EUROPEAN CHEMICALS AGENCY

Helsinki, 11 December 2018

Addressee: [redacted]

Decision number: CCH-D-2114453639-37-01/F
Substance name: Isotridecanol, ethoxylated
EC number: 500-241-6
CAS number: 69011-36-5
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15/08/2017
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:

1. **Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105) with the registered substance;**

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

3. ***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) with the registered substance;**

4. ***In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490) with the registered substance, provided that both studies requested under 2. and 3. have negative results;**

5. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the registered substance;**

6. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD 421/422) in rats, oral route with the registered substance;**

7. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

8. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;**

9. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

10. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**

11. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**

12. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

13. **Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD TG 209) with the registered substance;**

14. **Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2; test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei), OECD TG 222, or Enchytraeid reproduction test, OECD TG 220 with the registered substance;**

15. **Long-term toxicity to plants (Annex IX, Section 9.4.3., column 2; test method: Terrestrial plants, growth test, OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or, Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030) with the registered substance;**

16. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216) and carbon transformation test, EU C.22/OECD TG 217 with the registered substance;**

17. **Robust study summaries for ready biodegradability studies (Annex VII, Section 9.2.1.1. in conjunction with Annex I, Section 3.1.5.)**

    OR

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B)

    OR

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C)

    OR

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D)

    OR

    Ready biodegradability (Annex VII, Section 9.2.1.1.; test method:

Manometric respirometry test, OECD TG 301F).

18. **Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption using an appropriate test method) with the registered substance;**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You have to submit the requested information in an updated registration dossier by **20 September 2021**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Authorised[1] by **Claudio Carlon**, Head of Unit, Evaluation **E2**

[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 1: Reasons

PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation.

1. Water solubility (Annex VII, Section 7.7.)

"Water solubility" is a standard information requirement as laid down in Annex VII, Section 7.7 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

Knowledge of the water solubility is a prerequisite for setting up test conditions for a range of fate (*e.g.*, biodegradation, bioaccumulation) and effects studies. Meaningful and reliable data need to be available. In this context, you are advised to take due account of the properties of the registered substance (*i.e.*, UVCB with surface active properties). For instance, as explained in ECHA *Guidance on information requirement and chemical safety assessement* (version 6.0, July 2017), Chapter R.7a, Section R 7.1.7.2, the meaning of 'solubility' for UVCB substances, should be understood as 'the composition of the aqueous solution formed at equilibrium under a defined set of conditions'. Further guidance for determining appropriate test methods for the water solubility is available in Section R.7.1.7 of the above ECHA document.
In your technical dossier you provided:

- A record for a study conducted according to ASTM E1148-02 (not GLP compliant) with the registered substance. Water solubility was determined using a flask method. 6 separatory funnels were prepared by adding either 50 or 250 µL of the registered substance in 100 ml of water (water quality not specified). The funnels were stored for 6 days without movement in order "*to avoid emulsification*". In the study summary, you did not specify how the undissolved material was removed prior to the quantification of the dissolved fraction and you state that "*2 mL of the slightly turbid aqueous phases are removed from the separatory funnels directly to HPLC vials*". The quantification was determined using HPLC-RI. The water solubility at the 50 µL and 250 µL loading rate was determined to be 20 mg/L and 29 mg/L. By averaging the values obtained at the two loading rates, you considered the water solubility to be 24.5 mg/L at 21°C.
- A water solubility estimate based on the EPI Suite WATERNT v1.01 QSAR. The prediction is based on the "*fragment constant*" method. As input to the model, you selected three chemical structures: a branched C13 fatty alcohol and two branched C13 alcohol ethoxylates with an EO degree of 1 and 2, respectively. Based on the water solubility estimated by the QSAR, you then calculated a weight-averaged water solubility for the registered substance. Using this method, the water solubility of the registered substance was determined to be 44.0 mg/L. You specified that "*the substance fits the applicability domain*" and that "*the prediction is valid*".

First, ECHA notes that under section 4.10 of your technical dossier, you reported that the surface tension of a 20 mg/L solution of the registered substance is 30 mN/m at 25°C. Accordingly, the registered UVCB shall be considered as surface active.

Then, ECHA identified the following deficiencies with the information provided for this endpoint:

- In the study conducted according to ASTM E1148-02, the loading rates used in the

water solubility study (50 or 250 µL per 100 mL of water) were likely above the critical micelle concentration and you specified that the sample collected for HPLC-RI analysis was slightly turbid. As specified in ECHA *Guidance on information requirements and chemical safety assessment* (Chapter R.7a, version 6.0, July 2017), the measurement of the solubility of sparingly soluble compounds requires extreme care to generate saturated solutions of the material without the introduction of dispersed material. ECHA considers that you did not demonstrate that the samples were adequate to quantify the water solubility of the registered substance. Then, the study record does not report any equilibration study to determine the time taken to equilibrate the test substance and water and to demonstrate that the substance is stable under the test conditions. Finally, you did not demonstrate the adequacy of the quantification method. The registered substances is a UVCB and the components of the substance may display a range of refractive index (RI) values that may interfere with the quantification.

- ECHA considers that you did not demonstrate that the water solubility estimate predicted using the WATERNT v1.01 software is reliable. ECHA notes that there is currently no universally accepted definition of the domain of this model. However, the model documentation specifies that predictions are expected to be less accurate for substances that have more instances of a given fragment than the maximum for all training set compounds or that have functional groups or other structural features not represented in the training set. In this context, ECHA notes that the alcohol with longest alkyl chain included in the training set is dodecanol (C12), the training set does not include any branched fatty alcohol or substances having ethoxy moieties. Accordingly, the proposed adaptation does not fulfil the requirements of Annex XI, section 1.3 as you did not demonstrate that the selected chemical structures fall in the applicability domain of the model. In addition, you did not justify that the selected chemical structures used for the prediction are representative of the registered substance (*i.e.*, branching of the alkyl chain). As a consequence, you did not demonstrate that the prediction is adequate for the purpose of risk assessment as per Annex XI, section 1.3.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments on the draft decision, you agreed that the selected experimental study has deficiencies. You stated that considering "*the available equipment at the time of the study, it was not possible to obtain non-turbid solutions*" and that "*effort to separate undissolved matter by centrifugation was not successful*". On the concern raised by ECHA regarding the analytical monitoring technique you provided RI values for C13 ethoxylated alcohols with an EO number ranging from 2 to 10. The RI values were found to be very similar and consequently the quantification data are not expected to be signifcantly biased by differences in refractives indices of the components of the UVCB substance. You decided to conduct a new study according to ASTM E1148-02 and you attached the study report to your comments. You specified that undissolved material was removed by centrifugation and that the centrifuge was coupled to a photometer to monitor the decrease in the turbidity of test solutions. At the two loading rates of 100 and 1000 mg/L, the water solubility was determined to be 58 and 240 mg/l, respectively.
On the concern raised by ECHA regarding QSAR calculations, you specified that you intend to conduct an evaluation of the applicability domain of the model and to provide a justification that the selected chemical structures are representative for the registered substance. Finally, you indicated that the determination of a single water solubility measurement for alcohol ethoxylates is complex as the individual homologues vary significantly in their water solubility depending on their ethoxylation degree. In addition, the

substance may form micelles which add further uncertainty to any experimentally determined water solubility value. Based on the above, you requested further guidance from ECHA in case the newly generated data are not considered adequate to fulfil the information requirement for this endpoint.

On the newly commissioned study attached to your comments, ECHA notes that despite the application of an improved method to prevent the presence of dissolved material (i.e. centrifuge coupled to a photometer) the water solubility estimates were determined to be c.a. 2 to 10 times higher than in the previous ASTM E1148-2 study. Considering that undissolved material was present in the original study, it is unclear why higher water solubility estimates were determined in this new study. ECHA further notes that the test description section of the attached study report is incomplete. Therefore, ECHA could not assess the adequacy of the study design. Finally, the analytical monitoring method does not allow a determination of the composition of individual constituents in the aqueous solution. More specifically, the constituents appear to be co-eluted in the HPLC chromatogram reported by you. As explained above 'solubility' for UVCB substances, should be understood as 'the composition of the aqueous solution formed at equilibrium under a defined set of conditions'. The available information does not provide details on the composition of the aqueous solution formed at equilibrium under the conditions of the test.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Water solubility (test method: EU A.6./OECD TG 105).

Note for your consideration

A reliable determination of water solubility may be difficult to achieve for surface active UVCBs composed of constituents with varying water solubility. However, as already explained, adequate information on water solubility is required to reliably determine the hazard and fate properties of the substance. OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 indicates that for substances forming emulsions, toxic effects should be compared to the critical micelle concentration rather than its solubility limit. ECHA considers that an estimate of the critical micelle concentration could also be considered a valuable additional information to characterize the behaviour of surface active substances solubilized in water.

TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.
Your registration dossier contains for multiple endpoints adaptation arguments in the form of a grouping and read-across approach according to Annex XI, Section 1.5. of the REACH Regulation. ECHA has assessed first the scientific and regulatory validity of your grouping and read-across approach in general before the individual endpoints (requests 2 to 10 and request 17).

Grouping and read-across approach for toxicological and ecotoxicological information

You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5, for the endpoints:

- *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.);
- Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.);
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.);
- 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.);
- Ready biodegradability (Annex VII, Section 9.2.1.1.).

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 substances within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological, ecotoxicological or fate property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological, ecotoxicological or fate properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus, physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

You consider to achieve compliance with the REACH information requirements for the registered substance namely Isotridecanol, ethoxylated (<2.5 moles EO), as identified in your technical dossier, (hereafter 'the registered substance' or 'the target substance') using data of structurally similar substances:

- Polyethylene glycols, 1EO (EC number 500-038-2),
- Oxoalkohol, C13, 3EO (No EC number),
- C13-alcohol branched ethoxylated, 3EO (EC 607-463-3),
- Alcohols, C9-11, ethoxylated, 6EO (EC number 614-482-0),
- 1-Dodecanol, ethoxylated, 4 EO (EC number 500-002-6),
- Alkyl (C12-14) polyethyleneglycolether, 6EO (EC number 500-213-3),
- Alcohols, C14-15, ethoxylated, 7EO (EC number 614-831-7),
- Alcohols, C16-18 (even numbered) and C18 unsaturated, ethoxylated, 10EO (EC number 500-236-9),
- Dodecan-1-ol (EC number 203-982-0),
- Hexadecan-1-ol (EC number 253-149-0),
- 11-methyldodecan-1-ol (EC number 248-469-2),

(hereafter the 'source substance').

You have provided a read-across documentation as a separate attachment in section 13.2 of you technical dossier.

You use the following arguments to support the prediction of properties of the registered substance from data for source substances within the group:

- The registered substance is an ethoxylated derivative of a fatty alcohol: C13, branched (Isotridecanol). You consider that the selected fatty alcohols and alcohol ethoxylates may be regarded as analogous substances due to structural similarity. You point out the structural differences between the target and source substances, namely the length of the alkyl chain, the ethoxylation degree and the branching of the alkyl chain.
- You consider that the physico-chemical properties of the target and source substances "*are similar or follow regular patterns*". You specify that all selected source substances are predominantly liquids under ambient conditions and that the melting point temperature increases with the length of the alkyl chain. You also state that "*water solubility decreases and octanol-water partition coefficient increases with the alkyl chain length*". Regarding variations in the degree of ethoxylation, you consider that a higher EO degree would lead to higher water solubility and boiling point but to lower vapour pressure, partition coefficient and melting temperature. You evaluated the impact of alkyl chain branching by providing QSAR predicted values of some physico-chemical properties for three selected structures (tridecan-1-ol ethoxylated (1EO), 2-

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

methyldodecan-1-ol ethoxylated (1EO), 2,4,6,8-methylnonan-1-ol ethoxylated (1EO)). You conclude that these data support a regular pattern in physico-chemical properties as a function of alkyl chain branching.

- You consider that the substance is readily biodegradable, which is according to you "*a common feature of alcohol ethoxylates <2.5 EO in general*", and that "*abiotic degradation like hydrolysis and photolysis are of no relevance for ethoxylated alcohols due to the chemical structure of these substances*". Then, you state that bioaccumulation is not a concern as "*surfactants are rapidly metabolised*".
- Regarding ecotoxicity, you state that the target and source substances share a common mode of action (*i.e.*, non-polar narcosis). You consider that "*environmental toxicity increases accordingly with the increase of the chain length, and correspondingly log Kow*". You specify that "*the range of ethoxylation < 2.5 EO, the influence of ethoxylation degree is not predominant for the variability in partition coefficient*" and that QSAR predicted log Kow on branched alkyl chain show that branching is of no greater significance. You conclude that the molecular size, which is mainly influenced by the alkyl chain length, is the main driver of the ecotoxicity of these substances.
- You consider that all selected source substances follow similar metabolic pathways. You state that "*metabolism is shown to be rapid and complete, the most likely pathway of AE metabolism being the hydrolysis of the ether linkage and subsequent oxidation of the resulting alcohol to fatty acids, which finally are degraded via ß-oxidation to C2-fragments and shorter alkyl chains and ultimately to carbon dioxide and water*". Based on a study of the oral absorption, distribution, metabolism and excretion of three ^{14}C-labelled alcohol ethoxylates (*i.e.*, C12AE3, C12AE6 and C12AE10), you report that absorption was similar and that "*it was hypothesized that the alcohol chain was oxidized and the ethoxylate residue remained intact*". You also provided data that you consider supportive of a limited impact of the branching of the alkyl chain on the metabolic pathways of alcohol ethoxylates.

As an integral part of this prediction, you propose that the source and registered substances have similar properties or follow a regular pattern for the above-mentioned information requirements. ECHA considers that this information is your read-across hypothesis.

ECHA's evaluation and conclusion

Your proposed adaptation argument is that the similarity in chemical structure, in some of the physico-chemical, fate, ecotoxicological and toxicological properties between the source and registered substance is a sufficient basis for predicting the properties of the registered substance for other endpoints. Structural similarity is a prerequisite for applying the grouping and read-across approach. However similarity in chemical structure and similarity of some of the physico-chemical, fate, ecotoxicological and toxicological properties does not necessarily lead to predictable or similar human health and environmental properties in other endpoints. Your justification based on structural similarity, similar physico-chemical, ecotoxicological and toxicological properties has not established why the prediction is reliable for the human health and environmental end-points for which the read across is claimed.

Regarding your read-across justification, ECHA notes the following:

- ECHA agrees that fatty alcohol and alcohol ethoxylates may be considered as potentially meaningful analogous substances to cover the information requirement of the registered substances. However, the registered substance and also a number of selected source substances are UVCBs. These complex substances may display significant differences regarding the relative abundance of 'unreacted' fatty alcohol and

of the ethoxylation degree of the individual ethoxylated constituents. You provided only very generic information on the identity of the source substances and this source of uncertainty is not addressed in your read-across justification. ECHA also identified inconsistencies between the information provided in your read-across justification document and the information provided under specific endpoints (for details see below under the endpoints concerned).

- As an integral part of your justification, you consider that the aquatic toxicity of this group of substances should follow a regular pattern as a function of their log Kow value. ECHA notes that the target and source substances are mostly complex surface active substances. Accordingly, QSAR predicted values are deemed unreliable. In addition, such substances should be characterized by a range of Log Kow in addition to a reliable weight averaged value. Finally, ECHA notes that (i) none of the Log Kow values reported in your read-across justification document were obtained using an appropriate experimental method on the substance itself and (ii) you did not demonstrate that environmental endpoints for which a read-across is applied can be predicted from this parameter.
- You did not provide supporting data showing that the variation in the degree of ethoxylation for substances with EO < 2.5 would not impact the prediction.
- Regarding the branching of the alkyl chain, you did not provide sufficient evidence to demonstrate that linear alcohol ethoxylates may be read-across to branched alcohol ethoxylates. In addition, ECHA considers that you did not demonstrate that (i) the structure of the branched alkyl chain (e.g. simple methylations *versus* occurrence of quaternary carbon atoms or more complex side chains) and (ii) the relative abundance of isomers would not impact the prediction of the properties for which a read-across is applied. Accordingly, the reliability of the read-across with the selected 'branched' analogues is not adequate. Under section 1.4, you provided a ^{1}H-NMR spectrum showing "*the typical signals for a high-branched alcohol ethoxylate*". A chemical structure considered typical of the isotridecyl isomers of the registered substance which shows a highly branched alkyl chain including a quaternary carbon atom. Alcohol ethoxylates with complex branched alkyl chains may undergo slower metabolism due to steric hinderance and branching may also impact their partitioning into living organisms. Accordingly, you did not demonstrate that target and selected source substances show similar metabolic pathways and similar metabolic rates.

Additionally, ECHA has taken into account all of your arguments together. ECHA firstly notes that you have not provided a reasoning as to why these arguments add to one another to provide sufficient basis for read-across. Secondly, the defects of each individual argument are not mitigated by the other arguments you have provided, and so ECHA considers that the arguments when taken all together do not provide a reliable basis for predicting the properties of the registered substance.

