~~Confidential~~

Helsinki, 06 May 2022

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

Date of submission of the dossier subject to this decision
17/08/2015

Registered substance subject to this decision ("the Substance")
Substance name: Alcohols, C12-13-branched
EC number: 941-187-7

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***13 May 2024***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

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

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

3. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

2. If negative results are obtained in test performed for the information requirements of Annex VII, Section 8.4.1 and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

3. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

C. Information required from all the Registrants subject to Annex IX of REACH

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats.

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method:

OECD TG 414) by oral route, in one species (rat or rabbit)

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

D. Information required from all the Registrants subject to Annex X of REACH

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rat or rabbit)

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

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

Information required depends on your tonnage band

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

- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

Appendix on Reasons common to several requests

1. **Assessment of the weight of evidence adaptations under Annex XI,**

You have adapted the following standard information requirements by applying weight of evidence (WoE) adaptation(s) under Annex XI, Section 1.2:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Pre-natal developmental toxicity study in a second species (Annex X, Section 8.7.2.)

You reasoning for the weight of evidence adaptation is: The Substance ia a member of the category 'C6-24 Alcohols. Long Chain Alcohols (C6-24 primary aliphatic alcohols; linear and essentially linear)' Whenever, sufficient data on the Substance is missing the data gap is filled using weight of evidence based on read-across from other category members.

Your weight of evidence adaptation raises the same decifiencies irrespective of the information requirement for which it is invoked. Accordingly, ECHA addressed these deficiencies in the present Appendix, before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

In any weight of evidence justification, the integration of the sources of information is fundamental to support a robust conclusion on whether the Substance has a particular dangerous property. Three main aspects must be addressed: (1) Analysis of to what extent the composition of the Substance is covered by the sources of information; (2) Analysis of to what extent the hazard data obtained from the sources of information cover the key aspects that is foreseen to be investigated by study normally required for the information requirement(s) where weight of evidence is invoked; and (3) Analysis of the residual uncertainty.

The Substance is a UVCB (unknown or variable composition, complex reaction products or of biological materials) substance. Which consists of mainly branched but also linear C12-C13 alcohols.

The sources of information provided have mainly been conducted using mono- or multi constituent substances or UVCB substances. You have not explained to what extent each source of information covers the composition of the Subtance.

Furthermore, you have not explained how the hazard data obtained with the sources of information, considering the relevance, reliability, coverage, consistency and results, can be brough together to reach conclusion on whether or not the Substance has a particular dangerous property with regard each of the infromation requirement(s).

Moreover, you have not analysed the residual uncertainty associated with the weight of evidence conclusion for each infromation requirment.

Based on the above, ECHA concludes that you have not provided adequate documentation to support a robust conclusions for your weight of evidence adaptations.

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

Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually. The common deficiencies are set out below, while the specific ones are set out under the information requirement concerned in the Appendices A to D.

1.1. Reliability of the provided information with analogue substances

ECHA understands that you use data obtained with analogue substances in a read-across approach as part of your weight of evidence adaptation. For this information to reliably contribute to the weight of evidence approaches, it would have to meet the requirements for Grouping of substances and read-across approaches.

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

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

Description of the grouping

In the CSR, you refer to a category of 'C6-24 Alcohols. Long Chain Alcohols (C6-24 primary aliphatic alcohols; linear and essentially linear)'. You identify the members of the category members and provide a category justification document in the CSR.

You define the the structural basis for the grouping as: a family of primary aliphatic alcohols within a carbon chain length range of C6-C24, limited to linear and essentially-linear alcohols.

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

1.2. Predictions for toxicological properties

You provide a read-across justification in the CSR.

For (eco)toxicological properties you read-across to the Substance from the following source substances:

- docosan-1-ol, EC No. 211-546-6;
- tetradecan-1-ol, EC No. 267-019-6;

[2] ECHA Guidance R.6
[3] Read-Across Assessment Framework (RAAF)
[4] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs

- dodecan-1-ol, EC No. 203-982-0;
- hexan-1-ol, CAS No. 111-27-3;
- hexadecan-1-ol, EC No. 253-149-0
- tetradecan-1-ol, EC No. 267-019-6;
- alcohols, C7-11-branched and linear; EC No. 287-623-3;
- Alcohols, C16-18 and C18-unsatd., EC No. 268-106-1;
- octadecan-1-ol; EC No. 204-017-6;
- C24-34 even chain alcohols (no numerical identifiers provided); and
- 3-methylbutan-1-ol ; EC No. 204-633-5.

You provide the following reasoning for the predictions of toxicological properties: "The hypothesis is that the long chain linear aliphatic alcohol Category has, at its centre, an homologous series of increasing carbon chain length alcohols. The structure of the Category is associated with a consistency and predictability in the physicochemical, environmental, and toxicological property data across its members. In addition, certain branched and unsaturated structures are considered to have such similar properties that their inclusion in the category is well justified."

"For all forms of repeated dose, reproductive and developmental effects and sensitisation, there is sufficient evidence for no effects at the maximum deliverable dose and this conclusion does not vary with carbon number."

"For all forms of genetic toxicity, there is sufficient evidence for no effects and this conclusion does not vary with carbon number."

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

ECHA notes the following shortcomings with regards to predictions of toxicological properties:

Predictions outside the applicability domain of the category

According to Annex XI, Section 1.5., predictions can only be made within the defined group.

In the CSR, you refer to a category of 'C6-24 Alcohols. Long Chain Alcohols (C6-24 primary aliphatic alcohols; linear and essentially linear)' and define the applicability domain to be alcohols within a carbon chain length range of C6-C24, limited to linear and essentially-linear alcohols. For pre-natal developmental toxicity in the first and the second species, source of infromation (vi), you read across to 3-methylbutan-1-ol which is a C5 alcohol.

ECHA concludes that 3-methylbutan-1-ol is outside the applicability domain of your read-across approach. Therefore, no reliable predictions can be made from this substance.

Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)". For this purpose "it is important to provide supporting information to strengthen the rationale for the read-across" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include bridging studies to compare properties of the category members.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant,

reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

The Substance contains mainly branched but also linear alcohols. You have not provided supporting information for allowed structural elements; i.e. linear alcohols, branched alcohols, and position of the branching within the alcohols. While there is information on the UVCB substances which may contain various linear and branched components, there are no information on test substance composition to confirm the coverage of the constituents tested (see below) or the test substance(s) are not covering the structural elements present in the target substance. You have not provided any supporting information to mitigate this fact.

