (Large, 1992) and
- Test material not reported (Kluver and Donker, 1926).

You indicated that information from these substances above will still be used to justify the grouping of polyamines and will be included in the updated read-across justification for ready biodegradation endpoint.

[4] ECHA Guidance R.6, Section R.6.2.3.1
[5] ECHA Guidance R.6, Section R.6.2.5.5

You also indicated that you will reposition some of the studies as supporting study and/or lower the Klimisch score if sufficient information is not available for these studies.

However, in your comments you did not provide any data on the qualitative and quantitative description of the composition of the source substance(s) and of the test material to confirm the identity of these analogue substances.

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).

It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation or any other adaptation. If you do so, you are responsible for demonstrating the fulfilment of the requirements of the relevant Annex(es) of REACH. If it fails and the resulting data does not support, or even contradict, your read-across hypothesis or any other adaptation, you remain responsible for complying with this decision by the set deadline.

Without this information, no qualitative or quantitative comparative assessment of the compositions of the source substances can be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

II.2. Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should:
- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

II.2.1. Test material identity

As explained in section I.3.1., detailed information on 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 and thus relevant to the Substance.

The information on the composition of the test materials of the source data provided in your dossier is limited to the generic name of the UVCB substance and/or numerical identifier and it does not contain the chemical identity and quantitative occurrence of its constituents. This issue concerns the following studies (studies listed under the relevant request in the Appendices below):
- studies (ii)-(v), used to cover the requirement for short-term toxicity testing on invertebrates;
- studies (iii)-(x) used to cover the requirement for ready biodegradability;
- studies (ii)-(vi), used to cover the requirement for Short-term toxicity testing on fish.

Due to the above deficiency, 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.

In your comments to the draft decision, you indicated your intention to provide data on the test material identity and composition for several studies. Since you did not provide any such data in your comments, you have not demonstrated that test material is representative for

the source substance(s). 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 studies listed above are not adequate for the purpose of classification and labelling and/or risk assessment.

II.2.2. Further deficiencies

A. For aquatic toxicity only

According to Annex XI, Section 1.5., if the grouping concept is applied then a source study must have adequate and reliable coverage of the key parameters of the corresponding test method, in this case OECD TG 201/202/203. Therefore, the following requirements must be met:

1. The analytical measurement of test concentrations is conducted (OECD TG 203);

2. 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;

3. The methods used to prepare stock and test solutions is reported.

4. Analytical monitoring of test concentrations was not conducted for following aquatic toxicity studies performed with analogue substances;
   - studies (ii), (iii) and (v), used to cover the requirement for short-term toxicity testing on invertebrates (OECD TG 202);
   - studies (ii), (iii) (iv) and (vi), used to cover the requirement for short-term toxicity testing on fish (OECD TG 203).

5. For short-term fish study listed in (v), you indicated that analytical monitoring was performed. However, only initial nominal concentrations are reported and measured concentrations are not reported. You reported effect concentrations as estimated. However you did not explain how these estimated effect concentrations were derived.

6. For short-term daphnia study listed in (iv), you have not specified the use of vehicle for the study listed in (iv.) above

Hence you have not demonstrated that the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test. Despite this, you reported the result based on the nominal concentration.

Therefore, the validity criteria are not met for the OECD TG 203 studies, and lack of analytical monitoring is a critical methodological deficiencies affecting the reliability of the test results for OECD TG 202 studies. Hence we are not in a position to conduct an independent assessment of the study reliability.

B. Endpoint specific issues

None of the following studies were performed according to the testing specifications set out in the corresponding OECD TGs (studies listed under the relevant request in the Appendices below):

i. studies (ii)-(v), used to cover the requirement for short-term toxicity testing on invertebrates;
ii. studies (iii)-(x) used to cover the requirement for ready biodegradability;

Therefore, the studies listed above are not adequate for the purpose of classification and labelling and/or risk assessment. The specific reasons are explained further below in the relevant information requirement sections A.1 and A.3

For aquatic toxicity studies only

II.4 *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[6] indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s)/category members. The observation of differences in the ecotoxicological 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. Your read-across hypothesis is based on your claim that the source substance, dodecyl triamine Y is the most toxic triamine and thus it can be considered as the worst-case. However, in the endpoint summary on short-term toxicity testing on fish and short-term toxicity testing on aquatic invertebrates, you have stated that toxicity of oley tetramine (4N) (LC50(96h)=0.13 mg/L and EC50(48h)=0.032 mg/L for short-term fish and daphnia respectively) is more toxic than dodecyl triamine Y (LC50=0.43 mg/L and EC50=0.0775 mg/L for short-term fish and daphnia respectively), without any explanation of the impact of that difference for your claim.

