Helsinki, 14 May 2020

Addressees
Registrant of 410-190-0-132983-41-6 listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision
11 March 2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: A mixture of isomers of: mono-(2-tetradecyl)naphthalenes; di-(2-tetradecyl)naphthalenes; tri-(2-tetradecyl)naphthalenes
EC number: 410-190-0
CAS number: 132983-41-6

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***21 November 2022***.

A. Requirements applicable to 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: Bacterial reverse mutation test, EU B.13/14. /OECD TG 471), with the Substance to be performed with E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.;

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

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Only if a negative result in Annex VII, Section 8.4.1. is obtained, in vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method OECD TG 476 or TG 490) with the Substance;

C. Requirements applicable to all the Registrants subject to Annex IX of REACH

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

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

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance;

4. Identification of degradation products (Annex IX, Section 9.2.3.) of each relevant constituent present in concentration at or above 0.1% (w/w), using an appropriate test method with the Substance;

5. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method EU C.21/OECD TG 216) with the Substance;

D. Requirements applicable to 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) in a second species (rabbit), oral route with the Substance;

2. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.; test method: OECD TG 222 or OECD TG 220 with the Substance;

3. Long-term toxicity to plants (Annex X, Section 9.4.6.; test method OECD TG 208, with at least six species tested (with as a minimum two monocotyledonous species and four dicotyledonous species) or ISO 22030) with the Substance.

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII to X of REACH, if you have registered a substance at above 1000 tpa.

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

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

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where relevant.

Appeal

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

Failure to comply

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

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix on general considerations

(i) Assessment of the Grouping of substances and read-across approach, in light of the requirements of Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5 for:

- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.).

ECHA has considered the scientific and regulatory validity of your read-across approach in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. 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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and the ECHA RAAF document.

A. Scope of the grouping

i. Description of the grouping

You have provided a read-across justification document in IUCLID Section 13.

In your read-across justification document you have proposed a category approach that includes the following substances:

- A mixture of isomers of: mono-(2-tetradecyl)naphthalenes; di-(2-tetradecyl)naphthalenes; tri-(2-tetradecyl)naphthalenes (EC: 410-190-0; CAS: 132983-41-6), hereafter as the Substance
- mono-, and di-(sec-hexadecyl)naphthalene (EC: 930-936-3), hereafter source substance MCP917;
- diisopropylnaphthalene (EC: 254-052-6; CAS: 38640-62-9), hereafter source substance DIPN;
- naphthalene, sec-eicosyl (EC: 304-231-0; CAS: 94247-62-8), hereafter source substance MCP 2395.

You have provided the following reasoning for the grouping: "*The use of surrogates having close structural similarities and same chemical group functionality as in the case of the alkylated naphthalenes (e.g., MCP 917, MCP 2395, DIPN) would be appropriate for read-across for MCP 2484"* (the Substance).

You define the structural basis for the grouping as all substances being alkylated naphthalene

analogues.

ii. Assessment of the grouping

ECHA notes the following deficiencies with regard to the grouping:

Applicability domain – not defined

According to the ECHA Guidance, a category (grouping) hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint*".[2] Particularly, "*the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members*".[3] Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

You have not defined the applicability domain, you have not provided any inclusion/exclusion criteria which would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the category members.

B. Predictions for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties: "*Based on the close chemical similarity between MCP 2484 (MCP 968) and its alkylated naphthalene analogues, we believe that the read-across data for MCP917, and MCP2395 is adequate to support hazard characterization of MCP 2484*".

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 deficiencies with regard to the grouping and the prediction of toxicological properties:

Structural similarity

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

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on

[2] ECHA Guidance R.6, Section R.6.2.4.1
[3] ECHA Guidance R.6, Section R.6.2.1.2

recognition of the structural similarities and differences between the substances[4]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the structural similarity between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance.

While structural similarity is a prerequisite for applying the grouping and read-across approach, it does not necessarily lead to predictable or similar human health ecotoxicological properties. You have not provided a well-founded hypothesis to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

In your comments on the draft decision, you noted your intention to update your read-across justification in 2020 following the principles laid out in ECHA's RAAF. You have not submitted any information to support your read-across adaptation. You remain responsible for complying with this decision by the set deadline and ECHA expects you to submit the missing information required in the present decision.

C. Conclusions on the read-across approach

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

[4] ECHA Guidance R.6

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

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

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

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

You have provided a key study in your dossier, for *in vitro* gene mutation in bacteria (1990) with the Substance.

We have assessed this information and identified the following issue:

To fulfil the information requirement, the study has to meet the key parameters of OECD TG 471 (1997), which indicates that the test should be performed with 5 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).

You have provided an Ames test with the following strains, TA 98, TA 100, TA 1535, TA 1537, and TA 1538, which all gave negative results.

The study you have provided was not conducted with the appropriate 5 strains as it does not include results in the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

Therefore, the information provided does not cover a key parameter required by OECD TG 471.

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

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

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

You have provided a key study ([redacted] 2010) conducted according to OECD TG 201 with the Substance.