ECHA also notes that you have provided additional summaries of information and data matrices in the CSR. As the information on these studies provided in the CSR is limited and not sufficient for an independent evaluation, this informaiton has not been further considered in this assessment of your adaptation.

Therefore, it is not possible to demonstrate that the toxicity profile of the Substance containing linear and branched components can be predicted from the source substances. There are no supporting information to explain why the structural differences do not influence toxicokinetics and toxicodynamics of the substances.

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

Missing information on the test material

Under Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

In order to predict the properties of the Substance, the test material used in the study on the source substance must be representative for the source substance (Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). Therefore, the unambiguous characterisation of the composition of the test material used to generate the source data is required to assess whether the test material is representative for the source substance.

For most of the studies provided, you have identified the test material by name and chemical identifiers, without further information, including composition of the test material.

In the absence of the information on the composition, impurities of the test material, you have not demonstrated that the test material is representative for the source substance. Therefore, the study is not adequate for the purpose of classification and labelling and/or risk assessment.

1.2.1. Conclusion on the reliability of the information on the analogue substances

Based on the above, the information from the analogue substances cannot reliably contribute to your weight of evidence adaptations.

2. Information provided in your comments on the draft decision

2.1. Information provided in your comments on the draft decision regarding the toxicological endpoints

In your comments to the draft decision, you do not agree to perform the requested studies for the following endpoints:

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

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

Instead, you now indicate your intention to adapt all the above standard information requirements by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

You "acknowledge the need to strengthen the mentioned endpoints to ensure that the chemical safety assessment is robust" and accept the rejection of the adaptations of the information requirements. Rather than conducting the tests required in the decision, you propose "to perform sufficient studies to support the toxicity information requirements of the C6-C24 alcohols within the category using a targeted testing approach, applying the scientific rationale for the use of those data in a read-across strategy".

You present a tiered testing strategy for the generation of additional supporting information on some category members.

More specifically, you intend to conduct approximately five combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests (OECD TG 422) with linear, branched and linear and unsaturated substances; an oral Sub-chronic toxicity study (OECD TG 408) will be conducted on Alcohols, C9-11, branched and linear (EC No. 288-284-4); and Pre-natal developmental toxicity studies (OECD TG 414) in the first and second specied will be conducted on Alcohols, C9-11, branched and linear (EC No. 288-284-4); C6 linear (CAS 111-27-3; EC 203-852-3); and C24 linear (CAS 506-51-4; EC 208-043-9).

Thereafter, the decision to read across data between category members or conduct more tests on additional category members will then be made accordingly.

Based on your comments ECHA understand that you accept the reasoning for the rejection of the adaptations currently in the registration.

ECHA acknowledges your intention to generate additional data and to strengthen the support for a read-across approach within the category of C6-C24 Alcohols. However, ECHA notes the following.

Firstly, as indicated in your comments, the testing strategy relies on data which is yet to be generated and an anticipated outcome of these tests.

Therefore, your testing strategy does not allow for a clear conclusion on compliance with the information requirements for the substances concerned.

Secondly, the current compliance checks concern three substances, i.e. Alcohols, C9-11, branched and linear (EC No. 288-284-4), Nonanol, branched and linear (EC No. 614-557-8), and Alcohols, C12-C13, branched (EC No. 941-187-7; i.e. the Substance).

In contrast, your testing strategy aims to achieve compliance for a larger group of substances, i.e the entire category of C6-C24 Alcohols, which is well beyond the scope of the this compliance check.

Thirdly, you propose to conduct five Combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests (OECD TG 422) to strengthen the support for your read-across approach across the category. However, the identity of the category members to be tested in these OECD 422 studies are uncertain at this point in time.

ECHA is unable to assess whether these proposed studies would support read-across for the Substance. This is because the substances tested may differ in their structures from the constituents of the Substance, in particular on the length of the carbon chain. Therefore the results from the supporting studies may not directly inform on the properties of some of constituents of the Susbtance and further explanations may be needed in order to reliably use this information to predict the properties of the Substance

Regardless, you may at your own discretion generate any additional information to support read-across within the categogry of C6-C24 Alcohols; as long as the tests conducted are not listed in Annexes IX or X to REACH.

In summary, as your strategy relies on a read-across hypothesis and on supporting information that needs to be fully described and justified, as well as on data/information which is yet to be generated for the proposed category members, no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

2.2. *Information provided in your comments on the draft decision regarding the environmental endpoints*

In your comments to the initial draft decision, you do not agree to perform the requested studies for the following environmental endpoints:Growth inhibition study on algae (Annex VII, Section 9.1.2.)

- Long-term toxicity in aquatic invertebrates (Annex IX, Section 9.1.5.)
- Long-term toxicity in fish (Annex IX, Section 9.1.6.)

Instead, you now indicate your intention to adapt all the above standard information requirements by means of grouping and read-across according to Annex XI, Section 1.5, of the REACH Regulation.

In your proposed read-across adaptation, you refer to a C6-24 Alcohols Category, which consists of a family of primary aliphatic alcohols with carbon chain lengths in the range C6-C24. The category members have varied compositions and are linear or have a single short-chain alkyl side-branch at the 2-position in the alkyl chain (usually an α-methyl or α-ethyl group). In the comments, you propose a strategy relying on the generation of further evidence to strengthen the category approach and for this you indicate your intention to first undertake a new programme of literature research and QSAR modelling. You indicate that you then intend to incorporate in the category data any new experimental data available for substances within the chain length of the category members. You will then reassess the selection of key studies.

You also indicate that you intend to do this "*together with experimental work as necessary*" and you further specify that "*Short-term toxicity data may be generated (preferably for single constituent mono-branched alcohols) as needed, to ensure that sufficient relevant evidence is available to justify the category approach for the ecotoxicity endpoints and for validation of QSARs*".

You do not specify which category members you intend to use in experimental testing other than your proposal to conduct OECD TG 210 tests in C6 and C14 linear saturated alcohols (Hexan-1-ol (EC 203-852-3) and Tetradecanol (EC 204-000-3)) within the category. You expect that these substances are at the extremes of the range where ecotoxicity effects may be observed.