The available data indicates a deviation in your claim that the source substance dodecyl triamine Y is the most toxic triamine and thus it can be considered as the worst-case. Therefore, you have not demonstrated and justified that the properties of the category members are likely to follow a regular pattern despite the observation of a deviation in the claimed trend.

For the reasons listed above, the predictions outside the category fail.

C. Conclusions on the grouping of substances and read-across approach

As explained above, based on the information in the technical dossier and your comments, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. Therefore, your adaptation is rejected.

Further, specific considerations are addressed under the individual information requirements.

In addition, in your comments to the draft decision, you requested ECHA to extend the deadline. ECHA has addressed your comment on this matter in Appendix F, below.

[6] ECHA Guidance R.6, Section R.6.2.2.1.f

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

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided:

i. EPA OTS 797.1300, Key study (1997) with the Substance A;
ii. OECD TG 202, key study (2002) with the test material identified as N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (EC 219-145-8, CAS 2372-82-9);
iii. OECD TG 202, supporting study (1992) with the test material identified as N-(3-aminopropyl) -N-tallow alkyl trimethylene diamine (EC 288-048-0, CAS 85632-63-9);
iv. OECD TG 202, supporting study (1999) with the test material identified as N-[(9E)-octadec-9-en-1-yl]propane-1,3-diamine (EC 230-528-9, CAS 7173-62-8);
v. OECD TG 202, weight of evidence (1992) with the test material identified as N-[(9E)-octadec-9-en-1-yl]propane-1,3-diamine (EC 230-528-9, CAS 7173-62-8);

As explained in the Appendix on general considerations your adaptation is rejected. In addition, ECHA has identified the following shortcomings:

A. Weight of evidence

You have adapted the standard information requirements according to Annex XI, Section 1.2 of REACH (weight of evidence (WoE) by providing an OECD TG 202 study with an analogue substance (study v. above).

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 dangerous (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 the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance 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 approach.

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

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

Furthermore, you have indicated only one study as source of information whereas the weight of evidence requires evidence from several sources of information. Nonetheless, we have treated all the provided studies under this endpoint as source of information although you have not indicated them as such.

These issues identified below are essential for all the information requirements in which you invoked a weight of evidence.

As already stated above, to fulfil the information requirement, normally a study performed according to OECD TG 202/the EU method C.2 must be provided. OECD TG 202 requires the study to investigate the following key parameter:

- Coverage of the key parameter which is the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test.

The source of information may provide relevant information on the immobilisation of 50% of daphnids at the end of the test.

1. Reliability of the read across approach

Appendix on general considerations identifies deficiencies of the grouping and read across approach used in your dossier. These findings apply equally to the sources of information relating to analogue substances submitted under your weight of evidence adaptations.

As explained in the above section "Reasons common to several requests", the reported read-across approach does not fulfil the criteria in Annex XI, Section 1.5. Thus the information from study listed in v. with an read across source substance cannot be used as part of the weight of evidence adaptation.

It is therefore not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not a particular dangerous property.

In your comment to the draft decision, you have indicated to re-position the study v. as supporting study rather than weight-of-evidence and agree to perform a new study with the Substance. As a supporting study, it still does not meet the requirements of Annex XI, Section 1,5 and the OECD TG 202 (Article 13(3) of REACH) and thus must be rejected on that basis,

Therefore, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the adsorptive, surface active and ionisable properties. OECD TG 202 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 210. 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.

In your comments to the draft decision, you agreed that the Substance is difficult to test due to the properties of the substance to sorb to negatively charged surfaces and to the test organisms. However, you do not agree to perform the standard testing approach following OECD GD 23, instead you provided your justification on the use of "bulk approach" taking account the loss due to sorption to test organisms and glassware only.

OECD GD 23 is intended for applying to difficult to test substances, such as the Substance. You have not demonstrated why OECD GD 23 would nevertheless not be appropriate.

In addition, in your comments to the draft decision, you "*have recognised that the Bulk approach test are less adequate for Classification and labelling purposes as tese studies indeed do not allow the quantification of the intrinsic toxicity*". One of the objectives of registration is, however, to investigate the intrinsic properties of the Substance. Therefore, that argument cannot be used to not apply OECD GD 23.

