

Helsinki, 03 September 2020

Addressees

Registrants of PFAEO_OLEYL as listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of this decision

26 February 2019

Registered substance subject to this decision, hereafter 'the Substance'

Substance name: 2,2'-(octadec-9-enylimino)bisethanol

EC number: 246-807-3

CAS number: 25307-17-9

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadlines provided.

A. Requirements applicable to 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) with the Substance;
2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310) with the Substance;

B. Requirements applicable to 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) with the Substance;

C. Requirements applicable to 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) with the Substance;
2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210) with the Substance;

Conditions to comply with the requests

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annex VII of REACH, if you have registered a substance at 1-10 tonnes per annum (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- you have to comply with the requirements of Annexes VII and VIII of REACH, if you have registered a substance at 10-100 tpa;
- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa
- you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

Registrants are only required to share the costs of information that they must submit to fulfil the information requirements for their registration.

The Appendix on general considerations addresses issues relevant for several requests while the other Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in point A.2 above in an updated registration dossier by **8 June 2021**, and the information requested in all other points above by **8 September 2022**. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

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.

Authorised¹ 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 general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of 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/or 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.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

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

In your registration dossier you have formed a group (category) of 'Primary Fatty Amine Ethoxylates' (PFAEO), consisting of the members noted below. You have provided a read-across justification document in IUCLID Section 13.

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

- [1] Substance A (EC No. 233-520-3), PFAEO C18;
- [2] Substance B (EC No. 246-807-3), PFAEO O (the Substance);
- [3] Substance C (EC No. 276-014-8), PFAEO C12-18;
- [4] Substance D (EC No. 620-540-6), PFAEO C16-18, 18:1; and
- [5] Substance E (EC No. 620-539-0), PFAEO C16-18.

You provide the following reasoning for the grouping of the substances: "*The Primary Fatty Amine Ethoxylates Category are substances derived from Primary Fatty amines, ethoxylated with two mole ethylene oxide to form a tertiary amine structure. The structure varies only with the length of the fatty amine alkyl chain length. The physicochemical, fate and tox-and ecotoxicology properties are expected to vary in a predictable pattern based only on the variation in chain length*".

You define the applicability domain of the category as follows: The boundaries of the category are for the low end an alkyl chain with a majority of C12 alkyl chain length and in the high end a majority of C18 alkyl chain length. The amount of tertiary amine is [REDACTED] and residual

primary or secondary amine is [REDACTED] The amount of ethylene oxide in adduct is in average [REDACTED] moles.

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

B. Predictions for ecotoxicological properties

I. Predictions within the category

You have provided the following reasoning for the prediction of (eco)toxicological properties: "read across can be done within the category, taking into account the general trend of properties when the Fatty Alkyl Chain length increases".

Specifically for ready biodegradability, you claim that: "*All substances within the group 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.

ECHA notes that with regards to prediction(s) of 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.

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 a toxicological or 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. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

According to the information provided in your dossier, you consider that the properties of the Substance can be predicted from information on other category members as a result of similarities in their chemical structures and in their physico-chemical properties.

While structural and physico-chemical similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a 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*"². The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include 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 substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects.

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

In your technical dossier you have provided ready biodegradability studies on the category members, as listed under the relevant information requirement section(s) A.2 below.

However, all the aquatic toxicity studies and the 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.

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.

For aquatic toxicity, in your comments 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 differences in alkyl chain length and degree of unsaturation: short-term toxicity to fish studies for Substances B (i.e. the Substance) and C, and long-term toxicity to *Daphnia* studies for Substances B (i.e. the Substance), C and E.

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.3 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, your proposed plan to test only few category members for short-

² ECHA Guidance R.6, Section R.6.2.2.1.f

term toxicity to fish and for long-term toxicity to *Daphnia* is not acceptable.

For ready biodegradability, in your comments you indicated your intention to have ready biodegradability data for all category members and to update the read-across approach by providing a more specific read-across hypothesis and a justification explaining the rationale for the prediction. ECHA notes that your intentions seem to be contradictory. Also, as explained under the relevant information requirement section A.2 below, the information provided in the comments indicates non ready biodegradability as result in some of the studies. This information will have to be considered as it contradicts your current read-across hypothesis..

Consequently, since there are no adequate and reliable studies provided for the aquatic toxicity and ready biodegradability across the category, no comparison of 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.

1.3. 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).