In the comments, you further acknowledge that the category approach and the use of data for purposes of exposure assessment and risk characterisation could be documented more clearly and you commit to improve the documentation in the dossier update.

In the comments, you also foresee that validated QSAR predictions based on logKow are likely to be applicable since the mechanism of action for the category member alcohols is narcosis and a consistent trend in ecotoxicity correlated with carbon number is expected.

ECHA acknowledges your intention to generate additional information/data and your plans to refine the read-across approach. However, as your strategy relies on a read-across hypothesis and on supporting information that needs to be fully described and justified, as well as on data/information which is yet to be generated for the proposed category members (including

bridging studies and supporting information), no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

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

1. In vitro gene mutation study in bacteria

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

1.1. Information provided for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with substances other than the Substance:

i. Bacterial reverse mutation assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
ii. In vitro mammalian chromosome aberration test (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
iii. In vitro mammalian chromosome aberration test (1998) conducted with tetradecan-1-ol (Alcohols, C10-16), EC No. 267-019-6
iv. In vitro mammalian cell gene mutation test (1983) conducted with 2-ethylhexan-1-ol, EC No. 203-234-3.
v. In vitro mammalian cell gene mutation test (2002) conducted with docosan-1-ol EC No. 211-546-6.
vi. In vitro Saccharomyces cerevisiae, mitotic recombination Assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0
vii. Mammalian erythrocyte micronucleus test (1992) conducted with dodecan-1-ol, EC No. 203-982-0.

1.2. Assessment of the information provided

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.1 at Annex VII include:

- Detection and quantification of gene mutations (base pairs, substitution, or frame shift) in cultured bacteria including data on the number of revertant colonies; and
- Data provided on 5 bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

Sources of information (ii-vi) have not investigated gene mutation in bacteria. Consequently, these studies do not provide relevant information for this information requiremnt.

The source of information (i) provides relevant information on gene mutations in bacteria, but it has the following deficiency affecting its reliability:

Reliability of information provided with the analogue substances

As explained in Section 1.1. of the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Conclusion on the weight of evidence

As indicated above, while one source of information provides relevant information, the reliability of this information is hampered by the use of read-across which increases the uncertainty of the conclusion for the Substance.

Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 471 test.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

1.3. Information on study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

In your comments to the draft decision, you agree to conduct the test.

2. Growth inhibition study aquatic plants

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

2.1. Information provided for the information requirement

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

You have provided the following studies according to OECD TG 201:

i. a key study ([redacted] 2000) with substance Alcohols, C12-13 (EC No. 278-306-0, CAS No. 75782-86-4);
ii. a supporting study ([redacted], 2000) with substance Alcohols, C12-13-branched and linear (CAS No. 740817-83-8);
iii. a supporting study ([redacted] 2001) with substance Alcohols, C12-13;
iv. a supporting study ([redacted] 2001) with substance Alcohols, C12-13-branched and linear;
v. a supporting study ([redacted] 2003) with substance Alcohols, C12-13-branched and linear.

2.2. Assessment of the information provided

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

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

Additional information on what is necessary when justifying a read-across approach can be

found in the ECHA Guidance R.6. and related documents[5,6].

You have provided a read-across justification in IUCLID Section 6.1.5.

You predict the properties of the Substance from the structurally similar substances (i.e. source substances):

- Alcohols, C12-13 (EC No. 278-306-0, CAS No. 75782-86-4) (source substance 1);
- Alcohols, C12-13-branched and linear (CAS No. 740817-83-8) (source substance 2).

You have provided the following reasoning for the prediction of aquatic toxicity: *"The presence of branched structures does not appear confer it any different ecotoxicological properties compared to the Alcohols, C12 -13 linears only substance. Therefore the data is freely read-across between Alcohols, C12 -13 -branched and Alcohols, C12 -13 substances."*

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

ECHA notes the following shortcoming(s) with regards to prediction(s) of aquatic toxicity.

a) Missing supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include e.g. supporting information and bridging studies to compare properties of the Substance and source substances.

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

The Substance and the source substances have the same carbon chain lengths (i.e. C12 and C13). The Substance consists of about [redacted] constituents. The source substance 1 contains [redacted] constituents. The source substance 2 contain [redacted] constituents and no information on the composition is provided.

Your registration dossier provides algae growth inhibition studies (listed above) and short-term toxicity to fish and to aquatic invertebrates studies with source substances, and no aquatic toxicity studies with the Substance.

[5] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[6] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

From the information provided, it is not possible to compare the properties of the Substance and of the source substance, for the following reasons. The short-term toxicity to fish and to aquatic invertebrates studies with the source substances cannot be used to conclude on the aquatic toxicity since the Substance is poorly water soluble, as explained in A.3. and B.4. below. Specific reasons why the algae studies with the source substances cannot be considered reliable are explained below under section b) *Reliability of studies on the source substance(s),* in particular: b.2) the effect values of all algae studies are expressed based on nominal concentrations even if exposure concentrations were not stable, therefore they currently do not reflect reliable toxicity values; b.1) you have not provided any information on the composition of the test material in the algae studies with the source substances, therefore it is not possible to establish to what degree the composition of the Substance is covered by the constituents of the source substances. Finally, you have provided no supporting information which demonstrates that the ecotoxicity profiles of C12-13 branched is similar to that of C12-13 linear.
Thus the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and for the source substance(s) to support your read-across hypothesis.

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

b) *Reliability of studies on the source substance(s)*

b.1) Missing information on the test material

Under Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

In order to predict the properties of the Substance, the test material used in the study on the source substance must be representative for the source substance (Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). Therefore, the unambiguous characterisation of the composition of the test material used to generate the source data is required to assess whether the test material is representative for the source substance.

For studies (i) to (v) listed above, you have identified the test material by the name and the trade name cited in study report only, without further information, including composition of the test material.

In the absence of the information on the composition and impurities of the test material, you have not demonstrated that the test material is representative for the source substance.

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

b.2) *Reliability of information provided with the analogue substances*

Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case the OECD TG 201, and meet the requirements of the OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

a) the results can be based on nominal or measured initial concentration only if

the concentration of the test material has been maintained within 80-120 % of the nominal or measured initial concentration throughout the test;
b) the test design is reported (*e.g.*, number of replicates, number of test concentrations);
c) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

Your Substance is considered as difficult to test, due to the reasons described below in section 2.3.

