Helsinki, 17 December 2020

Addressees
Registrant(s) of [redacted] as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
15/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C10-16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts
EC number: 500-343-0
CAS number: 157627-92-4

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***3 January 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method EU B.13/14. / OECD TG 471);
2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method EU C.2./OECD TG 202);
3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method EU C.3./OECD TG 201);
4. 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. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487);
2. Only if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. is obtained, In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490);
3. and 4. Combined repeated dose toxicity study with the reproduction/developmental toxicity screening study (Annex VIII, Sections 8.6.1. and 8.7.1.; test method: OECD TG 422) in rats, oral route (gavage)
5. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method OECD TG 203);

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

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

Information required depends on your tonnage band

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

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

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.

Approved[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

i. Assessment of the Grouping of substances and 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:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)
- 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

i. Description of the grouping

In your registration dossier you have formed a group (category) of 'alcohol ethoxylate sulphates' (AES). You have provided a read-across justification document in IUCLID Section 13.

Registered category members are listed here. Your category justification document also covers unregistered substances without further data in the dossier, and therefore they are not addressed.

Substance name	EC number	CAS number
Alcohols, C12-13, branched and linear, ethoxylated, sulfates, sodium salt (EO 1-2,5)	500-513-4	161074-79-9

Alcohols, C12-14, ethoxylated, sulfates, sodium salts (EO 1-2,5)	500-234-8	68891-38-3
Alcohols, C12-18, ethoxylated, sulfates, sodium salts (EO 1-2,5)	500-189-4	68081-91-4
Alcohols, C9-11, branched and linear, ethoxylated, sulfates, ammonium salts (EO 1-2,5)	500-464-9	160901-27-9
Alcohols, C8-10, ethoxylated, sulfates, ammonium salts (EO 1-2,5)	500-233-2	68891-29-2
Alcohols, C12-14 (linear, even-numbered), ethoxylated, sulfates, ammonium salts, < 2.5 mol EO	939-575-6	n.a.
Alcohols, C12-14 (even-numbered), ethoxylated (<=2.5 moles EO), sulfated, monoisopropanolamine salt	932-185-7	1187742-72-8
Alcohols, C12-14 (even-numbered), ethoxylated, magnesium salts, < 2.5 mol EO	939-578-2	n.a.
Alcohols, C8-10, ethoxylated, sulfates, sodium salts	939-523-2	n.a.
Alcohols, C9-11, branched and linear, ethoxylated, sulfates, sodium salts (EO 1-2,5)	500-465-4	160901-28-0
Alcohols, C10-12 (even-numbered), ethoxylated (EO 1-2,5), sulfated, sodium salts	939-597-6	*68610-66-2*
Alcohols, C16-18 and C18-unsatd., ethoxylated, sulfates, sodium salts (EO 1-2,5)	500-345-1	157627-95-7
Alcohols, C10-16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts (EO 1-2,5)	500-343-0	157627-92-4
Alcohols, C10-16, ethoxylated, sulfates, triethanolammonium salts (EO 1-2,5)	500-344-6	157627-94-6

Your reasoning for the grouping the substances can be summarised as: Alkyl ether sulfates are anionic surfactants with common characteristics. These are an aliphatic ethoxylated chain with a polar sulfate group neutralized with a counter-ion. The hydrophobic part is a hydrocarbon chain with a length of 8 to 18 carbon atoms (C8-C18). The polar and hydrophilic ethoxy-sulfate group confers the surfactant properties and enables the use of these substances as anionic surfactants.

Your definition of the applicability domain of the category can be summarised as: alkyl ether sulfates with predominantly linear but also branched alkyl chains, with lengths of C8-C18, including C18 unsaturated chains. The ethoxylation degree is less than 2,5. Permissible counter-ions are: sodium(Na^+), magnesium (Mg^{2+}), ammonium (NH_4^+), and ammonium alcohols: mono(hydroxyethyl)ammonium (MEA), tri(hydroxyethyl)ammonium (TEA), mono-(2-hydroxypropyl)ammonium (MIPA), or tri-(2-hydroxypropyl)ammonium (TIPA).

ii. Assessment of the grouping

ECHA notes the following shortcomings with regards to your grouping approach.