2. Growth inhibition study aquatic plants

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

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 by providing an OECD TG 201 study with the substance C (key study, 2009).

As explained in the Appendix on general considerations your adaptation is rejected. In addition, ECHA has identified the following shortcomings:

Deviation from the study guideline

As provided under Appendix on general considerations, Section 1. B.I.3., a source study must have adequate and reliable coverage of the key parameters of the corresponding test method, in this case OECD TG 201. Therefore, the following requirements must be met:

1. One of the two alternative growth medium (*i.e.* the OECD or the AAP medium) is used. Any deviations from recommended test media must be described and justified;
2. 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 is used;

You have provided an OECD TG 201 study with the following:

1. non-standard medium (i.e. natural river water) with following description: DOC 2.8 mg C/L, TOC 2.9 mg C/L and suspended matter 24 mg/L. You have provided following justification for modification to the standard test medium:
   "*Oleyl dipropylene triamine(CAS no. 28872-01-7) is practically insoluble in water and also has a strong tendency to adsorb to negatively charged surfaces such as suspended matter, algae and test vessels or organic material (including dissolved organic matter such as humic acids). [...] The aquatic ecotoxicity tests with polyamines were therefore performed in river water to allow a PECaquatic,bulk/PNECaquatic,bulkapproach and is considered to be conservative but more environmentally realistic than the standard method. This approach is based on PEC estimations representing 'total aquatic concentrations'. [...]For ecotoxicity tests performed using the bulk approach, however,*

adsorption to suspended matter and DOC is acceptable and only adsorption to glassware should be accounted for. For a valid bulk approach test the concentration-effect relationship should be based on the sum of adsorbed and dissolved substance in the volume of the medium tested.[...] The results of these bulk approach tests are therefore much easier and more realistic, and if compared to PECbulk clearly provide a more appropriate assessment of risks for the environment."

2. Measured concentrations at the start and end of the test for only two test concentrations (0.32 and 3.20 mg/L).

We have assessed this information and identified the following issues:

1. you indicated that the effect concentrations are defined as *'total aquatic concentrations'* i.e. *"the sum of adsorbed and dissolved substance in the volume if the medium tested"*. As you indicated in your justification, the test substance is highly adsorptive cationic surfactant and is therefore expected to sorb strongly to suspended matter and DOC. Since river water differ from the standard media with regard to the content of higher organic and suspended matter, the use of this modified test medium impacts the exposure of the test substance to the test organisms. Your justification for the use of modified test medium only considers the relevance of the study for risk assessment. However, since the applied modification impacts the exposure concentrations and it not possible to separate truly dissolved concentration from *'total aquatic concentrations'*, the study does not provide information on the intrinsic properties of the test substance. Therefore your justification is rejected.

2. the frequency of the measurement is not sufficient to account for the kinetics of disappearance of the substance from the medium. In addition, not all test concentrations were analytically monitored. Therefore, you have not demonstrated the decrease in measured concentrations of test substances for all the test concentrations. Hence it is not possible to determine whether the decrease in measured concentrations of the test substance during the test is not accompanied by a decrease in growth inhibition. Despite this and the fact that the measured concentrations are significantly lower (i.e. <LOQ at the end of the test), you have reported the effect concentrations based on nominal concentrations.

Therefore, there are critical methodological deficiencies affecting the reliability of the test results.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you agree to perform the requested study with the Substance.

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 Section A.1.

3. Ready biodegradability

Ready biodegradability is a standard information requirement under Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 by providing the following study records flagged as read-across in your dossier:

i. OECD TG 301D, Key study (2009) with the Substance D;
ii. OECD TG 301B, supporting study (1992) with the test material identified as N-tallowalkyltripropylenetriamamine/ Amine 760 (EC 272-787-0, CAS 68911-79-5) showing 7.2 % degradation after 30 days;
iii. Raymond & Alexander (1977), TG not reported;
iv. van Ginkel (1995) TG not reported;
v. van Ginkel (1996) TG not reported;
vi. van Ginkel (2007) TG not reported;
vii. [redacted] (2009) TG not reported;
viii. Rothkopf and Bartha (1984), TG not reported;
ix. Large (1992) TG not reported and
x. Kluver and Donker (1926), TG not reported.