Your registration dossier provides studies (i) to (v) listed above according to an OECD TG 201 showing the following:
a) the results in studies (i) to (v) are based on nominal concentrations. The measured test material concentrations in key study (i) and supporting study (iii) were not reported but it was concluded that they were not maintained within 80-120 % of nominal or measured initial concentration. The test material concentrations in supporting study (iv) were reported and showed to be only 20-52 % of nominal at the end of the test. In supporting studies (ii) and (v) it was not reported if the test material concentrations were maintained within 80-120 % of nominal or measured initial concentrations;
b) on the test design, you have not specified *e.g.* the number of replicates in studies (ii) and (iv) and the number of test concentrations in study (iv);
c) tabulated data on the algal biomass determined daily for each treatment group and control are not reported in studies (ii), (iii) and (v).

Based on the above, the Substance is UVCB and difficult to test due to low water solubility (<0.5 mg/L) and high logKow (5.2) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically,
a) the effect values in all provided studies (i-v) are reported based on nominal concentrations but the information on test substance concentrations indicates that they are not maintained within 80-120 % of nominal or measured initial concentration (studies i, iii, iv), or it is not reported whether or not they are maintained within 80-120 % of nominal or measured initial concentration (studies ii, v).
b-c) the reporting of the studies, *e.g.* on the test design (studies ii and iv) and the test results in each treatment and control (studies ii, iii and v), are not sufficient to conduct an independent assessment of their reliability.

Therefore, the studies submitted in your adaptation, as currently reported in your dossier, do not provide an adequate and reliable coverage of the key parameter(s) in the corresponding OECD TG.

Conclusion

Therefore, your read-across approach under Annex XI, Section 1.5. is rejected. On this basis, the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2 of the Appendix on Reasons common to several requests above.

2.3. Study design

The Substance is difficult to test due to the low water solubility (<0.5 mg/L), high logKow (5.2) and UVCB nature of the Substance. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified

and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

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

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

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

3. Long-term toxicity testing on aquatic invertebrates

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

3.1. Information provided for the information requirement

You have provided an OECD TG 202 study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

3.2. Assessment of the information provided

We have assessed this information and identified the following issue:

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

In the provided OECD TG 105 (2013) study, the saturation concentration of the Substance in water was determined to be <0.5 mg/L.

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

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix C.3.

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

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

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

1.1. Information provided for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with substances other than the Substance:

i. Bacterial reverse mutation assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
ii. *In vitro* mammalian chromosome aberration test (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
iii. *In vitro* mammalian chromosome aberration test (1998) conducted with tetradecan-1-ol (Alcohols, C10-16), EC No. 267-019-6
iv. *In vitro* mammalian cell gene mutation test (1983) conducted with 2-ethylhexan-1-ol, EC No. 203-234-3.
v. *In vitro* mammalian cell gene mutation test (2002) conducted with docosan-1-ol EC No. 211-546-6.
vi. *In vitro* Saccharomyces cerevisiae, mitotic recombination Assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0
vii. Mammalian erythrocyte micronucleus test (1992) conducted with dodecan-1-ol, EC No. 203-982-0.

1.2. Assessment of the information provided

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.2. at Annex VIII includes:

- Detection and quantification of structural or numerical chromosomal aberrations in cultured mammalian cells including data on the cytotoxicity and the frequency of cells with chromosomal aberrations or micronuclei.

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

The sources of information (i), (iv), (vi) and (v) have not investigated chromosomal aberrations in mammalian cells. Consequently, these studies do not provide relevant information.

The sources of information (ii), (iii) and (vii) provide relevant information on chromosomal aberrations in mammalian cells.

However, they have the following deficiencies affecting their reliability:

Reliability of information provided with the analogue substances

As explained in Section 1.1. of the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Results obtained from studies (ii) and (iii) not fully reliable when compared to the OECD TG 473

Investigations/specifications in an *in vitro* mammalian chromosome aberration test (OECD TG 473) include:

a) Two separate test conditions must be assessed: in absence of metabolic activation and in presence of metabolic activation.
b) At least 300 well-spread metaphases must be scored per concentration
c) Data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures must be reported.

In the source of information (ii), the following investigations/specifications are not to the requirements of OECD TG 473:

a) test was conducted only in absence of metabolic activation.
b) the studies scored 100 cells per concentration.
c) data on the cytotoxicity and the frequency of cells with structural chromosomal aberrations for the treated and control cultures are not reported

In the source of information (iii), the following investigations/specifications are not to the requirements of OECD TG 473:

a) the study scored 200 cells per concentration.

Based on the above, the reliability of the contribution of the results obtained from this study to the weight of evidence is limited. The lower statistical power of the studies i and the unclarity regarding how the results were obtainedintroduce uncertainty in the results which must be considered.

Results obtained from study (vii) is not fully reliable when compared to the OECD TG 474

Investigations/specifications in a Mammalian erytrocyte microneucleus test (OECD TG 474) include that the proportion of immature among total (immature + mature) erythrocytes must be determined for each animal (by counting a total of at least 2000 erythrocytes for peripheral blood).

In the source of information (vii), the following investigations/specifications are not to the requirements of OECD TG 474 as the study has counted 1000 erythrocytes.

Based on the above, the reliability of the contribution of the results obtained from this study to the weight of evidence is limited. The lower statistical power of the studies introduce uncertainty in the results which must be considered.

Conclusion on the weight of evidence

As indicated above, there are sources of infromation relevant for the information requirement. However, the reliability of this information is hampered by the use of read-across and issues related to how the results were obtained in the studies which increases the uncertainty of the conclusion for the Substance. In addition, as explained in the Annex common to several requests, you have not provided adequate documentation addressing how you integrate the evidence to reach a robust conclusion on the weight of evidence.
Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in a OECD TG 473 or OECD TG 487 test.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

1.3. Information on study design

To fulfil the information requirement for the Substance, either *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) are considered suitable.