Characterisation of the group members

Annex XI, Section 1.5 of the REACH Regulation provides that *"substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."*

According to the ECHA Guidance, *"in identifying a category, it is important that all potential category members are described as comprehensively as possible"*, because the purity profile and composition can influence the overall toxicity/properties of the potential category

members.[2] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to confirm the category membership.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; 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.[3]

You have defined the applicability domain of the category as explained above. Your read-across justification document contains limited compositional information for the members of your category. The category members include UVCBs of sulphated ethoxylated alcohols of various carbon chain lengths. However, the degree -or absence- of ethoxylation, as well as alkyl chain branching and its length, is not provided for the category members, and for all boundary compositions.

In your comments on the draft decision you indicate that you will "*include additional analytical data on the structure and compositional details of the substances*".

ECHA notes your intention to provide this information. Should you provide this information in a subsequent update to your dossier ECHA will assess this information after the set deadline of this decision.

Without information on the distribution of the ethoxylate groups amongst constituents, including for certain constituents with a lack of ethoxylation, no qualitative or quantitative comparative assessment of the compositions of the different category members can be completed. Furthermore, differences in the alkyl chains (length, potential branching and saturation, as relevant) need to be accounted for. For a practical example please refer to the Appendix on test material characterisation at the end of this decision.

Therefore, the category membership cannot be confirmed.

B. Predictions of eco-/toxicological properties

Your read-across hypothesis common for the prediction of toxicological, ecotoxicological and environmental fate properties can be summarised as: Common route of synthesis, similar structural features (surfactant) and similar physico-chemical properties result in similar properties for metabolism, environmental fate, and essentially identical hazard profiles regarding human health. In addition, a trend of increasing toxicity with increasing alkyl carbon chain length can be observed for aquatic toxicity.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have similar properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance for all endpoints except for aquatic toxicity, for which your prediction is based on an identified trend within the group.

You intend to predict the properties for the Substance from information obtained from studies

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[3] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

with category members:

Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)

1} 90-day oral study (OECD TG 408, 1994) with CAS 68891-38-3
2} 90-day oral study (1977a) with CAS 68585-34-2
3} 91-day oral study (1977b) with CAS 68585-34-2
4} 90-day oral study (1967) with "*Sodium lauryl (3EO) ethoxysulphate*"
5} Chronic toxicity study (1962/1991) with "*Lauryl ethoxysulphate*"

In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

6} Ames test (OECD TG 471, 1996) with CAS 157627-92-4

In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.) or adaptation through an *in vivo* study such as In vivo mammalian bone marrow chromosomal aberration test (Annex IX, Section 8.4., column 2)

7} In vivo mammalian chromosome aberration test (OECD TG 475, 1995) with CAS 68891-38-3

In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

8} In vitro mammalian cell gene mutation test (OECD TG 476, 1995) with CAS 68891-38-3

Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) and/or Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.)

9} Two-generation reproductive toxicity study (OECD TG 416, 1999) with CAS 68891-38-3

Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

10} Key study (OECD TG 202) with a substance named Alkylethoxysulfate monoethanolamine salt (AES-MEA) / AES(C12-13, 0.85EO)MEA.
11} Supporting study (OECD TG 202) with a substance named fatty alcohol (C12 - C14)- polyethyleneglycol (2EO)-ethersulfate natrium salt (EC number 500-234-8).
12} Supporting study (OECD TG 202) with a substance named Fatty alcohol C12 - C14-ethoxylated (2EO) sulfated, monoisopropanol ammonium salt.

Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

13} Key study (OECD TG 201) with a substance named Alkylethoxysulfate monoethanolamine salt (AES-MEA) / AES(C12-13, 0.85EO)MEA.
14} Supporting study (OECD TG 201) with a substance named fetty alcohol (C12-C14) polyethylenglycol-(2EO)-ethersulfate sodium salt (EC number 500-234-8).
15} Supporting study (OECD TG 201) with a substance named Fatty alcohol C12 - C14-ethoxylated (2EO), sulfated monoisopropanol ammonium salt.

Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

16} Key study (OECD TG 203) with a substance named fatty alcohol (C12 - C14)-polyethyleneglycol (2EO)-ethersulfate natrium salt (EC number 500-234-8 and EC number 500-513-4).
17} Supporting study (OECD TG 203) with a substance named Alkylethoxysulfate monoethanolamine salt (AES-MEA) / AES(C12-13, 0.85EO)MEA.
18} Supporting study (OECD TG 203) with a substance named Fatty alcohol C12 - C14-ethoxylated (2EO) sulfated, monoisopropanol ammonium salt.

Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

19} Key study (OECD TG 211) with a substance named Alkyl Ethoxylate Sulfate; AES; Alkylethoxysulfate; C12-14E2.25S (EC number 500-223-8).
20} Supporting study (OECD TG 211) with a substance named sodium 2-(dodecyloxy)ethyl sulphate (EC number 239-925-1).
21} Supporting study (OECD TG 211) with a substance named sodium 2-(2-dodecyloxyethoxy)ethyl sulphate (EC number 221-416-0).
22} Supporting study (OECD TG 211) with a substance named C14EO1S alcohol ethoxylate sulfate.
23} Supporting study (OECD TG 211) with a substance named C14EO2S alcohol ethoxylate sulfate.

Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

24} Key study (OECD TG 204) with a substance named Alcohols, C12-14, ethoxylated, sulfates, sodium salts (EC number 500-234-8).

25} Supporting study (OECD TG 210) with a substance named sodium tetradecyl dioxyethylene sulfate.

Ready biodegradability (Annex VII, Section 9.2.1.1.)

26} Key study (according to OECD TG 301 D) with a substance named Alkyl ether sulfate C12-18 2-EO, sodium salt.
27} Supporting study (according to OECD TG 301 B) with a substance named Alkylethoxysulfate monoethanolamine salt (AES-MEA) / AES(C12-13, 0.85EO)MEA.

a. Shortcomings in the predictions common to both toxicological and ecotoxicological properties

ECHA notes the following shortcomings with regards to predictions of toxicological, ecotoxicological and environmental fate properties.

1. Adequacy and reliability of 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);
- have adequate and reliable documentation of the applied method.

a. 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 source substance and test material used to generate the source data is required to evaluate the reliability and uncertainty associated with predicting properties of substances with potential substantial compositional differences. The composition of the selected test material must be reported in the respective endpoint study record, under the test material section.

Your read-across justification document contains compositional information for the members of your category. It states that the category members are UVCBs of sulphated ethoxylated alcohols of various carbon chain lengths and ranges of ethoxylation. The information on test materials provided in your dossier is limited to the generic name of UVCB substance and/or numerical identifier. The averaged degree of ethoxylation and test material purity are reported for some but not all studies. The range of ethoxylation (degree, including absence), as well as alkyl chain branching and its length, are not provided for any test materials.

Furthermore and in particular:

a) No information on the composition within the purity of the "active compound" is given for any study except study 10}, 13}, 17}, 20}, 21}, 22}, 23}, 25},27};
b) No information on the composition, other than the 'active compound', and the range of constituents* beyond the reported purity is given for any study except study 21}, 23};
c) No information is provided for any study on the ethoxylation range and quantity of individual constituents, especially constituents without information on the degree of ethoxylation except study 20}, 21}, 22}, 23}, 25}, 27};
d) No details are provided in any study on how the average ethoxylation degree is determined for a substance (not relevant for studies 20}, 21}, 22}, 23}, 25});
e) No quantification of constituents is provided for any study regarding the length, branching and saturation of alkyl chains.

*Note: "range of constituents" refers to identity and (definitive) concentrations of all constituents as explained below, to characterize a test material batch.

Without comprehensive reporting of all constituents present in the test material (including their identity and concentrations) and without consideration of the distribution or absence of the ethoxylation amongst constituents with different carbon chain length, no qualitative or quantitative comparative assessment of the compositions of the different category members as test material and as registered substance can be completed. Furthermore, differences in the alkyl chains (length, potential branching and saturation) need to be accounted for. For a practical example please refer to the Appendix on test material characterisation at the end of this decision.

In your comments to the draft decision, you indicate that "*further characterisation of test materials used to generate source data will be provided*" and that dossier updates have been submitted for two category members (EC 500-233-2, EC 500-234-8), for ECHA to evaluate.

As ECHA has explained to you in the notification letter of the draft decision, 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 the REACH Regulation. This is also reflected in ECHA's news alert of 26 November 2019 (https://echa.europa.eu/-/echa-does-not-consider-dossier-updates-during-evaluation-decision-making). The news alert explains that if new information becomes available after receipt of the draft decision, registrants must submit this information through their comments to the draft decision. The Agency will consider the information in the comments and may amend the decision accordingly.

However, you do not substantiate your comments with any of the above information, including definitive concentration of constituents. Therefore ECHA cannot assess from your comments if you have addressed the request(s).

Irrespective of whether or not the update addresses the shortcomings on test material, this does not address the other shortcomings identified for the affected endpoints. Therefore, this

information will not allow ECHA to remove any of the requests.