Therefore, ECHA considers that this grouping and read-across approach does not provide a reliable basis whereby the human health effects, environmental effects and environmental fate of the registered substance may be predicted from data for reference substance(s) within the group. Hence, this approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. of the REACH Regulation. ECHA notes that there are specific considerations for the individual endpoints which also result in a failure to meet the requirement of Annex XI, Section 1.5., and these are set out under the endpoint concerned.

In your comments on the draft decision, you agreed that an adequate chemical characterisation of the target and source substances is required to justify the read-across approach. You acknowledged that the dossier contains deficiencies regarding the analytical

information used to characterise the identity of the test material used in some of the reported studies. You intend to update your registration dossier with additional information to address ECHA's concerns. Furthermore, you acknowledged that besides an improved chemical characterisation of the source substances 'bridging studies' would strengthen the justification of the analogue read-across approach. In this context, you intend to perform one or more 'bridging study/studies'. In order to further support the analogue read-across approach, you propose to prepare a revised analogue read-across justification based on the principles of the RAAF document.

ECHA acknowledges that you intend to improve the justification of the proposed read-across approach. ECHA will evaluate the updated information on the revised read-across justification at the follow-up stage of the decision-making process (i.e. after the deadline set in the adopted decision has passed)

As described above, based on the information currently included in your technical dossier further elements are needed to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source and registered substances. This could be achieved (if it is possible) by a well-founded hypothesis of (bio)transformation to a common compound(s), or that the registered and source substances have the same type of effects, together with sufficient supporting information to allow a prediction of human health and environmental properties.

HUMAN HEALTH ENDPOINTS

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

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record ([redacted] 1994) for a *in vitro* gene mutation study in bacteria (according to OECD 471; GLP compliant; reliability score of 2) with the analogue substance Oxoalkohol (C13, 3EO) (referred as EC number 500-241-6)

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes the following shortcomings in the study provided:

- The test from the year 1994 used five different strains of *S. typhimurium* (TA 1535, TA 1537, TA 1538, TA 98 and TA 100) and it did not include tests with strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101). However, since the test was conducted, significant changes have been made to OECD TG guideline 471 and testing with *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is now required. Therefore, the provided study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, Section 1.1.2. of the REACH Regulation.
- Additionally, there is missing information on the identity of the test material, the experimental conditions and the results obtained (*i.e.*, detailed reporting of measured data including cytotoxicity data and historical control data). Hence, the endpoint study

records fail to meet the requirements of a robust study summary[4], as defined in Article 3(28) and as required under Article 10(a)(vii) of the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471).

In your comments on the draft decision you agreed to conduct the requested study with the registered substance.

3. In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing a published study (Loveday *et al.*, 1990) for a *in vitro* mammalian chromosome aberration test (claimed similar to OECD 473; GLP status not specified; reliability score of 2) with the analogue substance Dodecyl alcohol, ethoxylated (EC number 500-002-6; EO degree not specified).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that in the study record provided there is missing information on the experimental conditions (including a rational for top dose selection, experimental design specifying the exposure duration, number of metaphases analysed, criteria for scoring metaphases) and the results obtained (detailed reporting of measured data including cytotoxicity data and historical control data). Hence, the endpoint study record fails to meet the requirements of a robust study summary[5], as defined in Article 3(28) and as required under Article 10(a)(vii) of the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

[4] ECHA's practical guide for "*How to report robust study summaries*", available at: http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf

ECHA considers that the *in vitro* mammalian chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

In your comments on the draft decision you agreed to conduct the requested study with the registered substance.

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

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. In your technical dossier, you provided:

i. a study record ([redacted] 1995) for a mammalian cell gene mutation assay (according to OECD 476; GLP compliant; reliability score of 1) with the analogue substance Fatty alcohol ethyleneglycolether (C16-18, alcohol, EO 1; EC 500-212-8);
ii. a published study (Ballantyne & Vergnes, 2001) for mammalian cell gene mutation assay (claimed similar to OECD 476; GLP status not specified; reliability score of 2) with the analogue substance Diethylene glycol monohexyl ether, 2 EO (EC number 203-988-3).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that the study records do not include adequate information on the experimental conditions (cell line quality check, exposure and induction time, justification for the choice of solvent, pH or osmolality, justification of top dose) and the results obtained (detailed reporting of measured data including cytotoxicity data and historical control data). Hence, the endpoint study records fail to meet the requirements of a robust study summary[5], as defined in Article 3(28) and as required under Article 10(a)(vii).of the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490) provided that both studies requested under requests 2 and 3 have negative results.

In your comments on the draft decision, you agreed to conduct the requested study with the registered substance if both the *in vitro* gene mutation study in bacteria and *in vitro* gene mutation study in mammalian cells have negative results.

5. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. In your technical dossier, you provided:

i. a study record ([redacted] 1987) for a sub-chronic toxicity study in rats (claimed similar to OECD 408; GLP status not specified; reliability score of 2) via the oral route (gavage) with the analogue substance Alcohols, C16-18 and C18-unsatd., ethoxylated, 1-2.5 EO (EC number 500-236-9);
ii. a study record ([redacted] 1973) for a sub-chronic toxicity study in rats (claimed similar to OECD 408; GLP status not specified; reliability score of 2) via the oral route (diet) with the analogue substance Alcohols, C9-11 ethoxylated, < 2.5 EO (EC number 614-482-0);
iii. a study record ([redacted] 1982) for a sub-chronic toxicity study in rats (claimed similar to OECD 408; not GLP; reliability score of 2) via the oral route (diet) with the analogue substance Alcohols, C14-15, ethoxylated, 7 EO (EC number 614-831-7);
iv. a study record ([redacted] 1950; 1955) for chronic toxicity studies in rats and dogs (no guideline followed; GLP status not specified; reliability score of 2) via the oral route (diet) with the analogue substance Polyethylene glycol, 1 EO (EC number 500-038-2);
v. a study record ([redacted] 1992) for a combined repeated-dose and reproductive/developmental toxicity screening in rats (claimed similar to OECD 422; GLP status not specified; reliability score of 2) via the oral route (diet) with the analogue substance 1-Dodecanol (EC number 203-982-0);
vi. a study record ([redacted] 1966) for a sub-chronic toxicity study in rats (claimed similar to OECD 408; not GLP; reliability score of 2) via the oral route (diet) with the analogue substance 1-Hexadecanol (EC number 253-149-0).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted. In addition, ECHA notes the following shortcomings in the studies provided:

- For all reported study records (studies i. to vi. above) incomplete information is provided on the key parameters tested and the results obtained. Hence, the endpoint study records fail to meet the requirements of a robust study summary[5], as defined in Article 3(28) and as required under Article 10(a)(vii) of the REACH Regulation.
- In studies i. and ii. above there are also inconsistencies in the description of the test material in your technical dossier. In study i. ([redacted] 1987), you specified that the substance tested is Alcohols, C16-18 and C18-unsatd., ethoxylated, 1-2.5 EO while the

name of the test material as cited in the study report is "*Oleylcetylalkohol, Ethoxylation degree: 10*". Similarly, in study ii. ([redacted] 1973) you specified that the ethoxylation degree is < 2.5 while the description of the test material specifies that the ethoxylation degree of the tested substance is 6. Furthermore, in both studies i. and ii. the number of animals is not specified and no information is provided on the parameters monitored. In view of the above, the data provided in study records i. and ii. cannot be considered to be equivalent to the data generated by the required test method (OECD TG 408) since in both studies no adequate and reliable documentation was provided (as requested under Annex XI, Section 1.1.2. (4) of the REACH Regulation (use of existing data)).

- In study iii. ([redacted] 1982) only six animals per sex per dose were used (as specified in the HERA report on alcohol ethoxylates when referring to the same study). According to OECD TG 408 at least 10 males and females per dose group should be used. Hence, this study does not provide adequate and reliable coverage of the key parameters foreseen to be investigated in OECD TG 408 (as requested under Annex XI, Section 1.1.2. (2) of the REACH Regulation (use of existing data)).
- In study v. the exposure duration is less than 90 days hence the data provided in this study record cannot be considered to be equivalent to the data generation by the corresponding test method (OECD TG 408) (as requested under Annex XI, Section 1.1.2. (3) of the REACH Regulation). ECHA further notes that an OECD TG 422 study does not fulfil the standard information requirement of Annex IX, Section 8.6.2 as the OECD TG 422 has a shorter exposure duration, less animals are tested for organ weights and histopathological examinations, and less organs are examined, when compared to the OECD TG 408.

Therefore, your adaptation of the information requirement is rejected.