1.3.1. 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 the category members are mostly UVCBs with composition varying in the alkyl chain length and in the degree of unsaturation. 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 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):

- study (iii), used to cover the requirement for Short-term toxicity testing on fish;
- studies (xi) and (xvi), used to cover the requirement for Ready biodegradability.

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).

Therefore, the studies listed above cannot be considered as adequate for the purpose of classification and labelling and/or risk assessment.

I.3.2. Further deficiencies

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):

- study (iii), used to cover the requirement for Short-term toxicity testing on fish;
- study (xvi), 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 under the relevant information requirement section(s) A.2 and B.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 referred as category members in your read-across justification document, but source studies performed with these substances are included in the technical dossier for the following ecotoxicological endpoints:

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

- EC No 263-177-5, CAS No 61791-44-4
- EC No 236-062-2, CAS No 13127-82-7

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

- EC No 236-062-2, CAS No 13127-82-7

Ready biodegradability (Annex VII, Section 9.2.1.1):

- EC No 236-062-2, CAS No 13127-82-7
- CAS 26635-93-8
- EC No 291-276-3 (CAS No 90367-28-5)
- EC No 263-163-9 (CAS No 61791-31-9)
- EC No 263-177-5 (CAS No 61791-44-4)
- EC No 203-868-0, CAS No 111-42-2

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

II.1. *Lack of 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).³

You have provided studies conducted with analogue substances but not a category member in order to comply with the REACH information requirements. You have not provided documentation, containing the necessary elements as described above, as to why this information is relevant for your Substance.

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

II.2. 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

You 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.3.1* 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 specified that the identifiers of these analogues are alternative chemical descriptions for the category members used before REACH registration. You claim that the analogue substances listed above refer to the following category members:

- CAS 26635-93-8 corresponds to Substance [B]
- EC No 236-062-2, CAS No 13127-82-7 corresponds to Substance [B]
- EC No 263-163-9, CAS No 61791-31-9 corresponds to Substance [C]
- EC No 263-177-5, CAS No 61791-44-4 corresponds to Substance [D]
- EC No 291-276-3, CAS No 90367-28-5 corresponds to Substance [E]

³ ECHA Guidance R.6, Section R.6.2.6.1

⁴ ECHA Guidance R.6, Section R.6.2.3.1

⁵ ECHA Guidance R.6, Section R.6.2.5.5

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.

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.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).

II.3.1. 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):

- study (i), used to cover the requirement for Short-term toxicity testing on aquatic invertebrates;
- studies (i) and (iv), used to cover the requirement for Short-term toxicity testing on fish;
- studies (ii), (iii), (iv), (vi) to (x), (xii) to (xv), (xvii) and (xviii) used to cover the requirement for Ready biodegradability.

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).

Therefore, the studies listed above are not adequate for the purpose of classification and labelling and/or risk assessment.

II.3.2. Further deficiencies

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):

- study (iv), used to cover the requirement for Short-term toxicity testing on fish;

- studies (iii), (iv), (vi) to (x), (xii) to (xv), (xvii) and (xviii) 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, A.2 and B.1.

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 from the evaluated registration 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.

(ii) Referral of the decision to the Member States Competent Authorities

In your comments to the draft decision, you request ECHA to postpone the referral of this draft decision to the Member States Competent Authorities by 30 November 2020, so you can address the shortcomings identified and improve the read-across approach in the updated dossier.

As specified in the notification letter accompanying the draft decision, ECHA does not take into account any dossier updates submitted after the date on which you were notified the draft decision in the context of the adoption of the decision according to Article 51. In addition, the new data that you intend to provide and/or generate may or may not confirm your hypothesis. As a consequence, there is no reason to delay the current decision making process.

Appendix A: Reasons for the requests to comply with Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is a standard information requirement at Annex VII of REACH.

You have provided in your dossier the following study record claimed to be conducted with the Substance:

- i. [REDACTED] (2009), key study, according to OECD TG 202 with the test material identified as N-Alkyl "oleyl" N,N-bis(hydroxyethyl)amine (EC No 236-062-2, CAS No 13127-82-7)

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

A. Predictions outside of the category

You have provided a study claimed to be conducted on the Substance, but the identifiers of the test material (EC No 236-062-2, CAS No 13127-82-7) do not correspond to those of the Substance. These identifiers also do not correspond to any of the category members. In Section 1.1 of your CSR you indicate that based on the names EC No 236-062-2 correlates to the Substance. In your comments to the draft decision, you indicated that EC No 236-062-2 corresponds to the Substance. However, you have not provided qualitative and quantitative information on the composition to justify why the test material used to generate the data is consistent with the Substance.