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

Tests on substances must be conducted in accordance with the OECD test guidelines or another recognised international test method (Article 13(3) of REACH). OECD TG 201 is the preferred guideline to fulfil this information requirement. The guideline specifies that for difficult to test substances (UVCB, hydrophobic, adsorptive and poorly water-soluble), OECD GD 23 is to be followed. The OECD TG 201 and the OECD GD 23, require that you must (among others):

- provide evidence that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions;

- provide evidence that exposure concentrations have been maintained throughout the test (within ±80-120 % of the nominal or initial measured concentration);
- perform analytical monitoring of the substance to verify the initial concentrations and maintenance of the exposure concentrations during the test. For this purpose, a sufficiently sensitive analytical method must be used for the analysis of the test chemical in the test solutions or a statement from an analytical chemist must be provided in the study report to justify why lower detection limits (LOD) were not feasible (any preliminary analytical efforts should also be described in the report).

The study ([redacted] 2010) is conducted in accordance with OECD TG 201.

The Substance is a 'difficult to test' substance: it is a UVCB, hydrophobic with adsorptive properties (log Kow > 10) and poorly water soluble (<0.001 mg/L) indicating difficulties for test solution preparation and testing based on Table 2 of OECD GD 23.

You report that the test solutions were prepared by adding the test substance to the dilution medium in glass vessel, stirring the text mixtures for 24h and then allowing them to settle for 24h. An aliquot was then removed from the mid vessel to provide a water accomodated fraction (WAF). You have not provided any justification for the methods used to prepare the test solutions.

You have carried out analytical monitoring of the test concentrations with HPLC-UV method (limit of detection 0.01 mg/L). No test material was detected in the analysed test solutions. You have not provided any evidence that the exposure concentrations have been maintained for the Substance during the study period.

You have not justified nor demonstrated that the method applied in the aquatic toxicity test allowed achieving maximum dissolved concentrations.

The analytical method used was not sufficiently sensitive since its limit of detection (LOD, 0.01 mg/L) was above the water solubility of the Substance (<0.001 mg/L). You have not provided a justification why a lower LOD was not feasible.

Since no test material was detected, you have not verified the initial concentrations nor demonstrated the maintenance of the exposure concentrations during the test.

Therefore, the information requirement is not fulfiled.

Study design

The Substance is difficult to test due to the low water solubility, hydrophobicity and adsorptive properties as explained above. OECD TG 201 specifies that for difficult to test substances, the OECD GD 23 is to be followed. To get reliable results, the substance properties need to be considered when performing the test, in particular in test design including exposure system and test solution preparation, and sampling. OECD GD 23 (Table 1) describes testing difficulties related to a specific property of the substance. You may use the approaches described in OECD GD 23 or other approaches if more appropriate for your substance. The approach selected must be justified and documented. Due to the substance properties it may be difficult to achieve and maintain the exposure concentrations. Therefore, you have to demonstrate that the concentration of the substance is stable throughout the test (i.e. measured concentrations remains within 80-120% of the nominal concentration). If it is not possible to demonstrate the stability, you must express the effect concentration based on measured values as described in the applicable test guideline. In case the dose-response

relationship cannot established (no observed effects), you must demonstrate that the test solution preparation method applied was sufficient to maximise the concentration of the Substance in the test solution.

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

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 10 to 100 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII and VIII to REACH.

1. **Only if a negative result in Annex VII, Section 8.4.1. is obtained: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490), with the Substance;**

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

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

As explained in the Appendix on general considerations, ECHA takes note of the intention you expressed in your comments to update your read-across justification and recommends you to update the dossier by the set deadline submitting the missing information requested in the present decision.

As explained in the Appendix on general considerations your adaptation is rejected.

Your dossier contains (i) a negative result for *in vitro* cytogenicity study in mammalian cells and (ii) inadequate data for the *in vitro* gene mutation study in bacteria.

The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in section A.1.

The result of the request for information in section A.1.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.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria provides a negative result.

Information on the study design

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

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

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

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

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

You have provided the following study records in your dossier with the Substance:

(i) 2-generation reproductive toxicity study in rats, dietary route (supporting study, OECD TG 416, GLP compliant; 2013)

(ii) 28-day short-term toxicity study in rat, dermal route (key study, equivalent to OECD TG 410, GLP compliant, 1991)

(iii) 90-day sub-chronic toxicity study in rat, dermal route (key study, OECD TG 411, GLP compliant; 2012)

In addition, you sought to adapt the information requirement according to Annex XI, section 1.5. by providing the following information with the source substance MCP 917:

(iv) 90-day sub-chronic toxicity study in rat, dietary route (key study, equivalent to OECD TG 408, GLP compliant; 1991)

(v) 90-day sub-chronic toxicity study in rat, dermal route (supporting information, equivalent to OECD TG 411, GLP compliant; 1994).