In your comments on the draft decision, you indicated that you intend to address the shortcomings identified by ECHA regarding (i) the discrepancies in the description of test substances and (ii) the level of detail in the reported robust study summaries. You emphasized that the endpoint is covered by reading-across data from several adequate source substances in a Weight-of-Evidence approach. Therefore, provided that the analogue read-across approach will be enhanced in a sufficiently robust manner, you consider that performing a sub-chronic toxicity study would not be necessary. Nevertheless, in order to improve the read-across you indicated that you intend to perform one or more 'bridging study/studies'. You specified that you are currently in the process of defining the most suitable strategy in order to address the information requirement and you may improve the read-across justification and include higher-tier 'bridging study/studies'. You also indicate that you may conduct the required sub-chronic (90-day) toxicity study in rats, oral route.

ECHA acknowledges that you have also sought to adapt this information requirement according to Annex XI, Section 1.2., weight of evidence. However, considering that all the studies provided for this endpoint were conducted with analogue substances and the read-across approach is rejected (see Appendix 1, 'Grouping and read-across approach for toxicological and ecotoxicological information' of this decision), this information currently cannot be used as reliable source of information within a weight of evidence adaptation. In addition, the study design and/or reporting of the selected studies have deficiencies, as already noted above. Therefore, the available studies in the technical dossier currently do not provide scientific evidence, which can contribute to a weight of evidence adaptation with respect to the information requirement in question. Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and the

adaptation of the information requirement cannot be accepted.

As explained above, you intend to improve your read-across justification and the reporting of the sub-chronic toxicity studies. ECHA notes that you already provided some relevant information on the manufacturing process and the identity (i.e. chemical structure) of the registered substance as part of your comments on the draft decision, but this information does not allow ECHA to remove the information request. Any relevant dossier updates will be evaluated at the follow-up stage of the decision-making process (i.e. after the deadline set in the adopted decision has passed).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, including spray applications of the registered substance (PROCs 7 and 11), there is no concern for severe local effects following inhalation exposure, according to the information provided in the dossier. Furthermore, ECHA points out that no repeated dose toxicity study by the oral route is available with the registered substance.

Hence, the test shall be performed by the oral route using the test method OECD TG 408.

According to the test method OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: OECD TG 408) in rats.

6. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You have provided a study record for a study record ([redacted] 1985) for a two-generation reproduction toxicity study (claimed similar to OECD 416; not GLP; reliability score of 2) with the analogue substance Alcohols, C9-11, ethoxylated, <2.5 EO (EC number 614-482-0).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. In the study by [redacted] (1985), you specified that the substance tested is Alcohols, C9-11, ethoxylated, <2.5 EO while the name of the test material as cited in the study report is not specified but the ethoxylation degree is said to be equal to 6. In addition, ECHA notes that (i) the exposure route used in this study (*i.e.*, dermal route) is not adequate, (ii) some key methodological specifications are not reported (e.g., time of sacrifice) or are incompliant (e.g., treatment frequency) and (iii) that key parameters that should be monitored in a OECD 421/422 study are missing (*e.g.*, no weight or histopathology of male reproductive organs, no pup weights). Finally, no detailed description of the study results is reported. In view of the above, ECHA notes that no adequate and reliable documentation has been provided for this study ([redacted] 1985). Additionally, the study does not provide reliable coverage of the key parameters foreseen to be investigated in the corresponding test method.

For the reasons above, conditions (2) and (4) of Annex XI, Section 1.1.2. (use of existing data) are not met.

Therefore, your adaptation of the information requirement is rejected.

In your comments on the draft decision, you indicated that you intend to address the concerns raised by ECHA by improving the read-across justification document. Provided that the analogue read-across approach is enhanced in a sufficiently robust manner, you consider that performing a reproductive/developmental toxicity screening test or a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test is not necessary. However, you further state that, in the context of the improvement of the read-across justification, you may consider conducting a new study to serve as a higher-tier 'bridging study' between the target and selected source substance.

ECHA acknowledges your intention to improve the read-across justification by addressing the concerns raised above, regarding the relevance and reliability of the selected read-across study, and by also considering to perform the requested study as a 'bridging study'. However, as already indicated in this decision (see Appendix 1, 'Grouping and read-across approach for toxicological and ecotoxicological information') the read-across approach cannot be accepted on the basis of the information currently available. Hence, ECHA concludes that there is still a data gap for this endpoint. ECHA notes that all the updated information that you will provide will be evaluated at the follow-up stage of the decision-making process (i.e. after the deadline set in the adopted decision has passed).

Hence, as explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test methods OECD TG 421/422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment*

(version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:
Reproductive/developmental toxicity screening test (test method: OECD TG 421) *or*
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.
Notes for your consideration

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, Section R.7.5 and 7.6 (version 6.0, July 2017).

You should also carefully consider the order of testing of the requested screening (OECD TG 421/422) and the developmental toxicity studies (OECD TG 414) to ensure that unnecessary animal testing is avoided, paying particular attention to the endpoint specific guidance (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf).

7. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You have provided:

i. a study record ([redacted] 1985) for a two-generation reproduction toxicity study (claimed similar to OECD 416; not GLP; reliability score of 2) with the analogue substance Alcohols, C9-11, ethoxylated, <2.5 EO (EC number 614-482-0);
ii. a study record ([redacted] 2003) for pre-natal developmental toxicity study (OECD 414; GLP study; reliability score of 1) with the analogue substance 11-methyldodecan-1-ol (EC number 248-569-2).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. In study i. by ([redacted] 1985), you specified that the substance tested is Alcohols, C9-11, ethoxylated, <2.5 EO while the name of the test material as cited in the study report is not specified but the ethoxylation degree is said to be equal to 6. In addition, ECHA notes that in this study (i) the exposure route used in this study (i.e. dermal route) is not adequate, (ii) some key methodological specifications are not reported (e.g., time of sacrifice) or are incompliant (*e.g.*, treatment frequency) and (iii) that key parameters that should be monitored in a OECD 414 study are missing (*e.g.*, detailed examination of uterine content, examination of foetuses including skeletal and soft tissues alterations). Finally, no detailed description of the study results is reported. In view of the

above, ECHA notes that for the study by [redacted] (1985) there is no adequate and reliable documentation. Additionally, the study does not provide reliable coverage of the key parameters foreseen to be investigated in the corresponding test method.

For the reasons above, conditions (2) and (4) of Annex XI, Section 1.1.2. (use of existing data) are not met.
Therefore, your adaptation of the information requirement is rejected.

In your comments on the draft decision, you indicate that you intend to address the shortcomings identified by ECHA regarding (i) the discrepancies in the description of test substances and (ii) the level of detail in the reported robust study summaries. . You emphasized that the endpoint is covered by reading-across data from several adequate source substances in a Weight-of-Evidence approach. Therefore, provided that the analogue read-across approach will be enhanced in a sufficiently robust manner, you consider that performing a sub-chronic toxicity study would not be necessary. Nevertheless, in order to improve the read-across you indicated that you intend to perform one or more 'bridging study/studies'. You specified that you are currently in the process of defining the most suitable strategy in order to address the information requirement and you may improve the read-across justification and include higher-tier 'bridging study/studies'. You also indicate that you may conduct the required pre-natal developmental toxicity study in a first species (rat or rabbit) by the oral route.

ECHA acknowledges that you have also sought to adapt this information requirement according to Annex XI, Section 1.2., weight of evidence. However, considering that both study records provided for this endpoint are with the analogue substances and the read-across approach for those studies is rejected (see Appendix 1, 'Grouping and read-across approach for toxicological and ecotoxicological information' of this decision), this information currently cannot be used as reliable source of information within a weight of evidence adaptation. In addition, the study design and/or reporting of the selected studies have deficiencies. Therefore, the two studies specified above currently do not provide scientific evidence, which can contribute to a weight of evidence adaptation with respect to the information requirement in question. Therefore, the general rules for adaptation laid down in Annex XI, Section 1.2. of the REACH Regulation are not met and the adaptation of the information requirement cannot be accepted.

ECHA acknowledges your intention to improve the reporting of the selected developmental toxicity studies and to improve the read-across justification by also considering to perform bridging studies. ECHA already notes that you provided some relevant information on the manufacturing process and the identity (i.e. chemical structure) of the registered substance as part of your comments on the draft decision but this information does not allow ECHA to remove the information request. Any relevant dossier updates will be evaluated at the follow-up stage of the decision-making process (i.e. after the deadline set in the adopted decision has passed).).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

AQUATIC TOXICITY ENDPOINTS

The information provided in your technical dossier on the ecotoxicological properties of the registered substance towards aquatic organisms as per section 9.1 of the REACH Regulation is incompliant. The specific reasons are detailed under requests 8 to 13 below.

When conducting the tests required under the specific information requirements detailed below, ECHA points out that, due to the surface active and adsorptive properties of the registered substance, you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

Before conducting any aquatic toxicity testing, you shall carefully consider the properties of the registered substance and especially the water solubility of its components. Section 9.1, column 2 of the REACH Regulation specifies that long-term testing shall be conducted in place of short-term tests for substances (including constituents) that are poorly water soluble.