In your comments to the draft decision, you agree to conduct the study.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

The result of the requests for information in the Sections 1 of Appendix A and of this Appendix will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

2.1. Information provided for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with substances other than the Substance:

i. Bacterial reverse mutation assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
ii. *In vitro* mammalian chromosome aberration test (1998) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0.
iii. *In vitro* mammalian chromosome aberration test (1980) conducted with tetradecan-1-ol (Alcohols, C10-16), EC No. 267-019-6
iv. *In vitro* mammalian cell gene mutation test (1983) conducted with 2-ethylhexan-1-ol, EC No. 203-234-3.
v. *In vitro* mammalian cell gene mutation test (2002) conducted with docosan-1-ol EC No. 211-546-6.
vi. *In vitro* Saccharomyces cerevisiae, mitotic recombination Assay (1980) conducted with dodecan-1-ol (C12-13 alcohol), EC No. 278-306-0
vii. Mammalian erythrocyte micronucleus test (1992) conducted with dodecan-1-ol, EC No. 203-982-0.

2.2. Assessment of the information provided

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.3 at Annex VIII includes similar information that is produced by the OECD TG 476/490 and OECD TG 488. This includes:

- Detection and quantification of gene mutations (point mutations, frame-shift mutations, small deletions, etc.) including data on the frequency of mutant colonies in cultured mammalian cells (in vitro) or mutant frequency for each tissue in mammals (in vivo).

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

The sources of information (i) to (iii) and (vi) to (vii) have not investigated gene mutation in mammalian cells in mammalian cells. Consequently, these studies do not provide relevant information.

The sources of information (iv) and (v) provide relevant information on gene mutation in mammalian cells.

However, they have the following deficiencies affecting their reliability:

Reliability of information provided with the analogue substances

As explained in Section 1.1. of the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Results obtained from studies (iv) and (v) is not fully reliable when compared to the OECD TG 476

Investigations/specifications in an *in vitro* mammalian cell gene mutation tests using the Hprt and xprt genes (OECD TG 476) include:

a) The maximum concentration tested must induce 80-90% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration must correspond to 10 mM, 2 mg/mL or 2 µl/mL, whichever is the lowest.
b) One positive control must be included in the study. The positive control substance must produce a statistically significant increase in the response compared with the concurrent negative control.
c) Data on the cytotoxicity and the mutation frequency for the treated and control cultures must be reported.

In the source of information (iv), the following investigations/specifications are not to the requirements of the OECD TG 476:

b) You do not state which positive control was used nor do you provide data on the cytotoxicity and the mutation frequency for the positive control
c) You have not provided data on the cytotoxicity and the mutation frequency for the treated and control cultures.

In the source of information (v), the following investigations/specifications are not to the requirements of the OECD TG 476:

a) a maximum tested concentration tested in the study did not induce 80-90% of cytotoxicity compared to the negative control.

Based on the above, the reliability of the contribution of the results obtained from this study to the weight of evidence is limited. The unclarity regarding how the results were obtained introduce uncertainty in the results which must be considered.

Conclusion on the weight of evidence

As indicated above, there are sources of information relevant for the information requirement. However, the reliability of the contribution of this information to your adaptation is hampered by the use of read-across and issues related to how the results were obtained in the studies which increases the uncertainty of the conclusion for the Substance. In addition, as explained in the Annex common to several requests, you have not provided adequate documentation addressing how you integrate the evidence to reach a robust conclusion on the weight of evidence.

Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 476 or OECD TG 490 test.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

2.3. Information on study design

To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

In your comments to the draft decision, you agree to conduct the study.

3. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

4.1 Information provided for the information requirement

You have provided an OECD TG 203 short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

4.2 Assessment of the information provided

We have assessed this information and identified the following issues:

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

As already explained under Section A.3., the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.4.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day)

A Sub-chronic toxicity study (90 day) is a standard information requirement under Annex IX to REACH.

1.1. Information provided for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with substances other than the Substance:

i. Sub-acute toxicity study (28-days; 1999) conducted with tetradecan-1-ol, EC No. 267-019-6.
ii. Sub-chronic toxicity study (90 days; 1966) conducted with hexadecan-1-ol, EC No. 253-149-0.
iii. Combined Repeat dose and Reproductive/Developmental Toxicity Screening Test (1992) conducted with dodecan-1-ol, EC No. 203-982-0.
iv. Sub-chronic toxicity study (90 days; 1966) conducted with hexan-1-ol, CAS No. 111-27-3.
v. Sub-chronic toxicity study (90 days; 1973) conducted with Alcohols, C16-18 and C18-unsatd., EC No. 268-106-1.
vi. Sub-acute toxicity study (28-days; 1985) conducted with hexadecan-1-ol, EC No. 253-149-0.

1.2. Assessment of the information provided

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.6.2. at Annex IX includes similar information that is produced by the OECD TG 408. The following aspects of systemic toxicity are covered: 1) in-life observations, 2) blood chemistry, 3) organ and tissue toxicity.

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

Aspect 1) in-life observations

In-life observations must include information on survival, body weight development, clinical signs, functional observations, food/water consumption and other potential aspects of in life observations on the relevant physiological systems (circulatory, digestive/excretory, integumentary, musculoskeletal, nervous, renal/urinary, and respiratory).

The sources of information (ii) to (vi) provide relevant information on aspect 1).

The source of information (i) have not investigated the elements of aspect 1) apart from survival and cage side observations. Consequently, it provides partially relevant information on aspect 1).

However, these sources of information have deficiencies affecting their reliability:

Reliability of information provided with the analogue substances

As explained in Section 1.1. of the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Results obtained from studies (i), (iii) and (vi) not fully reliable when compared to the OECD TG 408

Investigations/specifications in a sub-chronic toxicity study (OECD TG 408) include:

a. At least 10 male and 10 female animals for each test and control group.
b. Dosing of the Substance daily for a minimum of 90 days.

In study (i), the following investigations/specifications are not to the requirements of the OECD TG 408:

a. 5 animals/sex/dose group
b. the study has an exposure duration of 28 days.

In study (iii), the following investigations/specifications are not to the requirements of the OECD TG 408:

a. the study has an exposure duration of 41-54 days.

In study (vi), the following investigations/specifications are not to the requirements of the OECD TG 408:

c. 5 animals/sex
d. the study has an exposure duration of 28 days.