Therefore, ECHA considers this study as conducted with other substance(s) than your Substance.

Consequently, ECHA considers that you have adapted this information requirement by using a Grouping of substance and read-across approach under Annex XI, section 1.5. However, as explained in the Appendix on general considerations your adaptation according to Annex XI, Section 1.5 is rejected.

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

Therefore, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the adsorptive, ionisable and surface active properties as explained above. OECD TG 202 specifies that for difficult to test substances, the OECD GD 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular with regard to the test design; including exposure system, test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented.

Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the

nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution. Furthermore, exposure concentrations must be below the critical micelle concentration (CMC). This will ensure that test organisms are exposed to the freely dissolved chemical species and not the micelle which can alter the uptake of the test chemical.

2. Ready biodegradability

Ready biodegradability is a standard information requirement at Annex VII of REACH.

You have provided the following studies claimed to be conducted with the Substance:

- i. [REDACTED] (1990b), key study, according to OECD TG 301D
- ii. [REDACTED] (2006), key study, according to OECD TG 301B, test material identified as CAS 26635-93-8
- iii. [REDACTED] (2005), key study, according to OECD TG 301F, test material identified as CAS 13127-82-7
- iv. [REDACTED] (1991), according to OECD TG 301D, test material identifiers not provided
- v. [REDACTED] (1990c), according to OECD TG 301D
- vi. [REDACTED] (1989b), according to OECD TG 301D, test material identifiers not provided
- vii. [REDACTED] (1993), TG not reported, test material identifiers not provided

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

- viii. [REDACTED] (2002a), key study, according to OECD TG 301F with the analogue substance EC No 291-276-3 (CAS No 90367-28-5)
- ix. [REDACTED] (1997a), key study, according to OECD TG 301B with the analogue substance EC No 263-163-9 (CAS No 61791-31-9)
- x. [REDACTED] (1997b), key study, according to OECD TG 301B with the analogue substance EC No 263-177-5 (CAS No 61791-44-4)
- xi. [REDACTED] (2005), according to OECD TG 301B with the analogue substance EC No 276-014-8 (Substance C)
- xii. [REDACTED] (2002b), according to OECD TG 301F with the analogue substance EC No 263-177-5 (CAS No 61791-44-4)
- xiii. [REDACTED] (1989), according to OECD TG 301D ("modified according to the recommendations of [REDACTED] 1985") with the analogue substance EC No 263-163-9 (CAS No 61791-31-9)
- xiv. [REDACTED] (1996), TG not reported, with fatty amine derivatives
- xv. [REDACTED] (2007), TG not reported, with fatty amine derivatives
- xvi. [REDACTED] (1993), TG not reported, with Substance A (EC No 233-520-3)
- xvii. [REDACTED] (1997), TG not reported, with Alkanolamines
- xviii. [REDACTED] (1982), TG not reported, with 2,2'-iminodiethanol (EC No 203-868-0, CAS No 111-42-2)

We have assessed this information and identified the following issues:

A. Predictions within the category

You have adapted the standard information requirement in accordance with Annex XI,

section 1.5. to REACH by providing in the technical dossier the studies listed in xi. and xvi. above conducted with PFAEO category member(s).

However, as explained in the Appendix on general considerations your adaptation according to Annex XI, Section 1.5 is rejected.

B. Predictions outside of the category

You have provided studies (listed in viii., ix., x., xii., xiii., xiv., xv., xvii., and xviii.) that you indicate were conducted with analogue substances but not a category member.

Furthermore, you have provided the following studies claimed to be conducted with the Substance:

- studies iv., vi. and vii. where identifiers and of test material, as well as qualitative and quantitative information on the composition, are not given. Therefore, it cannot be confirmed that the studies were conducted on the Substance;
- studies ii. and iii. where the identifiers of the test material (CAS 26635-93-8 for study iv. and CAS 13127-82-7 for study viii.) do not correspond to those of the Substance. These identifiers also do not correspond to any of the category members. In Section 1.1 of your CSR you indicate that based on the names CAS 26635-93-8 and CAS 13127-82-7 correlate to the Substance. However, you have not provided qualitative and quantitative information on the compositions to justify why the test materials used to generate the data is consistent with the Substance.

Therefore, ECHA considers studies ii., iii., iv., vi. and vii. as conducted with other substance(s) than your Substance and that these studies are used to adapt this information requirement under Annex XI, section 1.5.