In addition, regarding the use of the Water Accommodated Fraction (WAF) approach, please note that the WAF approach is problematic when used with a test substance containing several constituents, as in the case of the registered substance. In such cases the toxicity cannot be allocated to specific constituents directly and interpretation of the results in the risk assessment requires careful consideration taking into account differences in fate of the constituents in the environment. When constituents of varying solubility are present there can be partitioning effects which limit dissolution in the water. These effects should be minimised and appropriate loadings selected accordingly to allow an appropriate determination of the toxicity of the different constituents. In that respect, it is critical that a robust chemical analysis is carried out to identify those constituents present in the water to which the test organisms are exposed. Additionally, chemical analysis to demonstrate attainment of equilibrium in WAF preparation and stability during the conduct of the test is required. Methods capable of identifying gross changes in the composition of WAFs with time are required. Methods such as ultra-violet spectroscopy or total peak area have been used successfully for this purpose. The method used to prepare the WAF should be fully described in the test report and evidence of its compositional stability over time should be provided.

If based on the properties of the registered substance you identify that short-term aquatic toxicity studies (as specified under requests 8 to 10) are to be conducted, once the results of these studies are available you shall then consult the ECHA *Guidance on information requirements and chemical safety assessment (*version 4.0, June 2017*)*, Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

8. 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 as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study record ([redacted] 1994) for a short-term toxicity study to aquatic invertebrates (claimed to be similar to EU method C.2; GLP compliant; reliability score of 1) with the analogue substance Oxoalkohol (C13, 3EO) (No EC number provided).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. The test material is referred as corresponding to "*CAS 69011-36-5 (higher ethoxylation degree than 2.5)*" but the name of the test material (as cited in the study report) is "*Oxoalkohol (C13, 3EO)*". ECHA considers that the identity of the test material is not sufficiently clearly defined as 'Oxoalkohol' is only a generic term that can include branched (with varying branching patterns) and linear alcohol ethoxylates. In addition, it is unclear if (i) the identity of the starting material of the target and source substances are identical (which would suggest similar branching of the alkyl chain) and (ii) if the proportion of unreacted fatty alcohol is similar.

Furthermore, you specified in the study record that the analytical monitoring of exposure concentrations was conducted using a fluorescence detector. ECHA considers that the validity of the analytical monitoring is questionnable considering that the structure of alcohol ethoxylates lacks a chromophore. ECHA also notes that you report the following: "*Analytical measurements: All test substance concentrations were below the detection limit*". Finally, you mentionned that a Water Accommodated Fraction (WAF) was tested as you state that "*the test substance was added to deionised water at 1g/L and stirred for approx. 18 h prior to filtration. The filtrate was used as stock solution…*". As explained above under section 'Aquatic toxicity endpoints', ECHA considers that the WAF approach is problematic when used with a test substance containing several constituents.

Accordingly, based on the above ECHA considers that the study you provided is not reliable.

In your comments on the draft decision, you provided relevant information on the registered substance and on the analogue substance Isotridecanol, ethoxylated (3EO). You specified that that both substances are produced from the same starting material and using

the same manufacturing process. The only difference lies in an ethylene oxide/alcohol ratio of 3 for the analogue substance instead of < 2.5 for the registered substance.
On the concerns raised by ECHA regarding the analytical monitoring method and on the study design, you indicate that "*all reported studies were conducted to the most suitable method available at the time*". You intend to justify the reliability of the reported short-term toxicity study on aquatic invertebrates using the analytical monitoring data of a new growth inhibition study on aquatic plants with the registered substance (request 9).

Based on the additional data provided in your comments, ECHA considers that the read-across between the registered substance and the analogue substance Isotridecanol ethocylated (3EO) may be plausible, but this cannot be concluded on the basis of the information available. ECHA will re-evaluate the read-across justification at the follow-up stage of the decision-making process (i.e. after the deadline set in the adopted decision has passed) on the basis of your dossier updates to comply with the current decision. However, ECHA maintains the concerns identified on the reliability of the read-across study. Given that test solutions were prepared based on a WAF and that analytical monitoring data are unreliable, ECHA considers that there is significant uncertainty regarding the exposure to the test substance. ECHA further notes that the effect value derived from this study (EC50 = 1.5 mg/L based on nominal concentrations) is close to the threshold for classification as Aquatic Acute Category 1 (i.e. ≤ 1 mg/L).

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia* sp. acute immobilisation test (test method EU C.2. / OECD TG 202) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.1.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *Daphnia* sp. Acute immobilisation test, EU C.2./OECD TG 202).

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

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study record ([redacted] 1994) for a toxicity study to aquatic algae (claimed to be similar to EU method C.3; GLP compliant; reliability score of 1) with the analogue substance Oxoalkohol (C13, 3EO) (No EC number).
However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. The test material is referred as corresponding to "*CAS 69011-36-5 (higher ethoxylation degree than 2.5)*" but the name of the test material (as cited in the

study report) is "*Oxoalkohol (C13, 3EO)*". As explained above under request 8, ECHA considers that there is significant uncertainty in the identity of the test material.

Furthermore, you specified in the study record that the analytical monitoring of exposure concentrations was conducted using a fluorescence detector. As explained earlier in request 8, ECHA considers that the validity of the analytical monitoring is questionnable. In addition, you did not report any analytical monitoring of exposure concentrations but only a measurement of the stock solution concentration. Finally, you mentionned that a Water Accommodated Fraction (WAF) was tested as you state that "*the test substance was added to deionised water at 1g/L and stirred for approx. 18 h prior to filtration*". As explained above under section 'Aquatic toxicity endpoints', ECHA considers that the WAF approach is problematic when used with a test substance containing several constituents.

Accordingly, based on the above ECHA considers that the study you provided is not reliable.

In addition, you have sought to adapt this information requirement according to Annex XI, Section 1.3 (QSARs) of the REACH Regulation. You applied the QSAR published by Wind & Belanger (2006) to predict the toxicity of alcohol ethoxylates to *Desmodesmus subspicatus*. This approach proposes to predict EC20 values based on biomass and growth rate using Log Kow values. On the proposed approach, ECHA notes the following in line with Annex XI, Secion 1.3:

- The fit of the published QSAR to the training set is poor (the R^2 for the QSAR to predict log-transformed ErC20 values is only 0.609), which questions the accuracy of the prediction;
- The model was developed using experimental data obtained from high purity mono-constituent substances. You did not provide adequate information that the model is applicable to UVCBs. It is also unclear if the model has been validated for branched alcohol ethoxylates;
- You did not provide adequate information to evaluate the reliability of the weight averaged Log Kow value derived for the registered substance;
- You did not provide any QMRF (including a description of the applicability domain of the model) and QPRF to support the validity of the prediction;
- ErC20 values shall not be regarded as equivalent to NOEC values. Accordingly, such effect values is neither appropriate for the purpose of classification and labelling or for the chemical risk assessment.

Finally, you have sought to adapt this information requirement according to Annex XI, Section 1.2 (weight of evidence) as you selected 'weight of evidence' to describe the adequacy of the above information in your technical dossier. An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion. However, as explained above, none of the information provided is considered as adequate to cover the information requirement for this endpoint.

Therefore, your adaptation of the information requirement cannot be accepted.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In your comments on the draft decision you indicated that you intend to improve the read-across justification. You also agreed to conduct the requested study.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

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

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing:

i. a study record ([redacted] 1995) for a short-term toxicity study to fish (claimed to be similar to EU method C.1; GLP compliant; reliability score of 2) with the analogue substance Oxoalkohol (C13, 3EO) (No EC number provided);
ii. a study record ([redacted] 1989) for a short-term toxicity study to fish (claimed to be similar to Testverfahren mit Wasserorganismen (Gruppe L). Allgemeine Hinweise zur Planung, Durchführung und Auswertung biologischer Testverfahren (L1), adopted 1982; not GLP compliant; reliability score of 2) with an analogue substance referred as C13 alcohol ethoxylate (No EC 607-463-3);
iii. a study record ([redacted] 2007) for a short-term toxicity study to fish (according to EU C.1/OECD 203; not GLP compliant; reliability score of 2) with an analogue substance referred as C13 alcohol ethoxylate (No EC 607-463-3).

However, as explained above in section "Toxicological and ecotoxicological information" of this decision, your adaptation of the information requirement cannot be accepted.