We have assessed this information and identified the following issues:

A. To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the key parameters of OECD TG 408. The following key parameter(s) of this test guideline include, among others:

- Dosing of the Substance daily for a period of 90 days until the scheduled termination of the study
- At least 10 female and 10 male animals should be used at each dose level (including control group)
- Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of haematology, clinical biochemistry, including measures of T3, T4, and TSH

Study (i) does not investigate the following: clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, hematology, clinical biochemistry, including measures of T3, T4, and TSH. Study (ii) has an exposure duration less than 90-days and was conducted with less than 10 animals per sex per test dose group.

Therefore, studies (i) and (ii) do not meet the key parameters of OECD TG 408 and are thus rejected.

B. The study must be conducted with the most appropriate route of administration.

As provided in Annex IX, Section 8.6.2, Column 2, appropriate route shall be chosen. Testing by the dermal route is appropriate provided you fulfil the cumulative criteria, including among others that the physicochemical properties suggest a significant rate of absorption through the skin.

Studies (ii) and (iii) were performed with dermal administration. ECHA notes that in Section 7.1. of IUCLID, you reported dermal absorption of 0.04 % to 0.159 % for the Substance ([redacted] 2013). ECHA considers that this cannot be regarded as significant rate of absorption through the skin.

In addition, we further note that the reported oral absorption appears to be 10 times higher (from 0.55 % to 1.3 %; [redacted] 2013).

Based on the information provided, the dermal route is not the most appropriate route of administration and thus the dermal studies cannot be regarded as providing reliable information to predict the oral systemic toxicity of the Substance.

Therefore, studies (ii) and (iii) are rejected.

C. Studies (iv) and (v) are 90-day sub-chronic toxicity studies, performed with the source substance MCP 917. As explained in the Appendix on general considerations your adaptation is rejected. As explained in the Appendix on general considerations, ECHA takes note of the intention you expressed in your comments to update your read-across justification and recommends you to update the dossier by the set deadline submitting the missing information requested in the present decision.

Based on the above, the information you provided do not fulfil the information requirement.

Information on the design of the study to be performed

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

Referring to 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, due to the low dermal absorption of the Substance, as explained above. Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

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

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

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. with the key study ([redacted] 2003) conducted with the analogue substance Naphthalene, (1-methylnonadecyl)- (CAS: 135585-

40-9).

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. Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You predict the properties of the Substance from the analogue substance: Naphthalene, (1-methylnonadecyl)- (CAS: 135585-40-9; i.e. the source substance).

You have provided a read-across justification that addresses the current endpoint in the Endpoint Summary of IUCLID Section 6.1.4.

We have assessed your adaptation and note the following shortcomings with regards to the prediction of long-term toxicity on aquatic invertebrates properties.

i) Read-across hypothesis only based on structural similarity

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the source substance(s) and your Substance.[5] It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

You have provided the following reasoning for the prediction of long-term toxicity on aquatic invertebrates: "(..) *there are data for a structurally related alkylnaphthalene, MCP 2395 (i.e, eicosanylnaphthalene analog) for read-across assessment. (..) Based on the read-across data for the structurally related alkylated naphthalene surrogate, the submission substance, namely, the naphthalene, reaction products with tetradecene, is not expected to cause chronic toxicity to invertebrates at its maximum water solubility limits (if tested under WAF conditions).*"

Your read-across hypothesis is that the similarity in chemical structure between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance for other endpoints.

However, similarity in chemical structure does not necessarily lead to predictable or similar ecotoxicological properties. Additionally, there are structural differences between the source substance and the Substance and you have neither described them nor considered the impact of the structural differences on the prediction.

Therefore, you have not provided a well-founded hypothesis to establish a reliable prediction for a long-term toxicity on aquatic invertebrates property.

ii) Source study(ies) not meeting Annex XI Section 1.5 Requirements

[5] ECHA Guidance R.6

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

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

OECD TG 211 is the preferred guideline to fulfil this information requirement. The guideline specifies that for difficult to test substances (UVCB, hydrophobic, adsorptive and poorly water-soluble), OECD GD 23 is to be followed. The key parameters of OECD TG 211 and the OECD GD 23 include that you must (among others):

- provide evidence that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions;
- provide evidence that exposure concentrations have been maintained throughout the test (within ±80-120 % of the nominal or initial measured concentration);
- perform analytical monitoring of the substance to verify the initial concentrations and maintenance of the exposure concentrations during the test. For this purpose, a sufficiently sensitive analytical method must be used for the analysis of the test chemical in the test solutions. For example, sum parameter methods (e.g. total organic carbon) will not demonstrate the stability of individual UVCB components during the test and are limited by relatively poor sensitivity (approximately 1 mg/L).

The Substance is a 'difficult to test' substance: it is a UVCB, hydrophobic with adsorptive properties (logKow > 10) and poorly water soluble (<0.001 mg/L) indicating difficulties for test solution preparation and testing based on Table 2 of OECD GD 23.

You report that the test solutions were prepared by stirring the test mixtures for 22-24 hrs. allowing them to settle for 55 mins to 1 hr 25 min before the aqueous WAF solutions were removed. You have not provided any justification for the methods used to prepare the test solutions.

You have carried out total organic carbon (TOC) analyses, which did not indicate significant detectable dissolved test substances in any of the test solutions.