However, as explained in the Appendix on general considerations your adaptation according to Annex XI, Section 1.5 is rejected.

C. Studies are not adequate and reliable

To be adequate for the purpose of classification and labelling and/or risk assessment of the Substance, the study must be conducted in accordance with the applicable OECD test guidelines or other internationally recognised test methods (Article 13(3) of REACH). OECD TG 301 and 310 are the preferred guidelines to fulfil this information requirement. The OECD TG 301 require(s) that you must (among others):

- Apply the test conditions (e.g. inoculum concentration) specified in Table 2 and provide a scientific explanation for any change of procedure.
- Fulfil the validity criteria as set up in the test guideline, among others: the difference of extremes of replicate values of the removal of the test chemical at the plateau, at the end of the test or at the end of the 10-d window, as appropriate, is less than 20%.
- For studies according to OECD TG 301D and 301F with N-containing substances, determine the increase in concentration of nitrite and nitrate over 28d and calculate the correction for the oxygen consumed by nitrification.

For the studies listed in vii. and in xiv. to xviii. above, you have not provided information on

test conditions and validity criteria as described above.

For the studies listed in i., iii., iv., v., viii. and xii. above, you have not provided information on inoculum concentration.

For the studies listed in i., v. and vi. above, the following change of procedure was done: ammonium chloride was omitted from the test medium to prevent nitrification.

For the studies listed in i., iv. to vi., ix., x. and xiii. above, you have not provided information on results (e.g. data in tabular form and percentage removal at plateau, at end of test, and/or after 10-d window) to allow a verification that the validity criteria of the method were fulfilled.

For the studies listed in i., iii. to vi., viii. and xiii. above, conducted according to OECD TG 301D or OECD TG 301F, you have not determined the increase in concentration of nitrite and nitrate over 28d nor corrected for the oxygen consumed by nitrification.

For the studies listed in vii. and in xiv. to xviii., in the absence of information on test conditions and on results to verify the fulfilment of the validity criteria, it is not possible to verify that the key parameters of OECD TG 301 were met. In your comments to the draft decision, you specified that studies listed in vii. and in xiv. to xviii. are from publications and cannot be used to conclude on the endpoint.

For the studies listed in i., iii., iv., v., viii. and xii. in the absence of information on inoculum concentration, it is not possible to verify whether the test conditions set out in OECD TG 301 were met.

For the studies listed in i., v. and vi. you have not explained the impact of the change of procedure on the test results. In your comments to the draft decision, you justified that the change of procedure did not impact the test results for studies i., v. and vi.. You stated that ammonium chloride was omitted from test medium to prevent additional oxygen consumption due to nitrification of ammonium. Furthermore you state that omission of ammonium chloride from the medium does not result in nitrogen limitation as demonstrated by the biodegradation of the reference compound. ECHA considers that the information provided in your comments addresses this issue.

For the studies listed in i., iv. to vi., ix., x. and xiii. above, in the absence of information on results, it is not possible to verify that the validity criteria of OECD TG 301 were fulfilled.

For the studies listed in i., iii. to vi., viii. and xiii. above, since the test substances are N-containing substances and results were not corrected for the oxygen consumed by nitrification, the results are not reliable. In your comments to the draft decision, you stated that for studies listed in i., iii. to vi., viii. and xiii. above, the increase in concentration of nitrite and nitrate was only measured for study iii. and no additional nitrification was observed. For these studies, you indicated that in the dossiers the results were not corrected for the oxygen consumed by nitrification. You further indicated that, when the correction is applied, only studies iii. and viii. fulfil the pass test criteria for ready biodegradability, while studies listed i., iv., v., vi. and xiii. are considered as not readily biodegradable. ECHA considers that the information provided in your comments addresses this issue and that the new results and interpretations of the studies must be reported in the dossier.

In addition, in your comments to the draft decision you indicated your intention to provide information on inoculum concentration (for studies i., iii., iv., v., viii. and xii.) and results (for

studies i., iv. to vi., ix., x. and xiii.). ECHA notes that you did not provide any new information, so currently there is no information that could be used to support the adequacy of these studies.

Overall, based on your comments, some of the deviations can be considered as addressed (but you need to reflect them in the dossier), while other deficiencies still remain.

Hence, none of the studies provided meet the conditions listed above and therefore these studies are not adequate for the purpose of classification and labelling and/or risk assessment.

Therefore, the information requirement is not fulfilled.