In addition, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. In the study by [redacted] (1995), the test material is referred as corresponding to "*CAS 69011-36-5 (higher ethoxylation degree than 2.5)*" but the name of the test material (as cited in the study report) is "*Oxoalkohol (C13, 3EO)*". As explained above under section 8, ECHA considers that there is significant uncertainty in the identity of the test material. Then, in studies ii. and iii. by [redacted] (1989) and [redacted] (2007), the test material is referred as EC number 607-463-3 (*i.e.*, 1-Tridecanol, monoether with polyethylene glycol), while the test material as cited in the study report is "*C13-alcohol branched ethoxylated, 3EO*". Again, the identity of the test substance is unclear. Furthermore, none of the reported studies included an appropriate analytical monitoring of exposure concentrations. In the key study (study i. by [redacted], 1995), the concentrations in

the test item was monitored by DOC analysis which only monitors the presence of organic carbon and not of the constituents of the test item. In both studies by [redacted] (study ii. And iii.), no analytical monitoring was performed. Accordingly, ECHA considers that, in all studies selected for this endpoint, you did not provide compelling evidence that the exposure level were maintained over the course of the experiment.

Finally, in study i., you mentionned that a Water Accommodated Fraction (WAF) was tested as you state that "*the test substance was added to deionised water at 1g/L and stirred for approx. 18 h prior to filtration*". As explained above under section 'Aquatic toxicity endpoints', ECHA considers that the WAF approach is problematic when used with a test substance containing several constituents.

Accordingly, based on the above ECHA considers that none of the studies you provided is reliable.

In your comments on the draft decision, you indicated that you intend to improve your read-across justification and to revise the description of test materials description and the robust study summaries of the selected studies. You concluded that this additional information along with the newly commissioned growth inhibition study on aquatic plants will provide sufficient information to confirm the adequacy of available data.

As already explained, based on the new information provided as part of your comments, ECHA considers that the read-across with Isotridecanol, ethoxylated (3EO) may be plausible, but this cannot be concluded on the basis of the information available. However, ECHA maintains the concerns identified on the reliability of the read-across studies. Considering that test solutions were prepared based on a WAF in the study by [redacted] (1995) and that no reliable analytical monitoring data are available in any of the selected studies, ECHA considers that there is significant uncertainty regarding the exposure to the selected test substance.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

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

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3 (QSARs). You applied the QSAR published by Boeije *et al.* (2006) to predict the toxicity of alcohol ethoxylates to *Daphnia magna*. This approach proposes to predict 21d-EC20 values based on reproduction using Log Kow values. Contrary to Annex XI, Section 1.3, you did not provide any documentation, such as a QMRF and QPRF, to allow ECHA to assess the reliability of the proposed QSAR approach.

In addition, ECHA points out that EC20 values shall not be regarded as equivalent to NOEC values. Accordingly, contrary to Annex XI, Section 1.3, such an effect value is neither appropriate for the purpose of classification and labelling nor for the chemical risk assessment.

Finally, you have sought to adapt this information requirement according to Annex XI, Section 1.2 (weight of evidence) as you selected 'weight of evidence' to describe the adequacy of the above information in your technical dossier. An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion. However, as explained above, the information provided is not considered as adequate to cover the information requirement for this endpoint. In addition, you provided data from a single source of information which is not considered as sufficient to support a valid weight of evidence adaptation.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you agred that the provided documentation does not meet the current standard for reporting QSAR results and you intend to improve the information provided in your technical dossier. You indicated that alcohol ethoxylates and fatty alcohols were extensively reviewed in the past with regard to their impact on the environment and that their mode of action is considered to be non-specific (non-polar narcosis). You concluded that the applied QSAR models are reliable and suitable to predict the long-term aquatic toxicity for complex alcohol ethoxylates.

ECHA understands that you consider the selected QSAR as sufficiently robust to fulfil the information requirement for this endpoint. However, ECHA disagrees with your assessment. As explained in ECHA *Guidance on Information Requirement and risk assessment*, Chapter R.6, section R.6.1.5. (May 2008), the evaluation of (Q)SAR models validity should be based on the OECD validation principles (OECD Guidance on the validation of (Q)SAR models, ENV/JM/MONO(2007)2). ECHA notes that the selected QSAR is not based on sufficiently robust dataset to fulfil the 4th OECD principal of (Q)SAR validation. Indeed, this principle specifies that a (Q)SAR should be associated with "*appropriate measures of goodness-of-fit, robustness and predictivity*". This principle expresses the need to provide two types of information: a) the internal performance of a model (as represented by goodness-of-fit and robustness), determined by using a training set; and b) the predictivity of a model, determined by using an appropriate test set. ECHA notes that the model used to predict the 21d-EC20 in *Daphnia magna* is based on only 6 data points and that only the internal performance of the model has been evaluated (i.e. goodness of fit to the training set). Then, as already explained above, to be considered acceptable, your adaptation needs to fulfil the conditions set out in Annex XI, Section 1.3 of the REACH Regulation. ECHA

considers that there is insufficient evidence to demonstrate that the results are adequate for the purpose of classification and labelling and/or risk assessment.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) *Daphnia magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Daphnia magna reproduction test (test method: EU C.20./OECD TG 211).

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

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.3 (QSARs) . You applied the QSAR published by Boeije *et al.* (2006) to predict the toxicity of alcohol ethoxylates to *Pimephales promelas*. This approach proposes to predict 30d-EC20 values based on mortality using Log Kow values. Contrary to Annex XI, Section 1.3, you did not provide any documentation, such as a QMRF and QPRF, to allow ECHA to assess the reliability of the proposed QSAR approach.

In addition, ECHA notes that the effect value is based on mortality. However, as explained in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b, Section R.7.8, the evaluation of chronic toxicity should be based on sub-lethal endpoints. Finally, ECHA points out that EC20 values are not regarded as equivalent to NOEC values. Accordingly, contrary to Annex XI, Section 1.3, such an effect value is neither appropriate for the purpose of classification and labelling nor for the chemical risk assessment.

Finally, you have sought to adapt this information requirement according to Annex XI, Section 1.2 (weight of evidence) as you selected 'weight of evidence' to describe the adequacy of the above information in your technical dossier. An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion. However, as explained above, the information provided is not considered as adequate to cover the information requirement for this endpoint. In addition, you provided data from a single source of

information which is not considered as sufficient to support a valid weight of evidence adaptation.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you agred that the documentation does not meet the current standard for reporting QSAR results and you intend to improve the documentation. You consider the selected QSAR model as reliable and suitable to predict the long-term aquatic toxicity for complex alcohol ethoxylates.

As explained in request 11, your adaptation of the information requirement based on QSAR predictions should be based on a predictive model fulfilling the OECD validation principles and should fulfil the conditions set out in Annex XI, Section 1.3 of the REACH Regulation. On the selected QSAR, ECHA notes that Boeije *et al.* (2006) specify the following "*Based on a limited data set (with three early life stage studies), a QSAR for P. promelas was derived following the method of this paper. Due to the insufficient number of data points, this cannot be considered a reliable QSAR* [...]". ECHA concludes that the selected QSAR is not reliable.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215) can be performed to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b, Section R.7.8.4.1.*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD TG 210).

13. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.)

"Activated sludge respiration inhibition testing" is a standard information requirement as laid down in Annex VIII, Section 9.1.4. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.2. (weight of evidence). You provided a study record for toxicity test to *Pseudomonas putida* using an in-house protocol ([redacted] 1994; study claimed GLP compliant; reliability score of 2). In the test material information, you referred to the test substance as EC number 500-241-6.

An adaptation pursuant to Annex XI, Section 1.2. requires sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property with respect to the information requirement in question including an adequate and reliable documentation while the information from each single source alone is regarded insufficient to support this notion.

However, ECHA notes that your adaptation does not meet the general rules for adaptation of Annex XI, section 1.2. because:

- There are uncertainties regarding the identity of the test material. Indeed, while you refer to EC number 500-241-6, the name of the test material as cited in the study report is "*Oxoalcohol (C13, 3EO)*". 'Oxoalkohol' is only a generic term that can include branched and linear alcohol ethoxylates. In addition, it is unclear if (i) the identity of the starting material of the target and source substances are identical (which would suggest similar branching of the alkyl chain) and (ii) if the proportion of unreacted fatty alcohol is similar. Finally, the ethoxylation degree of the test material (*i.e.*, 3 EO) appears to be higher than the ethoxylation degree of the registered substance. Accordingly, while you did not explicitly claim an adaptation, ECHA considers that this study report is provided as an attempt to adapt the information requirement for this endpoint according to Annex XI, Section 1.5 (grouping and read-across). As explained previously, your adaptation according to Annex XI, Section 1.5 is rejected.
- ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7b, Section R.7.8.19 specifies that results of the cell multiplication inhibition test with *P. putida* (ISO 17012:1995) may be used for calculation of the PNECmicro-organisms in cases were no other test results are available. According to Annex XI, Section 1.1.2. (use of existing data), test methods other than those referred to in Article 13(3) should for instance provide adequate and reliable coverage of the key parameters to be investigated in the corresponding validated test method, the exposure should be comparable and adequate and reliable documentation should be provided. ECHA notes that the study you provided differs from ISO 17012:1995 as respiration inhibition was monitored instead of bacterial growth. ECHA considers that you did not demonstrate that respiration inhibition measured based on the described protocol is providing sufficient sensitivity to measure toxicity on STP microorganisms. In addition, exposure duration (*i.e.*, 5h) was shorter than the 16 h exposure period recommended in the guideline. Finally, you did not provide sufficient information to allow an independent assessment of the reliability of the study (for examples, detailed description of the methodology and measured data under a tabulated form).