ECHA will evaluate the relevance of your further test materials characterisation to address the specific properties under investigation for the category members, after the set deadline of this decision. This depends on whether the other shortcomings identified under the specific endpoint have been addressed.

ECHA is unable to confirm, based on the information in the original dossier and your comments to the draft decision, that the test materials are relevant for the Substance and to all the registrants of the Substance. Therefore, ECHA concludes that it is not possible to assess whether the attempted predictions are compromised by the composition of the test materials. Consequently, the corresponding study results are not adequate for the purpose of classification and labelling and/or risk assessment.

b. Further deficiencies

Other deficiencies are identified in the requests for specific information requirements in Appendices A-B.

They are explained in sections **i.B.b.** *Shortcomings in the prediction of toxicological properties* and **i.B.c.** *Shortcomings in the prediction of ecotoxicological properties* of this appendix, and endpoint-specific deficiencies under the request for a specific information requirement in Appendices **A-B**.

2. No basis for prediction

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)*".

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

The provided information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members. For categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the test materials; 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]

The information on test materials provided in your dossier is limited to the generic name of

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

UVCB substance and/or numerical identifier. The averaged degree of ethoxylation and test material purity are reported for some but not all studies. The range of ethoxylation (degree, including absence), as well as alkyl chain branching and its length, are not provided for any test materials.

No information on the ethoxylation degree of the individual constituents of the category members is provided in your dossier. Furthermore, no further details are provided on how the average ethoxylation degree is determined for a substance.

In your comments on the draft decision you indicate that "further characterisation of test materials used to generate source data will be provided". ECHA will evaluate this information after the deadline of this set decision has passed. You state that the registration dossiers of two category members (EC 500-233-2, EC 500-234-8) were updated before the end of the commenting deadline. Please refer to ECHA's reply to the same comment in the above section, **i.B**.A.1.a.

Without consideration of the distribution of the ethoxylation amongst constituents with different carbon chain length, no qualitative or quantitative comparative assessment of the compositions of the different test materials can be completed. Therefore, is not possible to assess whether the attempted predictions are compromised by the composition of the test materials and their relation to category members.

3. Data density

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.*

According to the ECHA Guidance, one of the factors in determining the robustness of a category is the density and distribution of the available data across the category.[6] To identify a regular pattern and/or to derive reliable prediction of the properties of the members of the category, adequate and reliable information covering the range of structural variations identified among the category members needs to be available.

Furthermore in larger categories there may be breaks in trends which could affect the reliability of interpolation.[7] To confirm that there are no such breakpoints, adequate and reliable information needs to cover also substances within a range of homologous series.

In your dossier, you have provided the studies listed above.

In addition, you have provided toxicity data after repeated administration only for category members with apparently predominant alkyl chain lengths of C12-C14, without explaining why these would be representative.

For *in vitro* genotoxicity endpoints, the available information was generated with a maximum of two (A.VIII, 8.4.3) to three (A.VII, 8.4.1) substances out of 25+ category members.

The data set reported for all endpoints does not include relevant, reliable and adequate information for the category members to support your read-across hypothesis. This is due to

[6] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.1.5.
[7] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.2.

the deficiencies of studies explained in the sections which relate to *adequacy*, *reliability* and *relevance* in sections **i.B.a.**, **i.B.b.** and **i.B.c.** of this appendix, as well as in the appendices on *reasons for the requests* **A-B**.

In the absence of such information for all endpoints, you have not established that the category members are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

Furthermore, information for category members with predominant alkyl chain lengths of 12-14 carbon atoms is not sufficient to establish a trend across a category with alkyl chains of 8-18 carbon atoms. In the absence of information on substances at the upper and lower borders of the category, it cannot be confirmed that there is no change in toxicity or breakpoint in trends within the given range of chain length.

For *in vitro* genotoxicity, information on a maximum of two to three substances per endpoint out of 25+ category members does not allow to conclude on the similarity of properties across the category, given the variations in alkyl chain length, branching, saturation and the effects of counter-ions.

In your comments to the draft decision, you indicate that "*representative substances will be identified for each sub-group. The definition of sub-groups and the identification of representative substances will be based on the most robust analytical characterisation and description of the compositions of the AES substances.*" Furthermore you agree to generate new experimental data to address the existing deficiencies. You may include information from new approach methods or computational methods to further strengthen the approach. It is in your discretion to generate and provide the necessary supporting information in order to justify your read-across adaptation. 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.