As explained in the Appendix on general considerations your adaptation is rejected. In addition, ECHA has identified the following shortcomings:

A. Studies are not adequate /relevant

As provided under Appendix on common reasons, Section 1. B.I.3., a source study must have adequate and reliable coverage of the key parameters of the corresponding test method, in this case OECD TG 301 or OECD 310. Therefore, the following requirements must be met:

1. Coverage of the key parameter which is the ultimate aerobic biodegradation of the test substance under low inoculum concentration as measured by CO_2 production at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation;
2. The difference of extremes of replicate values of the removal of the test chemical at the plateau, at the end of the test as appropriate, is ≤ 20%;
3. The test substance is the nominal sole source of added organic carbon;
4. The concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel. The suspended solid concentration is ≤ 30 mg/L.
5. For nitrogen-containing test substances, 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).

ECHA notes that you have provided:

1. study records listed in (iii)-(x) above as references which are quoted in your read-across justification on this endpoints. You have indicated that these studies as "*publication in peer reviewed journal*" and you have provided very limited information on each studies (e.g. only executive summary available). None of these studies cover the key parameter for OECD TG 301/310.
2. For key study (i), you have stated that differences between replicates at day 28 is <20 %. However, you have not provided raw data on replicates to verify this.
3. Natural river water was used for key study (i) and you have not demonstrated that river water constituents did not contribute to the source of added organic carbon.
4. For both studies (i) and (ii), you did not provide information on concentration of the inoculum and suspended solid concentration as specified in Table 2 of OECD TG 301.
5. In key study (i), you state that ammonium chloride was omitted from the test medium

to prevent nitrification. However, this procedure is not mentioned in the OECD TG. In addition, you did not determine the increase in concentration of nitrite and nitrate over 28 days nor corrected for the oxygen consumed by nitrification.

Furthermore, you have provided an OECD TG 303A not listed above showing 88% degradation after 44 days and 99.9 % after 56 days.

In your comments to the draft decision, you have provided the following information:

1. You stated that the study records (iii)-(x) are used as supporting information to justify the read-across. You have indicated that you will update the technical dossier with additional information on the key parameters for these studies when possible.

2. You have indicated to provide raw data on the replicates for the key study (i).

3. You have described the pre-conditioning of the river water and provided the measured endogenous respiration (1.0 mg/L) in the control bottles at day 28 to demonstrate that river water constituents did not contribute to the source of added organic carbon.

4. No data on the suspended solid concentration nor cell count are available for the supporting study (ii) and the key study (i) respectively. However, the total CO_2 evolution in the inoculum blank (25 mg/L) and the endogenous respiration in the control bottles (1.0 mg/L) are available for these studies respectively and thereby you argue that the validity criteria on the CO_2 production (i.e. <40 mg CO2/L medium) and the oxygen consumption (i.e. <1.5 mg/L) are fulfilled for the respective OECD TGs (301B and 301D). In addition, cell counts for recent OECD TG 301D test performed with the same river water collected from the same sampling point indicate that if the endogenous respiration is within the prescribed limits then the cell counts also meet the specification of the OECD TG 301D. Therefore you conclude that the results obtained in the key study (i) is valid.

5. A table containing the oxygen consumption (mg/L) and the calculated % biodegradation of sodium acetate and the Substance without and with nitrification. The % degradations after 28 days are 75 % without nitrification and (BOD/ThODNH3) and 62% with nitrification (BOD/ThODNO3).

6. The results from OECD TG 303A are used as evidence to support the ready biodegradability and to illustrate the ready biodegradability potential of n-alkyl polypropylene tetraamines in STPs in read-across document.

ECHA notes that:
Regarding point 1 ECHA notes that the information that is not included at this stage cannot be taken into account for supporting read-across justification. In addition, the supporting information must address the deficiencies addressed in this decision, in order to be considered as adequate. 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).

Regarding points 3 and 5 above, the information provided in your comments addressed the specific issues, but this information is not in the dossier.

Regarding point 4 above. You did not provide the cell counts nor the endogenous respiration of the river water in the recent OECD TG 301D study which you mention in your comments. Hence you did not demonstrate that your claim about the relationship between the endogenous respiration and the cell count is valid. In addition, you did not address the temporal changes of the bacterial population and there is no evidence that the cell count of the river water collected recently is the same or comparable to those used in the key study (i).

Regarding point 6 above, ECHA notes that the OECD TG 303 test is not simulating conditions in the aquatic environment and results from this test are not valid for classification (ECHA guidance &.7.9.5.1).