You have not justified nor demonstrated that the method applied in the aquatic toxicity test allowed achieving maximum dissolved concentrations.

The chemical analysis performed by TOC was limited by poor sensitivity and did not allow to detect the test substance in the test solutions. Therefore, you have not provided any evidence that exposure concentrations were maintained during the test.

Therefore, the information requirement is not fulfiled.

Due to the above mentioned deficiencies of the source study, it does not provide adequate and reliable coverage of the key parameters of OECD TG 211. Consequently, the study is not adequate for the purpose of classification and labelling and/or risk assessment.

iii) Conclusion

You have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your adaptation based on a grouping and read-across approach is rejected.

In your comments to the draft decision you indicated your intention to submit a dossier update with a robust study summary for an existing OECD TG 211 study (*Daphnia magna Reproduction test*) on the Substance, and you have updated your registration dossier with this study. However, ECHA notes that the new study provided has similar deficiencies as the source study addressed above. Specifically, you have not provided any justification nor evidence that the methods used to prepare the test solutions allowed achieving maximum dissolved concentrations. Furthermore, the total organic carbon (TOC) analyses did not allow to detect the test substance in the test solutions. Therefore, you have not provided any evidence that exposure concentrations were maintained during the test. This new study with the Substance thus cannot be considered adequate to fulfil the standard information requirement.

Therefore, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility, hydrophobicity, and adsorptive properties as explained above. OECD TG 211 specifies that for difficult to test substances, the OECD GD 23 is to be followed as explained above under request A.2.

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

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

You have provided an adaptation for this endpoint where you consider that long-term toxicity testing on fish is not needed since the Substance is not likely to pose chronic aquatic hazards based on the long-term toxicity to *Daphnia* study with an analogue substance and based on the lack of acute adverse effects in aquatic organisms.

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

As specified in Annex IX, Section 9.1., Column 2, long-term toxicity on fish must be performed unless the Chemical Safety Assessment demonstrates that risks towards the aquatic compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account all relevant hazard information from your registration dossier to support that long-term toxicity testing is not required.

The toxicity information must at least cover species of three trophic levels: algae/aquatic plants, invertebrates (Daphnia preferred), and fish.[6] For poorly water soluble and hydrophobic substances, risks cannot be reliably assessed based on short term toxicity tests (i.e. to derive a reliable PNEC for this substance).[7] Such substances require longer time to be significantly taken up by the test organisms and as a consequence steady state conditions are likely not reached within the duration of a short-term toxicity test. For this reason, short-term tests may not give a true measure of toxicity for this type of substances and long-term effects cannot be excluded.

[6] ECHA Guidance R.7b, Section R.7.8.5.3
[7] ECHA Guidance R.7b, Section R.7.8.4.3

Based on the information you provided, the Substance is poorly water soluble (water solubility < 0.001 mg/L) and hydrophobic (log Kow > 10).

You have provided short-term toxicity on fish and *Daphnia* studies, an algae growth inhibition and a read-across long-term toxicity on *Daphnia* study. You have not provided a long-term toxicity on fish study.

As indicated above, short-term studies are, due to the properties of the Substance, insufficient to assess the risks.

Furthermore, as specified in requests A.2 and C.2, the data on algae growth inhibition and the data on long-term toxicity to *Daphnia* are not compliant with the REACH relevant requirements.

Therefore, your dossier currently does not include adequate information to characterise the hazardous property of the Substance to aquatic organisms.

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

In your comments to the draft decision you refer to two existing studies with the Substance:
a) an existing OECD TG 215 study (*fish juvenile growth test*) which you consider would fulfil this standard information requirement;
b) an existing OECD TG 305 study (*Dietary Bioaccumulation in Fish*) you claim is relevant for the evaluation of long term toxicity to fish.

We have assessed the information provided in the comments and identified the following issue(s).

Tests on substances must be conducted in accordance with the OECD test guidelines or other recognised international test methods (Article 13(3) of REACH). OECD TG 210 is the preferred guideline to fulfil this information requirement since it is the most sensitive of the standard fish tests available (ECHA Guidance R.7b, Sections R.7.8.2 and R.7.8.4.1). It covers several life stages of the fish and also examines the potential toxic effects caused by bioaccumulation. Observational endpoints include, among others, hatching success, survival and growth.

You intend to fulfil this standard information requirement with an existing OECD TG 215 study.

Furthermore, you claim that OECD GD 23 indicates that to assess the toxicity of difficult to test substances information from dietary bioaccumulation study may be used. You therefore intend to incorporate information from an existing OECD TG 305 study where no treatment-related effects on growth or mortality were observed after 12 days of dietary exposure at a dose of 94 ppm.

Studies according to OECD TG 215 are of insufficient duration to examine all the sensitive endpoints in the fish life-cycle (ECHA Guidance R.7b, Section R.7.8.4.1). In addition, studies according to OECD TG 215 inform only on growth, but they do not provide information on the other observational endpoints foreseen to be investigated in an OECD TG 210 study, as listed

above. Therefore, studies according to OECD TG 215 are not adequate to fulfil this standard information requirement.