Therefore, the information provided in the assessed technical dossier and your comments to the draft decision is not sufficient to conclude that toxicological, environmental fate and ecotoxicological properties are likely to follow a regular pattern.

ECHA notes additionally the following shortcoming(s) with regards to prediction(s) of toxicological and ecotoxicological properties.

b. Shortcomings in the prediction of toxicological properties

1. *Adequacy and reliability of studies – key parameters according to the test method regulation*

Studies must be conducted in accordance with the corresponding test methods referred to in Article 13(3) and according to the provisions of the REACH Annexes. To be considered adequate, the studies you submitted have to cover the key parameters of OECD TGs 408, 452. According to these test guidelines the studies must cover key parameters such as:

a. Recommended species,
b. Applicable treatment schedule,
c. Investigations of clinical observations, clinical chemistry, histo-/pathology,
d. Reporting of findings,

e. Application of statistical methods used to derive effect levels.

You have not provided any information on the key parameters listed above for the studies 4}, 5}.

In the absence of such information, ECHA is unable to assess the adequacy of these studies and compliance with the above key parameters.

Therefore, ECHA is unable to assess whether the attempted predictions are compromised by the absence of key parameter investigations and concludes that the studies are unreliable.

2. Dosing regime

To be considered adequate, the studies you submitted have to cover the key parameters of OECD TGs 408, 416, 452, 475. According to these test guidelines, the dose levels must be set with the aim to induce systemic toxicity at the highest dose level but not suffering or death.

You have submitted the following studies, that have not achieved inducing systemic toxicity and the highest dose level is below the limit dose[8]: 1}, 3}, 4}, 5}, 7}, 9}. The data reported in the dossier does not include details confirming the basis for the selection of the maximum studied dose to aim to induce toxicity but not suffering or death. The test material is not fully characterised (see **i.B.a.**1) in any of the studies 1}-9}. No details were provided on the range of constituents and impurities of the test material in these studies. You did not explain for all studies whether the reported dose was corrected for purity or not.

The submitted studies have not investigated the hazardous properties using high enough dose levels. In addition to this, it is unclear for some studies whether the reported test doses are for the impure material tested or whether they have been corrected to the concentration of the Substance. If uncorrected, this aggravates the issue of low dosing. Therefore, you have not demonstrated that the the dose level selection was high enough.

None of the studies fulfil the criteria set out in the OECD TGs 408, 416, 452, 475.

Therefore, they cannot be used for the grouping approach.

c. Shortcomings in the prediction of ecotoxicological properties

i. Aquatic toxicity

1. Adequacy of studies provided for aquatic toxicity

The standard aquatic toxicity test guidelines OECD TG 202, OECD TG 203, OECD TG 210 and OECD TG 211 in combination with the revised OECD Guidance 23, ENV/JM/MONO(2000)6/REV1 applicable to difficult to test substances require that specific conditions listed in each guideline are met to ensure validity and reliability of the conducted test. The validity criteria and/or parameters of these TGs include (among other parameters):

a) analytical monitoring of exposure concentrations throughout the test; and the results of the analytical determination of exposure concentrations and (if necessary) calculation of effect levels as measured concentrations;

[8] ECHA Guidance, R.7a, Section 7.6

b) information on the total organic carbon concentration (TOC) present in the test medium;

Based on the information available in the registration dossiers of the category members and in the category justification document, members of the category are surface active, could be present in ionised form and have potential to degrade in the test medium. Therefore, these substances are difficult to test.

For the provided study 11}12}14}15}18}24} there is no information reported in the registration dossier about analytical monitoring of exposure concentrations throughout the test. Furthermore, for the provided studies 10}, 11}, 12}, 16}, 17}, 18}, 19}, 20}, 21}, 22}, 23}, 24}, 25} there is no information reported in the registration dossier about total organic carbon concentration present in the test medium.

In the comments to the draft decision you note that information on TOC concentration is neither a reliability criterion in the cited toxicity test guidelines nor in the OECD Guidance 23. You further note that Annex 3 of OECD Guidance 23 states that standard test media used for aquatic hazard testing usually have a typical TOC concentration of < 2 mg/L, which is much lower than the typical TOC of surface water. Therefore, adsorption to dissolved organic carbon is presumably negligible and a mitigating effect on toxicity due to adsorption to dissolved organic carbon can be excluded. The aquatic ecotoxicity tests submitted for the AES category substances are mainly prepared with standard test media. You emphasise that all aquatic ecotoxicity tests prepared with standard medium (as opposed to natural water from rivers, ponds, lakes etc.) are conducted under worst-case conditions and a mitigation of toxicity by adsorption can be excluded. For this reason, you cannot agree with ECHA's argumentation that the studies are not reliable.