Appendix B: Reasons for the requests to comply with Annex VIII of REACH

1. Short-term toxicity testing on fish

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

You have provided the following studies claimed to be conducted with the Substance:

- i. [REDACTED] (2009), key study, according to OECD TG 203, test material identified as N-Alkyl "oleyl" N, N-bis(hydroxyethyl)amine (EC No 236-062-2, CAS No 13127-82-7)
- ii. [REDACTED] (1990), according to OECD TG 203

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

- iii. [REDACTED] (1990), according to OECD TG 203 with the analogue substance EC No 276-014-8 (Substance C)
- iv. [REDACTED] (1997), according to OECD TG 203 with the analogue substance EC No 263-177-5 (CAS No 61791-44-4)

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

A. Predictions within the category

The study listed in iii. above was conducted with PFAEO category member(s). However, as explained in the Appendix on general considerations your adaptation according to Annex XI, Section 1.5 is rejected.

B. Predictions outside of the category

You have provided a study (listed in iv.) conducted with an analogue substance but not a category member.

Furthermore, you have provided a study (listed in i.) claimed to be conducted on the Substance, but the identifiers of the test material (EC No 236-062-2, CAS No 13127-82-7) do not correspond to those of the Substance. These identifiers also do not correspond to any of the category members. In Section 1.1 of your CSR you indicate that based on the names EC No 236-062-2 correlates to the Substance. In your comments to the draft decision, you indicated that EC No 236-062-2 corresponds to the Substance. However, you have not provided qualitative and quantitative information on the composition to justify why the test material used to generate the data is consistent with the Substance. Therefore, ECHA considers this study as also conducted with other substance(s) than your Substance and is used to adapt this information requirement under Annex XI, section 1.5.

However, as explained in the Appendix on general considerations your adaptation according to Annex XI, Section 1.5 is rejected.

C. Studies are not adequate and reliable

To be adequate for the purpose of classification and labelling and/or risk assessment of the Substance, the study must be conducted in accordance with the applicable OECD test guidelines or other internationally recognised test methods (Article 13(3) of REACH).

OECD TG 203 is the preferred guideline to fulfil this information requirement. The guideline specifies that for difficult to test substances (such as adsorptive, ionisable and/or surface active substances) the specifications given in the OECD GD 23 must be followed. The OECD TG 203 and the OECD GD 23, require(s) that you must (among others):

- Provide analytical monitoring to verify the initial concentrations and maintenance of the exposure concentrations during the test;
- Provide evidence that exposure concentrations have been maintained throughout the test (within $\pm 20\%$ of the nominal or initial measured concentration).

The Substance is a 'difficult to test' substance: it is a UVCB, with ionisable hence adsorptive properties and surface active (surface tension 27 mN/m) indicating difficulties for testing based on Table 2 of OECD GD 23.

For the studies listed in ii., iii. and iv. above, you have not carried out any analytical monitoring of the test concentrations nor provided any evidence that the exposure concentrations have been maintained for the test substances during the study period.

For the studies listed in ii., iii. and iv., in the absence of analytical monitoring, you have not demonstrated the maintenance of the exposure concentrations during the test. In your comments to the draft decision, you indicate that these 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.

Hence, with the exception of study i., none of the studies provided meet the conditions listed above and therefore these studies are not adequate for the purpose of classification and labelling and/or risk assessment.

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

Therefore, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the adsorptive, ionisable and surface active properties as explained above. OECD TG 203 specifies that for difficult to test substances, the OECD GD 23 is to be followed as explained above under request A.1.

Appendix C: Reasons for the requests to comply with Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is a standard information requirement at Annex IX of REACH.

You have provided the following studies with the Substance:

- i. [REDACTED] (2010), key study, according to OECD TG 211

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

To be adequate for the purpose of classification and labelling of the Substance, the source study must be conducted in accordance with the applicable OECD test guidelines or other internationally recognised test methods (Article 13(3) of REACH). For the purpose of classification and labelling, as set out in the CLP Regulation, the study must provide information on intrinsic properties i.e. the basic properties of a substance or mixture as determined in standard tests or by other means designed to identify hazards. This is to be derived without consideration of exposure under realistic environmental conditions.⁶

Similarly, for the purpose of PBT assessment Annex XIII of REACH requires generation of data under 'relevant conditions', i.e. those conditions that allow for an objective assessment of the PBT/vPvB properties of a substance and not the PBT/vPvB properties of a substance in particular environmental conditions.

As a consequence of the above, studies performed with modification to standard tests procedures impacting exposure cannot be considered relevant to derive intrinsic properties.