Therefore, your adaptation of the information requirement cannot be accepted.

In addition, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation (grouping and read-across) by providing:

i. a study record ([redacted] 1996) for a toxicity study to micro-organisms (according to DIN 38412-8; GLP study; reliability score of 2) with an analogue substance referred as EC number 500-213-3;

ii. a study record ([redacted] 1997) for a short-term toxicity study to micro-organisms (according to EG guideline 88/302/EG; GLP study; reliability score of 2) with an analogue substance referred as EC number 500-002-6.

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted.

Furthermore, ECHA notes that there are inconsistencies in the description of the test material in your technical dossier. In study i. by [redacted] (1996), the test material is described as EC number 500-213-3 (*i.e.*, Alcohols, C12-14, ethoxylated, 1-2.5 EO) but the name of the test material as cited in the study report is "*Alkyl (C12-14) polyethyleneglycolether (6EO)*". Similarly, in study ii. by [redacted] (1997), the test material is described as EC number 500-002-6 (*i.e.*, Dodecan-1-ol, ethoxylated, 1-2.5 EO) but the name of the test material as cited in the study report is "*1-Dodecanol, ethoxylated, (C12, 4 EO)*". Accordingly, there is an inconsistency and it appears that the test material have higher ethoxylation degrees than what is specified in your read-across justification document.

In your comments on the draft decision, you indicated that you intend to improve the documentation of the studies currently included in your technical dossier. You consider that, available data together with the information from the biodegradation screening tests are sufficient to fulfil the information requirement for this endpoint.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier currently does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) activated sludge respiration inhibition test (carbon and ammonium oxidation) (test method OECD TG 209) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.4.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Activated sludge, respiration inhibition test (carbon and ammonium oxidation) (test method: OECD TG 209).

TERRESTRIAL TOXICITY ENDPOINTS

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. Adequate information on effects on short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity to plants (Annex IX, Section 9.4.3.) needs to be present in the technical dossier for the registered substance to meet the information requirements. Column 2 of Annex IX, Section 9.4 specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information provided in your technical dossier on the ecotoxicological properties of the registered substance towards terrestrial organisms as per section 9.4 of the REACH Regulation is incompliant. The specific reasons are detailed under requests 14 to 16 below.

14. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1., column 2)

While you have not claimed an adaptation of the information requirement for this endpoint, ECHA considers that you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation (grouping and read-across).

You have provided a study record ([redacted], 1994) for a toxicity test towards earthworms (claimed similar to EU C.8; GLP study; reliability score of 1). In the test material information you identify the substance as corresponding to EC number 500-241-6 (*i.e.*, the registered substance). However, the name of the substance tested is Oxoalkohol (C13, 3EO). As already explained above, 'Oxoalkohol' is only a generic term that can include branched and linear alcohol ethoxylates. In addition, it is unclear if (i) the identity of the starting material of the target and source substances are identical (which would suggest similar branching of the alkyl chain) and (ii) if the proportion of unreacted fatty alcohol is similar. Finally, the ethoxylation degree of the test material (*i.e.*, 3 EO) appears to be higher than the ethoxylation degree of the registered substance.

As explained in section 'Toxicological and ecotoxicological information' of this decision, your adaptation according to Annex XI, Section 1.5 of the information requirement cannot be accepted.

In addition, ECHA notes that the provided study does not cover the information requirement according to Annex XI, section 1.1.2 (use of existing data) for the criteria (2), *i.e.* adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods. In your dossier, the provided study does not fulfill the information requirement of a long-term toxicity study to terrestrial invertebrates as (i) the exposure duration is shorter and (ii) only mortality is monitored instead of reproduction.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the registration dossier, the substance has a high potential to adsorb to soil. You provided a log Kow estimate of 4.73 for the registered substance.

Given that the registered substance is a complex UVCB, ECHA considers that some constituents are likely to have a log Kow > 5. In addition, the information currently provided in your technical dossier does not demonstrate that the substance is readily biodegradable. Accordingly, the substance shall be considered as very persistent, which is default setting for non-readily biodegradable substances when no degradation half-life value in soil is available. Therefore, ECHA considers that the column 2 of Annex IX, section 9.4 requiring long-term testing instead of short-term testing, applies to this substance.

According to section R.7.11.6., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can

be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

As explained in requests 8 to 12, you did not provide adequate data to derive a PNEC for aquatic organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based on the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

The earthworm reproduction test (OECD TG 222) and Enchytraeid reproduction test (OECD TG 220) are both considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (test method: OECD TG 222), or Enchytraeid reproduction test (test method: OECD TG 220).

In your comments on the draft decision, you agreed to conduct the requested study.

15. Long-term toxicity to plants (Annex IX, Section 9.4.3., column 2)

While you have not claimed an adaptation of the information requirement for this endpoint, ECHA considers that you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation.

You have provided a study record ([redacted] 1994) for a short-term toxicity test to terrestrial plants (claimed similar to OECD 208; GLP study; reliability score of 1). In the test material information you identify the substance as corresponding to EC number 500-241-6 (*i.e.*, the registered substance). ECHA identifies similar shortcomings on the test material as explained under point 14 above.

As explained in section 'Toxicological and ecotoxicological information' of this decision, your adaptation according to Annex XI, Section 1.5 of the information requirement cannot be accepted.

As explained above under point 14 above, ECHA considers that the column 2 of Annex IX, section 9.4 requiring long-term testing instead of short-term testing, applies to this substance. The study provided only included one monocotyledonous species and two dicotyledonous species. Accordingly, as further explained below, the information provided shall not be considered as equivalent to a long-term toxicity test to terrestrial plants.

As established within point 14 above, it is not currently possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4.

OECD test guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a

reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline. You should consider if testing on additional species is required to cover the information requirement.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD TG 208), with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

In your comments on the draft decision, you agreed that column 2 of Annex IX, section 9.4 requiring long-term testing instead of short-term testing applies to the registered substance. While you agreed to conduct a long-term earthworm test (OECD TG 222, request 14), you intend to cover the information requirement for this endpoint by applying the Equilibrium Partitioning Method (EPM).

16. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

You have waived the standard information requirements of Annexes IX and X, section 9.4. using the following justification: *"The substance is not supposed to be directly applied to soil and further is readily biodegradable. Hence in case of indirect exposure to soil, the substance is expected to rapidly degrade. Therefore soil is not expected to be a compartment of concern. Thus the risk to soil microorganisms is negligible".*

However, ECHA notes that in you chemical safety report you report a number of widespread uses where indirect release to soil is likely. In addition, you report that the substance is used as a co-formulant in agrochemicals. Accordingly, ECHA considers that direct exposure to soil organisms will occur. Therefore, based on the use pattern of the registered substance, you did not demonstrate that direct and indirect exposure of the soil compartment is unlikely.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you agreed that exposure of the soil compartment cannot be excluded. However, you specified that the substance will not be used as a co-formulant in agrochemicals and the respective uses will be withdrawn from the registration dossier. You specified that you intend to build a weight of evidence approach using data showing that that the registered substance is not inhibitory to microorganisms (e.g. OECD 301 ready biodegradability tests). Taking into account the proposed updated description of uses, you consider that the need to conduct tests on soil micro-organisms is not scientifically justified.

ECHA considers that, in the absence of direct application of the registered substance to soil, reliable data demonstrating the absence of significant toxicity of the substance to aquatic micro-organisms could be considered as relevant supporting evidence that the substance is not expected to cause risks to soil micro-organisms. However, currently the description of uses still includes usage as a co-formulant in agrochemicals. In addition, as explained in

requests 13 and 17, the information related to activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.) and ready biodegradability (Annex VII, Section 9.2.1.1.) is incompliant. Accordingly, the information currently included in the technical dossier does not rule out the need to evaluate the effects of the registered substance to soil micro-organisms.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier currently does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

ECHA notes that the tests requested under points 14 and 15 above are not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test.