ECHA notes that providing the TOC concentration is not a validity criteria of these test guidelines, however information on water characteristics used for the test medium preparation need to be reported, and information on the TOC concentration is part of the water characteristics. Therefore, it is an example of the test specification (parameter) of the test guidelines.

The CLP Guidance, Section 1.1.3. explains that classification must be based on intrinsic hazards, i.e. the basic properties of a substance or mixture as determined in standard tests or by other means designed to identify hazards. As the CLP Regulation is hazard-based, the data on intrinsic properties must not take exposure into consideration. Similar considerations apply for the PBT assessment. As per Annex XIII of REACH, the PBT assessment should be based on data generated 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.

To allow identification of the intrinsic hazard property of a substance aquatic toxicity test guidelines (OECD TG 202, OECD TG 203, OECD TG 211, OECD TG 210) specify that the test medium should contain ≤ 2 mg/L of TOC. However, you have not demonstrated that this was adhered too.

Respective guidelines further specify that information on TOC in the test medium should be reported and identify how quality parameters, including TOC, of the test medium or of the dilution water which is used for the preparation of the test medium are determined. As explained above, it is important for defining intrinsic hazard property of a substance and use of results of the studies for hazard assessment, including classification and labelling, and PBT/vPvB assessment. Indeed, it is expected for the aquatic ecotoxicity tests prepared with

standard media that there is no mitigation of toxicity by adsorption (e.g. for ionisable surface active substances which might posses high potential for adsorption). However, this should be confirmed with the information on TOC concentration in the test medium.

Thus, in order to allow an independent assessment of the studies submitted missing information on the TOC concentration in the test medium needs to be submitted.

Consequently, such studies (i) cannot address standard information requirements of REACH Annexes VII-X; (ii) are not adequate for the purpose of classification and labelling; and (iii) cannot be used as source studies.

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

As explained above, you have not established that relevant hazard and fate properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

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

1. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

Grouping and read-across rejected

As explained in the Appendix on Reasons common to several requests your adaptation is rejected. In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

No study fulfilling the requirements in OECD TG 471

To fulfil the information requirement and the requirements for read across adaptations as explained in the Appendix on Reasons common to several requests, a study has to cover the key parameters of the applicable test guideline, in this case OECD 471 whose key parameters include: The test must be performed with 5 strains. These are four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

None of the reported data for the studies you have provided for this information requirement includes results for the required fifth strain, *S. typhmurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

In your comments you state that the fifth Ames strain was not included in the test guideline OECD TG 471 at the time that the studies above were performed (Annex XI, 1.1.2). In support you provide reference to a recent publication ([redacted] 2019).

The adaptation rule in Annex XI, Section 1.1.2 imposes a number of cumulative conditions for an adaptation to be valid, in particular:

1. Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3), in this case those of OECD TG 471:
    a) 5 strains including S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).
2. Adequate and reliable documentation of the study is provided;

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

1. The above key parameters of an OECD TG 471 are not met by the provided study, because there is no
    a) information on the specific modes of action investigated by S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).
2. The provided documentation in the endpoint study record is very limited and does not contain e.g. tabulated data.

The literature reference cited in your comments states "When including an in vitro assay that detects clastogens such as the in vitro chromosome aberration assay, the resultant battery would detect 99% of bacterial mutagens". ECHA notes that

i. You did not provide reliable information with chromosome aberration assays, nor on gene mutation assays in mammalian cells which are part of genotoxicity testing batteries; and
ii. OECD TG 471 in its current form has been internationally agreed for mutual acceptance of data and is an information requirement under REACH Annex VII Section 8.4.1 including the five strains listed above.

The information provided in the above studies does not cover the key parameters required by OECD TG 471.

In the comments to the draft decision you state that your registration dossier was updated before the end of the commenting deadline. Please see ECHAs reply to the same comment in the above section, **i.B**.A.1.a.

Therefore, the information requirement is not fulfilled.