You refer to advice in OECD GD 23 in using a bioaccumulation dietary study to support the assessment of fish toxicity. However your interpretation of the OECD GD 23 appears to be not correct as the GD does not foresee using a dietary bioaccumulation study to assess toxicity of difficult to test substances. Footnote 1 of Paragraph 38 of OECD GD 23 only indicates that dietary exposure may be useful for difficult to test substances but that no such test for toxicity yet exists.

In addition, bioaccumulation studies do not provide information on the effect endpoints investigated in an OECD TG 210 study as listed above. As given in paragraphs 51 and 112 of the OECD TG 305, a bioaccumulation study must be performed at doses below those causing toxic effects. According to the validity criteria mortality and/or other adverse effects must be below 10% at the end of the test (paragraph 113 of OECD TG 305). Therefore, absence of effects in a fish bioaccumulation study does not provide relevant information for this endpoint.

Due to the above, the studies you refer to in your comments cannot be used to fulfil this standard information requirement. The information provided in your comments is not sufficient to demonstrate that the risks of the Substance are adequately controlled.

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

Study design

The Substance is difficult to test due to the low water solubility, hydrophobicity, and adsorptive properties as explained above. OECD TG 210 specifies that for difficult to test substances, the OECD GD 23 is to be followed as explained above under request A.2.

4. Identification of degradation products (Annex IX, Section 9.2.3.)

Identification of degradation products is a standard information requirement in Annex IX to REACH.

You have sought to adapt this information requirement based on Annex IX, Section 9.2, Column 2.

You justified the adaptation by stating that the chemical safety assessment according to Annex I has not indicated a need to investigate further the degradation of the test substance.

As specified in Annex IX, section 9.2., Column 2, testing on degradation must be performed unless the Chemical Safety Assessment demonstrates that risks arising from the use of the Substance are controlled (as per Annex I, section 0.1).

In particular according to Annex I elements to be taken into account for that demonstration include:

- PBT/vPvB assessment including information on constituents present in concentration at or above 0.1% (w/w) and on relevant degradation products (ECHA Guidance R.11, Sections R.11.4 and R.11.3.2.1).

You specify that the Substance is not expected to cause acute or chronic toxicity to aquatic organisms in the aqueous environment and that the Substance is not readily biodegradable

but it is expected to be inherently biodegradable under environmental conditions and therefore further simulation testing would provide only little additional information.

However, you have not provided any information on the identity and PBT properties of the degradation products of the Substance and you consider only the PBT properties of the parent substance in your Chemical Safety Assessment (CSA) and in your justification for the adaptation.

Taking into account the above, without the information on relevant degradation products no definitive conclusion can be reached for the PBT/vPvB assessment. Therefore, ECHA concludes that your CSA does not demonstrated that the risks of the Substance are adequately controlled. Therefore, your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.2., Column 2.

Therefore, the information requirement is not fulfilled.

Study selection and design

You are advised to consult ECHA Guidance R.7b (Section R.7.9.4) which describes the appropriate and suitable test method for the determination of degradation products. You may obtain information on degradation/transformation products from the applicable simulation test OECD TG 309 "pathway part", OECD TG 308, OECD TG 307 or by some other measures such as enhanced screening level degradation test. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound. In addition, degradation half-life, log Kow and potential toxicity of the metabolites may be investigated.

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the transformation/degradation producst of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

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

Effects on soil micro-organisms is a standard information requirement in Annex IX to REACH.

You have provided an adaptation for this endpoint where you consider that, based on the lack of adverse effects to aquatic microorganisms in the available activated sludge respiration inhibition study, the Substance is not expected to cause adverse effects to soil microorganisms and hence effects on soil micro-organisms testing is not required.

In order to adapt this information requirement, an adaptation has to comply with specific rules for adaptation in accordance with column 2 of Annex IX, Sections 9.4 or 9.4.2. or with the general rules of Annex XI to REACH.

The reasons that you provided for the waiving of the standard information requirement do not form any adaptation option as foreseen in the legal text.

As the conditions for adapting this information requirement are not fulfilled - neither in accordance with column 2 of Annex IX, Sections 9.4 or 9.4.2. nor with the general rules of Annex XI to REACH – your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Appendix D: Reasons for the requests to comply with Annex X of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier at a tonnage abve 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to X to REACH.

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

A pre-natal developmental toxicity (PNDT) study in two species is a standard information requirement in Annex X to REACH.

You have provided a pre-natal developmental toxicity (according to OECD TG 414) conducted in the first species (rats).

For the information on a PNDT in a second species, you have adapted the information requirement by using weight of evidence with reference to Annex XI, Section 1.2.