Based on the above, the reliability of the contribution of the results obtained from this study to the weight of evidence is limited. The lower statistical power and shorter exposure duration of the studies introduce uncertainty in the results which must be considered. This condition of exposure is essential because the effects observed over the longer exposure might be considerably more pronounced over a shorter study duration.

Aspect 2) blood chemistry

Information on blood chemistry must include haematological (full-scale) and clinical chemistry analysis (full-scale), and other potential aspects related to blood chemistry to address relevant physiological systems (circulatory digestive/excretory, endocrine, immune, musculoskeletal, and renal/urinary).

The sources of information (i) to (vi) provide relevant information on aspect 2).

The source of information (iv) has not investigated the elements of aspect 2) apart from haematocrit, haemoglobin, total and differential leukocyte count. Consequently, it provides partly relevant information on aspect 2).

The source of information (v) has not investigated the elements of aspect 2) apart from haemoglobin, red and white blood cells, and differential leukocyte count, glucose, calcium, urea, alanine transaminase and aspartate aminotransferase. Consequently, it provides partly relevant information on aspect 2).

However, these sources have deficiencies affecting their reliability. Specifically, the reliability issues related to read-across, low statistical power and shorter exposure duration identified for aspect 1) applly equally to this aspect.

Aspect 3) organ and tissue toxicity

Organ and tissue toxicity must include information on terminal observations on organ weights, gross pathology and histopathology (full-scale) and other potential aspects related to organ and tissue toxicity to address relevant physiological systems (circulatory, digestive/excretory,

endocrine, immune, integumentary, musculoskeletal, nervous, renal/urinary system, reproductive, and respiratory).

The source of information (iii) provides relevant information on aspect 3).

The source of information (i) has not investigated all the elements of aspect 3); the histopathology conducted in that study is limited to adrenals, heart, kidneys, liver, spleen, testes and gross lesions from all control and high dose animals. Consequently, it provides partly relevant information on aspect 3).

The sources of information (ii) and (iv) have not investigated all the elements of aspect 3); the histopathology of thymus, peripheral nerve, muscle, spinal cord, eye plus optic nerve, pituitary or trachea are missing. Consequently, it provides partly relevant information on aspect 3).

The source of information (v) has not investigated all the elements of aspect 3); histopathology limited detection of fat degeneration in the liver. Consequently, it provides partly relevant information on aspect 3).

The source of information (iv) has not investigated all the elements of aspect 3); the histopathology conducted in that study is limited to thyroid, adrenals, thymus, kidney, spleen, heart, brain, testes, and liver. Consequently, it provides partly relevant information on aspect 3).

However, these sources have deficiencies affecting their reliability. Specifically, the reliability issues related to read-across, low statistical power and shorter exposure duration identified for aspect 1) apply equally to this aspect.

Conclusion on the weight of evidence

As indicated above, while the sources of information provide (partially) relevant information, the reliability of this information is hampered by the use of read-across and issues related to how the results were obtained in the studies which increases the uncertainty of the conclusion for the Substance. In addition, as explained in the Annex common to several requests, you have not provided adequate documentation addressing how you integrate the evidence to reach a robust conclusion on the weight of evidence.

Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 408 study.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2.1 of the Appendix on Reasons common to several requests above.

1.3. Information on study design

Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance; Guidance on IRs and CSA, Section R.7.5.6.3.2.

According to the OECD TG 408, the rat is the preferred species.

Therefore, the study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

2. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

2.1. Information provide for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with other substances than the Substance:

(i) combined repeated dose and reproductive/developmental toxicity screening test (1992) in rats conducted with the analogue substance dodecan-1-ol; EC No. 203-982-0.
(ii) combined repeated dose and reproductive/developmental toxicity screening test (1992) in rats conducted with the analogue substance octadecan-1-ol; EC No. 204-017-6.
(iii) pre-natal developmental toxicity study (1997) in rats conducted with the analogue substance Alcohols, C7-11-branched and linear; EC No. 287-623-3
(iv) pre-natal developmental toxicity study (2002) in rat conducted with the analogue substance docosan-1-ol, EC No. 211-546-6
(v) pre-natal developmental toxicity study (1998) in rats conducted with the analogue substance C24-34 even chain alcohols (no numerical identifiers provided).
(vi) pre-natal developmental toxicity study (1995) in rats conducted with the analogue substance 3-methylbutan-1-ol ; EC No. 204-633-5 via inhalation route.
(vii) pre-natal developmental toxicity study (2002) in rabbit conducted with the analogue substance docosan-1-ol, EC No. 211-546-6.
(viii) pre-natal developmental toxicity study (1998) in rabbits conducted with the analogue substance C24-34 even chain alcohols (no numerical identifiers provided).
(ix) pre-natal developmental toxicity study (1995) in rabbits conducted with the analogue substance 3-methylbutan-1-ol ; EC No. 204-633-5 via inhalation route.

2.2. Assessment of the information provided

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.7.2. at Annex IX includes similar information that is produced by the OECD TG 414 on one species. The following aspects are covered: 1) prenatal developmental toxicity, 2) maternal toxicity, and 3) maintenance of pregnancy.

The sources of information provide information regarding developmental toxicity in two species. For the current information requirement of PNDT in one species, ECHA has considered the species with the most information available; i.e. rat.

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

Aspect 1) pre-natal developmental toxicity

Pre-natal developmental toxicity includes information after pre-natal exposure on embryonic/foetal survivial (number of live foetuses; number of resorptions and dead foetuses, postimplantation loss), growth (body weights and size) and structural malformations and variations (external, visceral and skeletal).

The sources of information (vii) to (ix) do not provide information in the rat. Therefore, it does not provide relevant information on aspect 1) in the first species.

The sources of information (iii) to (vi) provide relevant information on aspect 1).

The sources of information (i) and (ii) have investigated elements of survival and growth of the of the offspring. However, the studies have not investigated skeletal and visceral malformations and variations. Consequently, the studies provide partially relevant information on aspect 1).

However, these sources of information have deficiencies affecting their reliability:

Reliability of read-across predictions

As explained in the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Source of information (vi) route of administration not appropriate

A PNDT study according to the test method OECD TG 414 should be performed with oral administration of the Substance unless the substance is a gas or a highly volatile liquid (ECHA Guidance R.7a, Section R.7.6.2.3.2.). This is because the aim of a reproductive toxicity study is to maximise systemic exposure to be able to detect potential effects on reproduction and development.