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

Short-term toxicity testing on aquatic invertebrates is a standard information requirement in Annex VII to REACH. Pursuant to Annex VII, section 9.1.1, column 2, the study does not need to be conducted if a long-term aquatic toxicity study on invertebrates is available.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

– Grouping and read-across rejected

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

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

- *Reliability of studies*

The standard aquatic toxicity test guidelines require that specific conditions listed in each guideline are met to ensure validity and reliability of the conducted test. The key parameters of OECD TG 211 include (among other parameters):

For flow-through tests, a minimum of 20 animals per concentration divided into two or more replicates with an equal number of animals.

In all four supporting long-term aquatic invertebrates toxicity studies 20}, 21}, 22}, 23} provided in the registration dossier *Ceriodaphnia dubia* was used as test organism. All these studies were flow-through tests and had 10 vessels per test concentration with 1 organism per vessel. Thus, ECHA considers that these long-term aquatic invertebrates toxicity studies with lower number of test animals per concentration than recommended in OECD TG 211 do not enable reliable determination of (no)effect concentrations. Thus, ECHA considers these studies to be not reliable.

Comments to the draft decision specific to the short-term toxicity testing on aquatic invertebrates are addressed in the Appendix on Reasons common to several requests.

Thus, the information requirement is not fulfilled neither by the provided short-term nor long-term toxicity studies with aquatic invertebrates.

As the Substance is surface active, could be present in ionised form and have potential to degrade in the test medium, you need to consult the OECD Guidance Document (GD) 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test(s) and you best calculate and report the results of the test(s).

3. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

- *Grouping and read-across rejected*

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

Comments to the draft decision specific to the growth inhibition study aquatic plants are addressed in the Appendix on Reasons common to several requests.

Thus, the information requirement is not fulfilled.

As the Substance is surface active, could be present in ionised form and have potential to degrade in the test medium, you need to consult the OECD Guidance Document (GD) 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test(s) and you best calculate and report the results of the test(s).

4. Ready biodegradability

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

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

- *Grouping and read-across rejected*

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

Comments specific to the ready biodegradability are addressed in the Appendix on Reasons common to several requests.

Thus, the information requirement is not fulfilled.

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

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have provided a Grouping of substances and read-across approach adaptation to fulfill Column 2 of Annex VIII, Section 8.4.2., by providing an *In vivo* Mammalian chromosome aberration test (OECD TG 475, 1995) with an analogue substance.

We have assessed this information and identified the following issues:

Grouping and read-across rejected

As explained in the Appendix on Reasons common to several requests your adaptation is rejected. In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

Column 2 adaptation rejected

Column 2 of Annex VIII, Section 8.4.2. provides that an experimental study for this endpoint is not needed if adequate data from an *in vivo* cytogenicity test is available.

Based on the rejection of the grouping and read-across above, the information you provided does not fulfil the information requirement.

In the comments to the draft decision you state that your registration dossier was updated before the end of the commenting deadline. Please see ECHAs reply to the same comment in the above section, **i.B**.A.1.a.

Therefore, the information requirement is not fulfilled.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Assessment of trigger

Your dossier contains data for an *in vitro* gene mutation study in bacteria, and data for an *in vivo* cytogenicity study.

The information for the *in vitro* gene mutation study in bacteria and for the *in vivo* cytogenicity study provided in the dossier are rejected for the reasons provided in section 1 of Appendix A and section 1 of this Appendix.

The results of the requests for *in vitro* gene mutation study in bacteria and for the *in vivo* cytogenicity study will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study is triggered in accordance with Annex VIII, Section 8.4.3.

Assessment of information provided to address this information requirement

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

As explained in the Appendix on Reasons common to several requests your adaptation is rejected and the information requirement is not fulfilled.

3. Short-term repeated dose toxicity (28 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

You have provided an adaptation according to Column 2 of Annex VIII, Section 8.6.1 in your dossier, by providing four oral subchronic studies and one oral chronic study with analogue substances. Therefore, you have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

Grouping and read-across rejected

As explained in the Appendix on Reasons common to several requests your adaptation is rejected. In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

Column 2 adaptation rejected

Column 2 of Annex VIII, Section 8.6.1. provides that an experimental study for this endpoint is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

Based on the rejection of the grouping and read-across above, the information you provided does not fulfil the information requirement.

In the comments to the draft decision you state that your registration dossier was updated before the end of the commenting deadline. Please see ECHAs reply to the same comment in the above section, **i.B**.A.1.a.

Therefore, the information requirement is not fulfilled.