Therefore, the key parameter is not covered (for studies (iii)-(x)) or the validity criteria are not demonstrated to have been met (key study (i)) (there are critical methodological deficiencies affecting the reliability of the test results (key study (i) and supporting study (ii)). Hence, ECHA is not in a position to conduct an independent assessment of the study reliability and your comments do not change this conclusion.

Availability of OECD TG 303 A is not a basis of adaptation for this endpoint.

Therefore, the information requirement is not fulfilled.

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

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. and you have provided the following study records flagged as read-across in your dossier.

i. EPA OPPTS 850.1085, key study (1997) with the Substance A;
ii. OECD TG 203, key study (2002) with the test material identified as N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (EC 219-145-8, CAS 2372-82-9);
iii. OECD TG 203, supporting study (1990) with the test material identified as Genamin SPH 100 (EC 271-669-9, CAS 68603-64-5);
iv. OECD TG 203, supporting study (1991) with the test material identified as N-[(9E)-octadec-9-en-1-yl]propane-1,3-diamine (EC 230-528-9, CAS 7173-62-8);
v. EU C.1. supporting study (1997) with the test material identified as N-[(9E)-octadec-9-en-1-yl]propane-1,3-diamine (EC 230-528-9, CAS 7173-62-8); and
vi. OECD TG 203/EU C.1., supporting study (1990) with the test material identified as Duomeen T (263-189-0, CAS 6179-55-7).

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

As explained in the Appendix on Reasons common to several requests, your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments to the draft decision, you proposed to perform a short-term fish study (OECD TG 203) with a category member which will show the lowest EC_{50} in the new OECD TG 201 and OECD TG 202 studies.

The proposed read-across adaptation is rejected for the reasons set in the Appendix on Reasons common to several requests, therefore your proposal is also rejected.

Study design

OECD TG 203 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 Section A.1.

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 (Annex IX, Section 9.1.5) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 and you have provided an OECD TG 211 study with the substance C.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected. In addition, ECHA has identified the following shortcomings:

A. Studies are not adequate /relevant

As provided under Appendix on Reasons common to several requests, Section 1. B.I.3., a source study must have adequate and reliable coverage of the key parameters of the corresponding test method, in this case OECD TG 211.

1. The test medium fulfils the following condition(s): total organic carbon (TOC) < 2 mg/L;
2. At least five test concentrations are used, arranged in a geometric series with a spacing factor ≤ 3.2. If fewer than five test concentrations are used a justification must be provided;
3. In semi-static tests, if the concentration of the test substance:
   - is not expected to remain within ± 20 % of the nominal, then all test concentrations are analysed.

You have provided the following:

1. For the key study (2010), you specified that the test medium consists of natural river water with the following characteristics: DOC 3.0-3.9 mg C/L; TOC 3.1-3.9 mg C/L; suspended matter 11.7-16.2 mg/L. You have provided the same justification as stated under algae endpoint (request A.2 above) for the modification of the standard test medium.
2. You have indicated that only three test concentrations (30, 90, 270 µg/L) were used. You did not provide any justification for using fewer test concentrations.
3. You have used semi-static setting and you have indicated that the test material is a surfactant which "*is poorly water soluble in water and also has strong tendancy to adsorb to negatively charged surfaces such as suspended matter, algae and test vessels or organic material*". You have analysed only two test concentrations (30 and 270 µg/L) throughout the tests.

ECHA has assessed this information and identified the following deficiencies:

1. You have used a test medium (i.e. river water) which contains total organic carbon (TOC)>2 mg/L. In addition, as already explained in the request A.2. above, the use of river water as test medium is not accepted and the effect concentrations must be based on measured concentrations of truly dissolved fraction of the test substance.
2. You have used fewer than 5 test concentrations without providing justifications.
3. You have indicated that the test substance is adsorptive. In addition, based on the outcome of the other aquatic toxicity studies (e.g. algae) it is expected that the concentrations of test substance is not expected to remain within ± 20 % of the

nominal concentrations. Nonetheless, you did not analysed all the test concentrations throughout the test.

Therefore, as there are critical methodological deficiencies affecting the reliability of the test results, we are not in a position to conduct an independent assessment of the study reliability and these tests results are rejected.

In your comments to the draft decision, you proposed to adapt this information requirement by read-across approach and by future testing on two category members showing the highest toxicity in the new short-term daphnia studies only.