According to section R.7.11.3.1. of the above-mentioned guidance, the nitrogen transformation test is considered sufficient for most non-agrochemicals. However, as the substance has known agrochemical uses, ECHA considers that both the nitrogen and carbon transformation tests should be performed simultaneously.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD TG 216) and Soil microorganisms: carbon transformation test (test method: EU C.22./OECD TG 217).

Notes for your consideration

If the results of the requested toxicity tests on fish, aquatic invertebrates and algae allow the subsequent derivation of a PNECwater, you may consider the ITS (Integrated Testing Strategy) as recommended in section R.7.11.6., of the above-mentioned *Guidance* and determine the need for further testing on terrestrial organisms. If you conclude that no further investigation of effects on terrestrial organisms is required, you should update your technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annex IX, of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

ENVIRONMENTAL FATE ENDPOINTS

17. Robust study summaries for ready biodegradability studies (Annex VIII/ Annex VII, Section 9.2.1.1. in conjunction with Annex I, Section 3.1.5.) OR ready biodegradability study (Annex VII, Section 9.2.1.1.) with the registered substance

Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent

assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".
A "Ready biodegradability study" is a standard information requirement as laid down in Annex VII, section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement. Furthermore, pursuant to Article 10 (a)(vii) and Annex I, Section 3.1.5.where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified.

Generally, for the ready biodegradability endpoint, ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b, Section R.7.9.4 (version 4.0, July 2017) specifies that positive test results should supersede negative test results as ready biodegradability. When conflicting test results are reported, a robust study summary shall be prepared for all available studies and included as part of the technical dossier.

You have provided a study record for a ready biodegradability test ([redacted], 1999; claimed similar to OECD 301B/EUC.4-C; GLP status not specified; reliability score of 2) to meet the standard information requirement of Annex VII, section 9.2.1.1. In addition, you provided the following supporting studies:

i. a study record ([redacted], 2005) for a ready biodegradability test (claimed similar to OECD 301B/EUC.4-C; GLP status not specified; reliability score of 2) with the registered substance;
ii. a study record ([redacted], 2006) for a ready biodegradability test (according to OECD 301B; GLP study; reliability score of 1) with the registered substance.

ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of the key and supporting studies is insufficient and does not allow an independent assessment of the adequacy of these studies, the reported results and their use for hazard assessment. In particular, the following elements are missing: a detailed identification of the test material providing sufficient information to support that it is identical to the registered substance (*i.e.*, same branching of the alkyl chain, isomers proportions, ethoxylation degree and relative abundance of 'unreacted' starting material), a detailed description of the inoculum, a description of the test controls (*i.e.*, reference substance and toxicity control), an appropriate description of key methodological parameters (*e.g.*, amount of inoculum, test temperature *etc.*), a detailed description of the test results (including raw data in a tabulated form).

ECHA also points out that the OECD "*Guidelines for the Testing of Chemicals, Revised Introduction To The OECD Guidelines For Testing Of Chemicals, Section 3 Part I: Principles And Strategies Related To The Testing Of Degradation Of Organic Chemicals*" (OECD, 2006) indicates that ready biodegradability tests are intended for pure substances and are generally not applicable for complex compositions containing different types of constituents, like UVCBs. As mentioned in the guideline, "*a case by case evaluation should however take place on whether a biodegradability test on such a complex mixture would give valuable information regarding the biodegradability of the mixture as such (i.e. regarding the degradability of all the constituents) or whether instead an investigation of the degradability*

of carefully selected individual components of the mixture is required". As a consequence, ECHA considers the applicability of the ready biodegradability test to be restricted to UVCBs consisting of structurally similar constituents (*e.g.*, homologous series). Accordingly, you shall carefully consider the composition of the test substance (*e.g.*, structural variations among isomers) and provide appropriate information to support the applicability of the ready biodegradability test.

ECHA notes that depending on the study included in your technical dossier, the registered substance may or may not fulfil the criteria for ready biodegradability (as you reported results of 50.7%, 60.2% and 75% biodegradation in the 2005, 2006 and 1999 study, respectively). As conflicting test results are reported, you need to provide a complete robust study summary with the missing elements for the studies listed above. Furthermore, in the absence of appropriate information to judge the reliability of the information provided for this endpoint, ECHA considers that you did not demonstrate that the substance is readily biodegradable.

Finally, you have also sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation (grouping and read-across) by providing a study record for a ready biodegradability study according to OECD 301B/EU C.4-C/ISO DIS 9439 (GLP study; reliability score of 2) with the analogue substance 1-Tridecanol, monoether with polyethylene glycol (EC number 607-463-3).

However, as explained above in section 'Toxicological and ecotoxicological information' of this decision, your adaptation of the information requirement cannot be accepted. On the applicability of adaptation on the information requirement according to Annex XI, Section 1.5 for this endpoint, ECHA notes that you specifically mentioned in your read-across justification document that "*no read-across is performed for the endpoints related to environmental fate and pathways, and properties briefly summarized in this section are outside of the scope of the analogue approach*". ECHA would also like to point out that, to be considered valid, a read-across hypothesis would need to take due account of the structural differences between the target and the source substances. For instance, it may be expected that the branching of the alkyl chain (and for example the presence of quaternary carbon atoms) may significantly impact the biodegradability of the substance as a consequence of steric hindering.

In your comments on the draft decision, you agreed that the documentation of the key and supporting studies is not sufficiently detailed. In addition to the analytical data on the nature and composition of the registered substance and the source substance Isotridecanol, ethoxylated (3EO) already mentioned above, you intend to update the technical dossier by submitting improved robust study summaries. You consider that these data are sufficient to conclude that the registered substance is readily biodegradable.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier currently does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summaries for the ready biodegradability by [redacted] (1999, 2005, and 2006) containing the missing information listed above under this point.

Alternatively, if you cannot submit a complete RSS or the RSS indicates that the study is not reliable as per the criteria indicated above and/or not adequate to fulfil the information requirement, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:

Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: CO2 evolution test, OECD TG 301B)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: MITI test (I), OECD TG 301C)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Closed bottle test, OECD TG 301D)
or
Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: Manometric respirometry test, OECD TG 301F).

18. Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

"Adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, section 1.3. (QSARs) In your technical dossier, you provided:

i. A study record for a QSAR approach to predict the Log Koc of the registered substance using KOCWIN v2.00 and the MCI method (first-order molecular connectivity index), [redacted] (2012a), reliability score of 2;
ii. A study record for a QSAR approach to predict the Log Koc of the registered substance using KOCWIN v2.00 and the log Kow method for nonpolar organics, [redacted] (2012b), reliability score of 2.

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI, Section 1.3. because:

- You did not justify that the selected chemical structures are representative of the registered substance (e.g. branching of the alkyl chain; ethoxylation degree);
- The scientific validity of the selected QSAR approach for surface active substances is not established;
- You did not demonstrate that the selected chemical structures fall within the applicability domains of the selected QSARs.

Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision, you agreed that the reported QSAR calculations lack documentation and substance specific interpretation. You intend to revise the information provided for this endpoint and format the documentation according to the current standards (QMRF/QPRF). You also intend to include a detailed justification for the representativity of the selected chemical structures and a demonstration of the adequacy to the applicability domain of the model.

As explained above, the information currently provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Adsorption/desorption screening using an appropriate test method.

Guidance for determining appropriate test methods for the adsorption/desorption screening is available in the ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.1.15.3.

Deadline to submit the requested information in this decision

In the draft decision communicated to you the time indicated to provide the requested information was 33 months from the date of adoption of the decision.

In your comments on the draft decision, you requested an extension of the timeline to 39 - 42 months. You sought to justify this request by the need to conduct sequential testing. You also specified that this timeline does not allow a margin for unexpected events or technical difficulties. ECHA indicated to you that the deadline specified in the draft decision was set to allow sequential testing and also account for potential delays that can reasonnably be foreseen. ECHA concluded that your arguments are not sufficiently substantiated and requested you through a REACH-IT message to provide further justification to evaluate whether this request can be considered legitimate (e.g. detailed description of the testing strategy and documentary evidence from the selected test laboratory indicating the scheduling timelines for the studies).

You replied that you were unable to provide documentary evidence as you did not contact any testing laboratory yet. You consider that until the final decision is adopted it is not possible to foresee the time required to conduct the requested studies. You listed the necessary steps from requesting quotes until the generation of final reports. You concluded that the time frame of 33 months is very tight and would be too short to generate the data requested in the draft decision if unexpected events or technical difficulties are encountered.

ECHA notes that this justification does not provide any significant additional element to justify your request. Therefore, ECHA has not modified the deadline of the decision.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 14 March 2018.

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 requests or the deadline to submit the requested information.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

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

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 your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.