The source of infromation (vi) has been conducted via the inhalation route.

You have not provided information demonstrating that the systemic exposure to the Substance after administration via the inhalation route is likely to be equal to or higher than that achieved via the default oral route of administration. In addition, for the Substance the oral route is appropriate route of administration.

Based on the above, the results obtained are associated significant uncertainties with the route-to-route extrapolation. You have not taken these uncertainties into account.

Results obtained from studies (i) to (iv) are not fully reliable when compared to the OECD TG 414

Investigations/specifications in a pre-natal developmental toxicity study (OECD TG 414) include:

a) each group should aim to have 20 female animals with implantation sites at necropsy. Groups with fewer than 16 animals with implantation sites may be inappropriate.
b) examination of the foetuses for sex and body weight; external, skeletal, and soft tissue alterations (variations and malformations); number of resorptions and or live foetuses; and measurement of anogenital distance in live rodent foetuses.
c) examination of the dams for weight and histopathology of the thyroid gland/thyroid hormone measurements/gravid uterus weight/uterine content/body weight of the dams/clinical signs of the dams

In studies (i) and (ii), the following investigations/specifications are not to the requirements of the OECD TG 414:

a) the study started with 12 animals per group; no information on the number of pregnant animals.

In study (iii), the following investigations/specifications are not to the requirements of the OECD TG 414:

a) the study started with 8-10 animals per group; no information on the number of pregnant animals.

b) No data on foetal examinations of dams have been provided. It is unclear what has been investigated.
c) No data on examinations of dams have been provided. It is unclear what has been investigated.

In study (iv), the following investigations/specifications are not to the requirements of the OECD TG 414:

a) the number of animals used per group not specified
b) No data on foetal examinations of dams have been provided. It is unclear what has been investigated.
c) No data on examinations of dams have been provided. It is unclear what has been investigated.

Based on the above, the reliability of the contribution of the results obtained from this study to the weight of evidence is limited. The lower statistical power the study and unclarity on how the results were obtained introduce uncertainty in the results which must be considered.

Aspect 2) maternal toxicity and aspect 3) maintenance of pregnancy

Maternal toxicity includes information after gestational exposure on maternal survival, body weight and clinical signs and other potential aspects of maternal toxicity in dams.

Maintenance of pregnancy includes information on abortions and/or early delivery as a consequence of gestational exposure and other potential aspects of maintenance of pregnancy.

The sources of information (vii) to (ix) do not provide information in the rat. Therefore, it does not provide relevant information on aspect 2) and 3) in the first species.

The sources of information (i) to (vi) provide relevant information on aspect 2) and 3) .

However, these sources have deficiencies affecting their reliability. Specifically, the reliability issues related to read-across identified for aspect 1) above also applies equally to these aspects.

Conclusion on the weight of evidence

As indicated above, while the sources of information provide (partially) relevant information, there are two types of reliability issues associated with your weight of evidence adaptation: unjustified use of read-across and issues related to how the results were obtained in the individual lines of evidence. In addition, as explained in the Annex common to several requests, you have not provided adequate documentation addressing how you integrate the evidence to reach a robust conclusion on the weight of evidence.

Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 414 study in the firts species.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2.1 of the Appendix on Reasons common to several requests above.

2.3. Information on the study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[7] administration of the Substance.

[7] ECHA Guidance R.7a, Section R.7.6.2.3.2.

3. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

3.1 Information provided for the information requirement

You have provided the following justification to omit the study "*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because the needs associated with a sound understanding of long-term aquatic toxicity to invertebrates study (required in Section 9.1.5) are adequately met by the available data on constituents. For the purpose of risk assessment aquatic PNECs for individual constituents have been derived*".

3.2 Assessment of the information provided

We have assessed this information and identified the following issue:

Adapting the information requirement in accordance with the general rules for adaptation set out in Annex XI requires identifying clearly the specific legal basis of the adaptation invoked and complying with relevant conditions listed in the corresponding section of Annex XI. In all cases, adequate and reliable documentation must be provided, including relevant justification and study records.

You have not indicated any specific legal basis/section of Annex XI of REACH (e.g. 1.1. Use of existing data, or 1.2. Weight of Evidence, or 1.5. Grouping of substances and read-across approach) that you consider as a reason to adapt this information requirement. In addition, no relevant justification nor documentation (e.g. study record) is provided for this endpoint in the IUCLID dossier.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2.2 of the Appendix on Reasons common to several requests above.

3.3 Study design

The Substance is difficult to test due to the low water solubility (<0.5 mg/L), high logKow (5.2) and the UVCB nature of the Substance. OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

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

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among

others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

4. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

4.1 Information provided for the information requirement

You have provided the following justification to omit the study "*In accordance with Section 1 of REACH Annex XI, the study does not need to be conducted because the needs associated with a sound understanding of long-term aquatic toxicity to fish study (required in Section 9.1.6) are adequately met by the available data on constituents. For the purpose of risk assessment aquatic PNECs for individual constituents have been derived*".

4.2 Assessment of the information provided

We have assessed this information and identified the following issue:

Adapting the information requirement in accordance with the general rules for adaptation set out in Annex XI requires identifying clearly the specific legal basis of the adaptation invoked and complying with relevant conditions listed in the corresponding section of Annex XI. In all cases, adequate and reliable documentation must be provided, including relevant justification and study records.

You have not indicated any specific legal basis/section of Annex XI of REACH (e.g. 1.1. Use of existing data, or 1.2. Weight of Evidence, or 1.5. Grouping of substances and read-across approach) that you consider as a reason to adapt this information requirement. In addition, no relevant justification nor documentation (e.g. study record) is provided for this endpoint in the IUCLID dossier.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2.2 of the Appendix on Reasons common to several requests above.

4.3 Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

The OECD TG 210 specifies that for difficult to test substances the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix C.3.

Appendix D: Reasons to request information required under Annex X of REACH

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is a standard information requirement under Annex X to REACH.