The proposed read-across adaptation is rejected for the reasons set out in the Appendix on Reasons common to several requests, therefore your proposal is also rejected.

Therefore, the information requirement is not fulfilled.

Study design

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 Section A.1.

2. Long-term toxicity testing on fish

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5) is a standard information requirement in Annex IX to REACH.

You have adapted this information requirement according to Annex VIII, Section 9.1.3, Column 2 with the following justification: "[...] *based on the weight of evidence available on ecotoxicity data for several cationic surfactants a safety factor of 10 may be applied for the derivation of the PNECaquatic,bulk.*" and "*The safety assessment according to Annex 1 does not indicate the need to investigate further the effects on aquatic organisms. Therefore no chronic fish testing is required*".

You have applied the safety factor of 10 for deriving the $PNEC_{aquatic,bulk}$ using the results from long-term daphnia. You have stated that the 'bulk' approach based on the "*sum of adsorbed and dissolved substances*" is "*considered to be conservative*".

We have assessed this information and identified the following issue:

To adapt this information requirement the Chemical Safety Assessment (CSA) must demonstrate that risks towards the aquatic compartment arising from the manufacture and use of the Substance are controlled (Annex IX, Section 9.1., Column 2; Annex I, Section 0.1). The justification must be documented in the Chemical Safety Report (CSR) and include all of the following elements:

- the predicted no effect concentrations (PNEC) for the aquatic compartment is based on:
  - reliable information on the hazardous properties of the Substance on at least three trophic levels, and
  - an appropriate assessment factor (Section 3.3.1, Annex I), and
- an exposure assessment leading to derivation of predicted environmental concentrations (PECs),
- the outcome of the risk characterisation demonstrating that the risks are adequately controlled (*i.e.* PEC < PNEC).

For the reasons explained under request A.1, A.2, B.1 and C.1, your dossier does not include reliable hazard information for the Substance on at least three trophic levels.

Therefore, a reliable PNEC cannot be derived and your adaptation is rejected.

In your comments on the draft decision you propose a tiered approach to fulfil the data gap for this endpoint according to the integrated testing strategy. You agree to perform the short-term study on daphnia (request A-1 above). Successively, you would update the CSA and determine whether the long-term fish study requested in this decision is still needed.

If the CSA shows that further investigation of effects on aquatic organisms is required, you indicate to use read-across data to fulfil the data gaps for long-term aquatic toxicity studies. You also indicated that you will perform only one long-term toxicity test on fish (OECD TG 210) with the substance which shows highest toxicity in long-term daphnia.

ECHA notes that:
- following the recent Board of Appeal case (A-011-2018), column 2 is no longer applicable for aquatic toxicity testing and long-term studies are information requirements under Annex IX.
- the proposed read-across adaptation is rejected for the reasons set in the Appendix on Reasons common to several requests

Therefore your proposal is also rejected.

Study design

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 Section A.1.

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[7].

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

With that detailed information, ECHA can confirm 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[8].

[7] https://echa.europa.eu/practical-guides
[8] 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 synthetize its relevant constituents and/or fractions.

Appendix F: 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 25 March 2019.

During the commenting period, you informed ECHA of some administrative numbering errors to the draft decision. The draft decision has been corrected and provided to you.

The aspects corrected in the draft decision are as follows:

1. Page 16 of 29: Under 3. Ready biodgradability study records flagged as read-across, the first entry containing two studies has been separated, resulting in a total of **i-x** studies.
    - Page 17 of 29: under ECHA notes that you have provided (Under 3. Ready biodgradability A. studies are not adequate/relevant), the studies have been re-numbered, accordingly
    - Page 10 of 29: Under II.2.1. Test material identity the studies used to cover the requirement for Ready biodegradability has been updated to **(iii)-(x)**
    - Page 11 of 29: Under II.2.2. Further deficiencies B. Endpoint specific issues ii. studies used to cover the requirement for ready biodegradability has been updated to **(iii)-(x)**
2. Page 3 of 29: Removed numbering from the list of the abbreviations used for the group members, inserted buttet points, only:

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

Extension of deadline
In your comments to the draft decision, you request an extra 3 months to the current deadline of 18 months due to the laboratory capacity reasons. ECHA agrees and has extended the deadline of the draft decision to 21 months.

ECHA took into account your comments and did not amend the request(s) but amended the deadline.

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[9] 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)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[10]

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[11]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[11] 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 H: Addressees of this decision and the corresponding information requirements applicable to them

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.