In your justification for the weight of evidence adaptation the following independent sources of information (lines of evidence) are presented:

A.1. Summary information from toxicokinetic studies with the Substance and structural analogues, as follows:

- Toxicokinetic studies (oral and dermal) in rat (OECD TG 417; OECD TG 427; 2013) with the Substance
- Toxicokinetic studies in rat (1984) and rabbit (1987) with 2-isopropylnaphthalene (EC: 217-976-0; CAS: 2027-17-0)
- toxicokinetic study in rat (OECD TG 417; 2002) with 1-hexadecene and naphthalene (EC: 304-232-6; CAS: 94247-63-9)

A.2. Results from reproductive and developmental toxicity studies:

(i) screening for reproduction/developmental toxicity study in rat (according to OECD TG 421, GLP, 2012) with the Substance
(ii) two-generation reproductive toxicity study in rat (according to OECD 416, GLP, 2013) with the Substance
(iii) pre-natal developmental toxicity study in rats, oral-gavage (according to OECD TG 414, GLP, 2011) with the Substance
(iv) 2-generation reproductive toxicity study in mice via oral-gavage (no guideline, no GLP; 1977; KL 4) performed with source substance DIPN diisopropylnaphthalene (DIPN)
(v) pre-natal developmental toxicity study in rat, oral-gavage (EPA OPPTS 870.3700; GLP, 1999; KL 4), performed with source substance DIPN 2,6-diisopropylnaphthalene (DIPN; EC: 246-045-1)
(vi) pre-natal developmental toxicity study in rat, oral-gavage (OECD TG 414, GLP, 1993, KL 4), performed with source substance 1,2–di-isopropyl naphthalene EC: 254-052-6

A.3. Results from repeated dose toxicity studies:

(vii) 28-day repeated dose toxicity study in rats, via dermal route (equivalent to OECD TG 410, GLP; 1991), with the Substance

(viii) Sub-chronic (90-day) study in rats (equivalent OECD TG 411, GLP; 1994), performed with source substance MCP 917
(ix) 90-day dietary study in rat (key study, equivalent to OECD TG 408, GLP; 1991), performed with source substance MCP 917

Based on the presented lines of evidence you argue that the Substance is "*biologically inert and that species-specific differences are unlikely to provide further useful information to inform human health risk assessment*" and "*these substances are of a low order of toxicity, and the lack of bioavailability would be expected to be conserved across species, it is not foreseen that testing in a second species would further inform risk assessment.*"

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.

In accordance with the ECHA Guidance R.4.4, a WoE adaptation involves an assessment of the relative values/weights of different pieces of the available information which is defined by e.g. the reliability of the data, consistency of results/data, nature and severity of effects, and relevance of the information for the given regulatory endpoint. Subsequently, the lines of evidence should be integrated considering their relative values or weights in order to draw a conclusion. Adequate and reliable documentation shall be provided to describe your WoE approach, the assessment of relative weights of individual piece of information and the subsequent conclusions drawn.

In order to allow concluding on no prenatal developmental toxicity in two species for the Substance in a weight of evidence adaptation, the justification must cover the key elements (parameters) foreseen to be investigated in an OECD TG 414 study in two species. The key parameter(s) of this test guideline include, among others: external, skeletal and soft tissue alterations (variations and malformations).

ECHA has assessed to what extent the information submitted enables a conclusion of hazardous properties for prenatal developmental toxicity in a second sepcies and identified the following deficiencies:

1. Relevance of the information

First, with regard to the experimental data provided, only study (iv) provides information on a second species (mouse). However, it does not inform on external, skeletal and soft tissue alterations (variations and malformations) as foreseen to be investigated in OECD TG 414.

Further, the OECD TG 421, OECD TG 416, OECD TG 408, OECD TG 410 and OECD TG 411 studies as well as the OECD TG 417 and OECD TG 427 do not inform on external, skeletal and soft tissue alterations (variations and malformations) as foreseen to be investigated in OECD TG 414. Therefore, the provided information is not relevant for the endpoint.

Second, with regard to the toxicokinetic data, most of the studies provide information on one species (rat). You have provided only one source study in rabbit (publication, Honda, 1987; assigned reliability score 3 (not reliable). ECHA agrees with the reliability score of 3, assigned by you, because the documentation provided does not allow to assess the reliability of the study. Hence, it is not possible to compare the toxicokinetic between different species (rat

and rabbit). Therefore, your claim that *"species-specific differences are unlikely"* is not substantiated with relevant and reliable data on the two species.

Third, your claim that the Substance is "inert" is contradicted by its harmonized classification as skin sensitizer as well as by the reported effects in the repeated dose toxicity studies. Therefore, your claim is not substantiated with relevant and reliable data.

2. Reliability of the information

With regard to the information from analogue substances, used as part of WoE, read-across adaptation can be used to adapt the standard information requirement, provided that the criteria in Annex XI, Section 1.5. are fulfilled. However, as explained in the Appendix on general considerations, the reported read-across approach does not fulfil the criteria in Annex XI, Section 1.5. Therefore, studies (iv), (v), (vi), (viii) and (ix) cannot be used as part of weight of evidence adaptation according to Annex XI, Section 1.2.

In conclusion, none of the provided sources of information alone or together allows to conclude whether the Substance has or has not hazardous properties related to prenatal developmental toxicity in a second species. Therefore, your adaptation is rejected and the information requirement is not fulfilled.