Information on study design

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/ developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH

Annex VIII, 8.7.1.[9]

Referring to the criteria provided in Annex IX, Section 8.6.1, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a solid without a significant proportion (>1% on weight basis) of particles of inhalable size.

Therefore the Combined repeated dose toxicity study with the reproduction/ developmental toxicity screening study must be performed according to the OECD TG 422, in rats and with oral administration of the Substance.

4. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided a Grouping of substances and read-across approach adaptation to fulfill Column 2 of Annex VIII, Section 8.4.2., by providing a Two-generation study (1999) with an analogue substance.

We have assessed this information and identified the following issues:

Grouping and read-across rejected

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

In the comments to the draft decision you state that your registration dossier was updated before the end of the commenting deadline. Please see ECHAs reply to the same comment in the above section, **i.B**.A.1.a.

Therefore, the information requirement is not fulfilled.

Information on study design

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/ developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[10]

A study according to the test method EU B.64/OECD TG 422 must be performed in rats with oral[11] administration of the Substance.

[9] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)
[10] ECHA Guidance, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)
[11] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Therefore the Combined repeated dose toxicity study with the reproduction/ developmental toxicity screening study must be performed according to the OECD TG 422, in rats and with oral administration of the Substance.

5. Short-term toxicity testing on fish

Short-term toxicity testing on fish is a standard information requirement in Annex VIII to REACH. Pursuant to Annex VIII, section 9.1.3, column 2, the study does not need to be conducted if a long-term aquatic toxicity study on fish is available.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

– *Grouping and read-across rejected*

As explained in the Appendix on Reasons common to several requests your adaptation is rejected. In addition, the following endpoint-specific deficiency has been identified in your read-across adaptation:

- *Adequacy of study*

To meet this information requirement, a study must be a long-term fish test, which means studies in which sensitive life-stages (juveniles, eggs, larvae) are exposed (Section 9.1.6., Annex IX; Guidance R7b, section R.7.8.4.1).

You have provided key study 24} performed according to OECD TG 204.

This is a prolonged acute study with fish mortality as the major endpoint examined (*"additionally, the growth parameters weight and length of the test fish were determined at the start and the end of the test"*), but it does not cover any sensitive life-stages (e.g. eggs, larvae).

Therefore, the provided study is not adequate for this information requirement and is rejected.

Comments to the draft decision specific to the short-term toxicity testing on fish are addressed in the Appendix on Reasons common to several requests.

Thus, the information requirement is not fulfilled neither by the provided short-term nor long-term toxicity studies with fish.

As the Substance is surface active, could be present in ionised form and have potential to degrade in the test medium, you need to consult the OECD Guidance Document (GD) 23 and ECHA Guidance, Chapter R7b, Table R.7.8-3 relating to the aquatic toxicity testing of difficult substances, so that you choose the most appropriate design of the requested ecotoxicity test(s) and you best calculate and report the results of the test(s).

Appendix C: 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[12].

B. Test material

Selection of the test material(s) for UVCB substances

The Lead Registrant of the joint submission has to report boundary composition as part of their dossier. Each individual member has a responsibility to ensure that the data provided for Annex VII-X is relevant for their substance as it is manufactured. Members should ensure that their compositional information is reported so that it is coherent and within the boundaries of what is reported in the boundary composition record(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

[12] https://echa.europa.eu/practical-guides

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".

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.

Therefore, you must provide information on the distribution of the ethoxylate groups amongst constituents, including for certain constituents with a lack of ethoxylation. Furthermore, differences in the alkyl chains (length, potential branching and saturation, as relevant) need to be accounted for. This also means providing breakdown of the composition so that:

- Constituents must be reported based on the alkyl chain length
- Linear and branched constituents should be reported separately (if relevant)
- To the extent possible, each ethoxylation degree (per alcohol) should be identified and reported separately.
- If it is not possible to identify and quantify all individual constituents present in the test material, grouping may be needed for example for constituents with higher ethoxylation degrees (EO 4+).

As an example: [redacted] and sodium [redacted] would need to be listed as separate constituents.

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website[13].

[13] https://echa.europa.eu/manuals

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

A. 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 and testing needed.

B. Environmental testing for substances containing multiple constituents

Your Substance is a UVCB 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 E: 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 24 July 2019.

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

ECHA took into account your comments and did not amend the requests.

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

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

Appendix F: List of references - ECHA Guidance[14] 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)[15]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[15]

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[16]

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

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

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

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

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

Appendix G: 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]

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.