OECD TG 211 is the preferred guideline to fulfil this information requirement and it requires that you must (among others):

- use a fully defined medium with TOC below 2 mg/L;
- describe the analytical monitoring method used, including information on how the test samples were prepared for the quantification of the test substance.

For the study listed above, you specify that the test media consist of natural river water with the following characteristics: DOC 3.8 mg/L, TOC 3.7 mg/L and suspended matter 17.6 mg/L. You provide the following justification for the modification to standard tests media: *"The aquatic ecotoxicity tests with ethoxylated primary fatty amines were therefore performed in river water to allow a PECaquatic,bulk/PNECaquatic,bulk approach 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. 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."*

For the study listed above, exposure concentrations were analytically determined. However, you do not provide information on preparation of test sample for analytical monitoring.

⁶ CLP Guidance, Section 1.1.3.

You express the results based on nominal concentrations and you indicate that the effect concentrations are defined as the sum of adsorbed as well as dissolved substance in the volume of the medium tested.

The study listed above was conducted with non-standard test media (river water) with TOC above 2 mg/L, hence it does not meet the specifications given in OECD TG 211. The test substances are highly adsorptive cationic surfactants and are therefore expected to bind to dissolved organic matter and particulate matter. Since river water differs from standard media with regards to the content of higher organic matter and particulate matter, the use of this modified test medium impacts the exposure to the test substance. Your justification for the use of modified test medium only considers the relevance of the study for the risk assessment. However, since the applied modification to standard tests procedures impacts the exposure, the study does not inform on the intrinsic properties and the modification of the test media is not acceptable.

For the study listed above, in the absence of sufficient information on how test samples were prepared for the quantification of the test substance, ECHA cannot determine if the truly dissolved test substance concentrations were measured.

Hence, the provided study does not meet the conditions listed above and therefore the study is not adequate for the purpose of classification and labelling.

In your comments to the draft decision, for the study listed above conducted with deviations from the testing specifications set out in the corresponding OECD TGs (i.e. modification of test media), you indicated that *"we have recognised that the Bulk approach test are less adequate for Classification and labelling purposes as these studies indeed do not allow the quantification of intrinsic toxicity."* You hence agree that the study listed above is not adequate for the purpose of classification and labelling.

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

Therefore, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the adsorptive, ionisable and surface active properties as explained above. OECD TG 211 specifies that for difficult to test substances, the OECD GD 23 is to be followed as explained above under request A.1.

2. Long-term toxicity testing on fish

Long-term toxicity testing on fish is a standard information requirement at Annex IX of REACH.

You have adapted the standard information requirement based on column 2 of Annex IX, Section 9.1. with the following: *"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 considered to be required."*

As specified in Annex IX, Section 9.1., Column 2, a long-term toxicity study on fish must be performed unless the Chemical Safety Assessment demonstrates that risks towards the

aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account the following elements to support that long-term toxicity testing is not required:

- all relevant hazard information from your registration dossier.

As specified in requests A.1, B.1 and C.1, the data on short-term toxicity to *Daphnia* and to fish and the data on long-term toxicity to *Daphnia* are not compliant. Hence, your dossier currently does not include adequate information to characterise the hazardous property of the Substance to aquatic organisms.

In conclusion, in the absence of all this information, your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

In your comments to the draft decision, you confirmed your intention to provide adequate data on algae growth inhibition, short-term toxicity to *Daphnia* and to fish and long-term toxicity to *Daphnia* and to perform long-term toxicity testing on fish with the Substance if needed.

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

Study design

The Substance is difficult to test due to the adsorptive, ionisable and surface active properties as explained above. OECD TG 210 specifies that for difficult to test substances, the OECD GD 23 is to be followed as explained above under request A.1.

Appendix D: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 27 June 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

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

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

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

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

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: 'How to report robust study summaries'⁷.

4. Test material

Selection of the test material(s)

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account 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. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, 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*".

⁷ <https://echa.europa.eu/practical-guides>

In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible. For each constituent the concentration value in the test material must be reported in the Test material section of the endpoint study record.

Technical Reporting of the test material for UVCB substances

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website⁸.

5. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests.

6. List of references of the ECHA Guidance and other guidance/ reference documents⁹

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, 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.

⁸ <https://echa.europa.eu/manuals>

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>

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.

OECD Guidance documents¹¹

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.

Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

¹¹ <http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm>

Appendix F: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[REDACTED]	[REDACTED]	[REDACTED]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.