Information on study design

The test in the first species was carried out by using a rodent species (rat). A PNDT study according to the test method OECD TG 414 must be performed in rabbit as preferred non-rodent species.

In your comments to the draft decision you state that *"Based on prior experience with developmental toxicity testing in rabbits, it is likely the rabbit will not be a suitable species for toxicity testing"*. You *"request that ECHA expand the decision to explicitly identify mouse as a potentially suitable second species [...]"*.

ECHA points out that according to the OECD TG 414 *"The preferred rodent species is the rat and the preferred non-rodent species is the rabbit. Justification should be provided if another species is used"*.

You did not provide any information on studies with rabbits or other scientific explanation why the rabbit is not suitable species for prenatal developmental toxicity testing of your Substance, as well as you did not provide a scientifically solid justification why you consider mouse as more suitable second species.

Therefore, ECHA considers that the PNDT study according to the test method OECD TG 414 must be performed in rabbit as preferred non-rodent species. You can deviate from this only by providing solid scientific substance-specific evidence (e.g. a tolerability and/or a range-finding study) that rabbits are not suitable for oral administration of your Substance. In this specific situation another species is acceptable when selection is scientifically justified.

Administration route

In your justification for the weight of evidence adaptation you suggest that dermal route is the most approriate route to test the Substance. However, the oral route is the most appropriate route of administration to investigate reproductive toxicity[8].

In your comments to the draft decision you dispute ECHA's request for oral route of administration. You argue that the text in the ECHA guidance[8] pointing out that "*for reproductive toxicity which focus on the detection of reproductive hazards, the oral route (gavage, in diet, or in drinking water) is the "default" route, except for gases*" is not in line with the OECD TG 414 guideline which indicates "*The test substance or vehicle is usually administered orally by intubation. If another route of administration is used, the tester should provide justification and reasoning for its selection, and appropriate modifications may be necessary*". You also consider that ECHA's interpretation that oral route is the most appropriate route for reproductive toxicity is inconsistent with that for the repeated dose toxicity at Annex VIII, Section 8.6.1 and Annex IX, Section 8.6.2. You refer to Annex IX Column 1, section 8.7.2. of Annex IX and X which refers to the "*most appropriate route [...] having regard to the likely route of human exposure*" highlighting the different wording of that provision in comparison with in column 2 for repeated dose toxicity. Based on the above you request ECHA to "*[...] explicitly indicate dermal exposure would also be an acceptable route of exposure for rabbit*". You provided the following justification: "*Given the intended uses of this substance in lubricants, the most likely route of human exposure is dermal*".

ECHA notes that according to the test method (OECD TG 414) and the ECHA guidance[8] alike, the oral route is the most appropriate route of administration, unless a scientific justification for other route (inhalation or dermal) is provided. Regarding your reference to information requirements for repeated dose toxicity under REACH, the criteria for route of administration are different, and this is because the hazard classes for specific target organ toxicity (repeated dose toxicity) depend on dose levels but for reproductive toxicity on intrinsic properties of the Substance. According to the the ECHA guidance[9] for reproductive toxicity "*Testing via dermal route might be necessary under specific circumstances, for example for substances with high dermal penetration and indications for a specific toxicity following dermal absorption*". According to the toxicokinetic data reported in your technical dossier and in the Chemical Safety Report, your Substance does not have a significant rate of absorption through the skin in rats (see under Annex C.1).

As also cited by you in your comments, for cases when the oral route is not considered suitable, the registrants have to provide a reasoning for selecting a different route of administration and "*appropriate modifications may be necessary*". According to the OECD TG 414 "*Such adaptation is acceptable, when convincing scientific evidence suggests that the adaptation will lead to a more informative test. In such a case, this scientific evidence should be carefully documented in the study report*".

ECHA notes that you did not provide any scientific evidence and/or reasoning why you consider dermal exposure "*an acceptable route of exposure for rabbit*" but not the oral route.

It is necessary for the purposes of the REACH regulation that intrinsic properties of the Substance are investigated in order to allow the determination of appropriate hazard classification. To achieve this, it is necessary to aim to the highest possible internal exposure of the Substance for reproductive toxicity and this is usually achieved for solids and liquids by using oral administration unless proven otherwise.

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

Hence, the study must be performed with oral administration of the Substance.

2. Long-term toxicity to terrestrial invertebrates (Annex X, Section 9.4.4.)

Long-term toxicity to terrestrial invertebrates is a standard information requirement in Annex X to REACH.

You have not provided any study on Long-term toxicity to terrestrial invertebrates, but you have provided a key study with the Substance on short-term toxicity to terrestrial invertebrates according to OECD TG 207.

For substances that have a high potential to adsorb to soil or that are highly persistent, the effect of long-term exposures must be estimated for the hazard assessment (ECHA Guidance R.7c, Table R.7.11-2, and Column 2 of section 9.4 of Annex IX).

Based on the information you provided, the Substance is adsorptive (Log Koc > 6, Log Kow > 10) and potentially P/vP (19.3% degradation in 28 days, OECD TG 301F).