1.1. Information provided for the information requirement

You have adapted this information requirement by using Weight of evidence based on the following experimental data with the Substance:

(i) combined repeated dose and reproductive/developmental toxicity screening test (1992) in rats conducted with the analogue substance dodecan-1-ol; EC No. 203-982-0.
(ii) combined repeated dose and reproductive/developmental toxicity screening test (1992) in rats conducted with the analogue substance octadecan-1-ol; EC No. 204-017-6.
(iii) pre-natal developmental toxicity study (1997) in rats conducted with the analogue substance Alcohols, C7-11-branched and linear; EC No. 287-623-3
(iv) pre-natal developmental toxicity study (2002) in rat conducted with the analogue substance docosan-1-ol, EC No. 211-546-6
(v) pre-natal developmental toxicity study (1998) in rats conducted with the analogue substance C24-34 even chain alcohols (no numerical identifiers provided).
(vi) pre-natal developmental toxicity study (1995) in rats conducted with the analogue substance 3-methylbutan-1-ol ; EC No. 204-633-5 via inhalation route.
(vii) pre-natal developmental toxicity study (2002) in rabbit conducted with the analogue substance docosan-1-ol, EC No. 211-546-6.
(viii) pre-natal developmental toxicity study (1998) in rabbits conducted with the analogue substance C24-34 even chain alcohols (no numerical identifiers provided).
(ix) pre-natal developmental toxicity study (1995) in rabbits conducted with the analogue substance 3-methylbutan-1-ol; EC No. 204-633-5 via inhalation route.

1.2. Assessment of the information provided:

You have adapted this information requirement using weight of evidence under Annex XI, Section 1.2.

As explained under Appendix on Reasons common to several requests, the weight of evidence adaptation must fulfil the information requirement based on relevant and reliable sources of information. These sources of information must provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

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

Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.7.2 at Annex X includes similar information that is produced by the OECD TG 414 on a second species (two species taking the first species into account to address the potential species differences). The following aspects are covered: 1) prenatal developmental toxicity in two species, 2) maternal toxicity in two species, and 3) maintenance of pregnancy in two species.

The sources of infromation provide information regarding developmental toxicity in two species. For the current information requirement of PNDT in the second species, ECHA has considered the rabbit, as the rat has already been considered for information requirement of PNDT in the one species (Appendix C, Section 2).

We have assessed the individual sources of information with regard to relevance and identified the following issue(s):

Aspect 1) pre-natal developmental toxicity

Pre-natal developmental toxicity includes information after pre-natal exposure on embryonic/foetal survivial (number of live foetuses; number of resorptions and dead foetuses, postimplantation loss), growth (body weights and size) and structural malformations and variations (external, visceral and skeletal). This information in two species should be covered to address the potential species differences.

The sources of information (i) to (vi) do not provide information in the rabbit. Therefore, they do not provide relevant information on aspect 1) in a second species.

The sources of information (vii) and (ix) provide relevant information on aspect 1) in a second species.

However, these sources of information have deficiencies affecting their reliability:

Sources of information (vii) to (ix) reliability of read-across predictions

As explained in Section 1.1. of the Appendix common to several requests, you have not demonstrated that you reliably can predict the properties of the Substance by using test results obtained with other substances.

Source of information (ix) does not provide reliable information

The issues on the use of information obtained after inhalation administration identified for source of information (iv) in Appendix C, Section 2 apply equally for this source of information.

Aspect 2) maternal toxicity and aspect 3) maintenance of pregnancy

Maternal toxicity includes information after gestational exposure on maternal survival, body weight and clinical signs and other potential aspects of maternal toxicity in dams.

Maintenance of pregnancy includes information on abortions and/or early delivery as a consequence of gestational exposure and other potential aspects of maintenance of pregnancy.

The sources of information (i) to (vi) do not provide information in the rabbit. Therefore, they do not provide relevant information on aspect 2) and 3) in a second species.

The sources of information (vii) and (ix) provide relevant information on aspect 2) and 3) in a second species.

However, these sources have deficiencies affecting their reliability. Specifically, the reliability issue related to read-across identified for aspect 1) above also applies equally to these aspects.

Conclusion on the weight of evidence

As indicated above, there are two types of reliability issues associated with your weight of evidence adaptation: unjustified use of read-across and issues related to how the results were obtained in the individual lines of evidence. In addition, as explained in the Annex common to several requests, you have not provided adequate documentation addressing how you integrate the evidence to reach a robust conclusion on the weight of evidence.

Therefore, it is not possible to conclude, based on any source of information alone or together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 414 study in a second species.

Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

Your comments on the draft decision are addressed in section 2.1 of the Appendix on Reasons common to several requests above.

1.3. Information on study design

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred second species, depending on the species tested in the first PNDT study (request C.2. in this decision).

The study must be performed with oral[8] administration of the Substance.

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix E: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[9].

B. Test material

1. *Selection of the Test material(s)*

   The Test Material used to generate the new data must be selected taking into account the following:
   - the boundary composition(s) of the Substance,
   - the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. *Information on the Test Material needed in the updated dossier*
   - You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
   - The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[10].

[9] https://echa.europa.eu/practical-guides
[10] https://echa.europa.eu/manuals

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

A. Environmental testing for substances containing multiple constituents

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

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

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

Appendix G: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS. Similarly the information requirement for a Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 05 January 2021.

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

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

Comments on the deadline to submit the requested information in this decision

In your comments you requested an extension of the deadline for providing the requested information from 24 months to 45 months. You argue that the extension is needed to perform sufficient studies to support read-across the toxicity information requirements of the larger category of C6-C24 alcohols of which the Substance is a member. In response, ECHA notes the following.

Your read-across testing strategy as explained in your comments refers to conducting tests on substances which are not addressed by this compliance check decision. In addition, the testing strategy covers information requirements which are not within the scope of this compliance check. However, for the calculation of the deadline ECHA can only take into account the requests in this decision.

Therefore, an extension of the deadline set in the decision to accommodate your intention to follow a tentative testing strategy as described in your commens which may or may not result in compliance for the Substance is not considered justified.

The deadline set in this decision allows for generating the required data on the Substance as a result of incompliances identified in your registration. This deadline has already been set to allow sequential testing where appropriate.

ECHA took into account your comments and did not amend the deadline

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

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

Appendix H: List of references - ECHA Guidance[11] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[12]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[14]

[11] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[12] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[13] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[14] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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

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

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

Appendix I: Addressees of this decision and their corresponding information requirements

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

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.