You have provided a key study for short-term toxicity on terrestrial invertebrates. You have not provided any long-term toxicity studies on terrestrial invertebrates.

As indicated above, due to the properties of the Substance, short-term terrestrial toxicity studies are not sufficient and long-term terrestrial toxicity studies are necessary to assess the hazards.

Therefore, the information requirement is not fulfilled.

3. Long-term toxicity to plants (Annex X, Section 9.4.6.)

Long-term toxicity to plants is a standard information requirement in Annex X to REACH.

You have provided an adaptation for this endpoint where you consider that based on the available information (i.e. read-across data for short-term toxicity to terrestrial plants endpoint, lack of acute and chronic adverse effects in aquatic organisms), the Substance is not expected to pose a chronic hazard and hence long-term terrestrial toxicity to plants testing is not required.

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

As specified in Annex X, Section 9.4.6., Column 2, long-term toxicity on plants must be performed unless the Chemical Safety Assessment demonstrates that risks towards the terrestrial compartment arising from the use of the Substance are controlled (as per Annex I, section 0.1). The justification must be documented in the Chemical Safety Assessment.

In particular, the Chemical Safety Assessment must take into account all relevant hazard information from your registration dossier to support that long-term toxicity testing is not required.

The effects on terrestrial organisms must be addressed for different taxonomic groups: invertebrates, soil micro-organisms and terrestrial plants. For substances that have a high potential to adsorb to soil or that are very persistent, the effect of long-term exposures must

be estimated for the hazard assessment (ECHA Guidance R.7c, Table R.7.11-2, and Column 2 of section 9.4 of Annex IX).

Based on the information you provided, the Substance is adsorptive (Log Koc > 6, Log Kow > 10) and potentially P/vP (19.3% degradation in 28 days, OECD TG 301F).

You have provided a short-term toxicity study on terrestrial invertebrates. You have not provided a soil micro-organisms study. You have provided a study on short-term toxicity to plants according to OECD TG 208, in which three species were tested, *i.e. Triticum aestivum* (monocotyledonous species), *Phaseolus aureus* and *Brassica campestris var. chinensis* (dicotyledonous species), conducted on the analogue substance Naphthalene, (1-methylnonadecyl)- (CAS: 135585-40-9).

As indicated above, due to the properties of the Substance, long-term terrestrial toxicity studies are necessary to assess the hazards.

You have not provided any long-term terrestrial toxicity studies, and specifically only short-term toxicity study on plants. In addition, this short-term study has been conducted with the analogue substance Naphthalene, (1-methylnonadecyl)- (CAS: 135585-40-9). Due to the same deficiencies of your read-across approach with regards to the hypothesis as already described in section C.2 above (point *i) Read-across hypothesis only based on structural similarity)*, you have not established that the terrestrial property of the Substance can be predicted from data on this analogue substance and your grouping and read-across approach is rejected.

Finally, in your justification referring to lack of chronic and acute effects to aquatic organisms, you do not explain how the aquatic data can be used to adapt this standard information requirement. Furthermore, as specified in request C.3, there is currently no adequate information to conclude on the aquatic hazards of the Substance and new aquatic toxicity data is currently requested (requests A.1, C.2 and C.3).

Therefore, your dossier currently does not include adequate information to characterise the hazardous property of the Substance to terrestrial organisms.

In conclusion, in absence of all this information, your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.4.6., Column 2.

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

Test design

OECD TG 208 with six species or ISO 22030 is the preferred guideline to fulfil this information requirement. OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline.

Appendix E: Procedural history

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

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

The compliance check was initiated on 7 May 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

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

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

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

Appendix F: Observations and technical guidance

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

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

3. Test guidelines, GLP requirements and reporting

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

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

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

4. Test material

   Selection of the test material(s) for UVCB substances

   While selecting the test material you must take into account the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity. Any constituents that have harmonised classification and labelling according to the CLP Regulation (Regulation (EC) No 1272/2008) must be identified and quantified using the appropriate analytical methods.

   The OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 11 [ENV/MC/CHEM(98)16] requires a careful identification of the test material and description of its characteristics. In addition, the Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a* [...] *UVCB* [...] *sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*".

   In order to meet this requirement, all the constituents of the test material used for each test must be identified as far as possible.

   Technical Reporting of the test material for UVCB substances

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

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

Technical instructions are available in the manual "How to prepare registration and PPORD dossiers" on the ECHA website (https://echa.europa.eu/manuals).

5. Testing strategy for the terrestrial toxicity testing

You are advised to consult ECHA Guidance R.7c, (Section R.7.11.6) which describes the Integrated Testing Strategy for toxicity testing on terrestrial organisms.

6. List of references of the ECHA Guidance and other guidance/ reference documents[10]

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

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

ECHA Read-across assessment framework (RAAF, March 2017)[11]

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

[10] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[11] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

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

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

OECD Guidance documents[12]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.
Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

[12] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

Registrant Name	Registration number	(Highest) Data requirements to be fufilled
[redacted]	[redacted]	[redacted]

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