~~Confidential~~

Helsinki, 13 April 2022

Addressees
Registrant(s) of JS_701-339-3 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
22/04/2021

Registered substance subject to this decision ("the Substance")
Substance name: 1,2-Benzenedicarboxylic acid, benzyl isononyl alkyl esters
EC number: 701-339-3
CAS number: NS

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 ***21 October 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. *Skin sensitisation (Annex VII, Section 8.3.):*

   i. in vitro/in chemico skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

   ii. Only if the *in vitro*/*in chemico* test methods specified under point 1.i. are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, in vivo skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429)

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

3. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2)

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

5. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310) on relevant constituent(s)/fraction(s) of the Substance

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 the test performed to cover the information requirement of 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 also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

4. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s): Soil simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

5. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s) then: Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

6. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s) then: Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)

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

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

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

3. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s): Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12°C on relevant constituent(s)/fraction(s) of the Substance. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s) then: Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C on relevant constituent(s)/fraction(s) of the Substance. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

5. If the study requested under A.5. shows the Substance includes non-readily biodegradable constituent(s)/fraction(s) then: Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

6. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220)

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

8. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column

2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

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 IX 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, VIII, IX and X to REACH, for registration at above 1000 tpa.

For certain endpoints, ECHA requests the same study at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted.

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".

The studies relating to biodegradation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

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 your read-across approach under Annex XI, Section 1.5.**

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

- Skin Sensitisation (Annex VII, Section 8.3.)
- 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.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

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

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[2,3].

A. Predictions for toxicological properties

You have not provided a read-across justification document in your CSR.

You read-across between the structurally similar substances,

- Di(isonyl) phthalate; bis(7-methyloctyl) phthalate (DINP), EC No. 271-090-9 (CAS No. 68515-48-0)
- 1,2-benzenedicarboxylic acid, butyl phenylmethyl ester (BBP), EC No. 201-622-7 / CAS No. 85-68-7)
- Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate (S278), EC No. 240-920-1 (CAS No. 16883-83-3)

as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties: *"No genotoxicity data are available on S261a, but in vivo and in vitro studies on structurally related phthalates including DINP, BBP and S278 provide reassurance that genotoxicity is unlikely to be an issue.".*

ECHA understands that you predict the properties of the Substance using a read-across

[2] 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)

[3] 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

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:

a) *Absence of read-across documentation*

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies) (ECHA Guidance R.6.2.6.1).

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

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

b) *Read-across hypothesis*

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 recognition of the structural similarities and differences between the substances (ECHA Guidance R.6.). 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 properties. You have not provided a well-founded hypothesis to establish a reliable prediction for toxicological properties, based on recognition of the structural similarities and differences between the source substance(s) and your Substance.

B. Predictions for ecotoxicological properties

i. Aquatic toxicity

You have not provided a read-across justification document but you have provided the following reasoning for the prediction of aquatic toxicity: the target substance and source substance are expected to have similar properties as a result of structural similarity.

You read-across between the structurally similar substances, Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate, EC No. 240-920-1 (CAS No. 16883-83-3) as source substance and the Substance as target substance.

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 prediction of aquatic toxicity:

a) The issues a) and b) identified in Section A ('Predictions for toxicological properties') apply to your prediction of ready biodegradation.

ii. Ready biodegradability

You have provided the following reasoning for the prediction of ready biodegradability: the target substance and source substances are expected to have similar properties as a result of structural similarity.

You read-across between the following structurally similar substances:
- bis(2-ethylhexyl) phthalate, EC No. 204-211-0 (CAS No. 117-81-7)
- 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich, EC No. 271-090-9 (CAS No. 68515-48-0)
- 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich, EC No. 271-091-4 (CAS No. 68515-49-1)

as source substances and the Substance as target substance.

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 substances.

ECHA notes the following shortcomings with regards to prediction of ready biodegradability:

a) The issues a) and b). identified in Section A ('Predictions for toxicological properties') apply to your prediction of ready biodegradation.

C. Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:
- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3);
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

Specific reasons why the studies on the source substances do not meet these criteria are explained further below under the applicable information requirement sections A.1, A.2, A.4, A.5, B.1 and B.2. Therefore, no reliable predictions can be made for these information requirements.

D. 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 substances. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

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

1. Skin sensitisation

Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Under Section 8.3., Column 1, the registrants must submit information allowing (1) A) a conclusion whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and (2) risk assessment, where required.

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. a non-guideline Guinea Pig skin sensitisation test with the analogue BBP ([redacted], 1980);
ii. a non-guideline Mouse ear swelling test with the analogue BBP (AKR mouse; [redacted], 1980);
iii. a non-guideline report with human data with the analogue BBP ([redacted], 1980);
iv. a non-guideline Mouse ear swelling test with the analogue BBP (balb/c mouse; [redacted], 1980);

We have assessed this information and identified the following issues:

A. Assessment whether the Substance causes skin sensitisation

a. Read-across rejection

As explained in the Appendix on Reasons common to several requests your read-across adaptation under Annex XI, Section 1.5. is rejected for the studies (i) to (iv).

Therefore studies (i) to (iv) cannot be taken into account in the assessment of whether the Substance causes skin sensitisation.

b. Adequacy of studies on the source substance(s)

As explained in the Appendix on Reasons common to several request, 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 OECD TG 406. Therefore, the following specifications must be met:

- Dose level selection rationale
- The induction concentration should be the highest causing mild-to-moderate irritationto the skin and the challenge dose should be the highest non-irritation concentration.
- Appropriate number of animals: minimum of 10 animals in test group and 5 animals in control group, in case of negative results 20 animals in test group and 10 animals in control group highly recommended.

In the provided studies i, ii and iv:

- No dose level selection rationale was provided
- No information was provided whether the concentration used for induction did cause mild-to-moderate irritation and whether the challenge concentration was the highest non-irritating concentration.
- Only 4 or 5 animals were used in the studies.

Therefore, the studies (i, ii and iv) do not allow to make a conclusion whether the Substance causes skin sensitisation

c. Adequacy of the study for hazard identification

As explained in the Appendix on Reasons common to several request, under Annex XI, Section 1.5., the results to be read across must be adequate for the purpose of classification and labelling and/or risk assessment.

The study (iii) seem to have been conducted on humans for the purpose of risk assessment and with the objective of identification of safe levels for specific intended uses.

Whilst the study (iii) seem to have been designed to establish safe levels for specific intended uses, they do not investigate the intrinsic properties of the Substance as required for the purpose of hazard identification. In particular, the dose levels used in these studies are far lower (dose approximately 34 µg/cm$^{2)}$ than the doses expected to be used for hazard identification purposes. Therefore, the study does not meet the information requirements and does not allow to make a conclusion whether the Substance causes skin sensitisation.

Based on the above, no conclusion can be made whether the Substance causes skin sensitisation.

B. Assessment whether the Substance can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

No assessment of potency

To be considered compliant and enable concluding whether the Substance causes skin sensitisation, in case the substance is considered to cause skin sensitisation the information provided must allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section A above), this condition cannot be assessed.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you acknowledge that the read-across approach has been rejected by ECHA due to the shortcomings identified above. You specify that you agree to perform the requested study.

Study design

To fulfil the information requirement for the Substance for skin sensitisation, *in vitro/in chemico* studies (OECD TG 442C, OECD TG 442D and EU Method B.71/OECD TG 442E) are considered suitable. In case *in vitro/in chemico* methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (EU Method B.42/OEDC TG 429) is considered as the appropriate study.

2. 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.).

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. a study similar to OECD TG 471 with the analogue S278 ([redacted], 1982);
ii. a study according to OECD TG 471 with the analogue DINP (McKee, 2000);
iii. a study similar to OECD TG 471 with the analogue BBP ([redacted], 1997);
iv. a study similar to OECD TG 471 with the analogue BBP ([redacted], 1976).

We have assessed this information and identified the following issues:

A. For the reasons explained in the Appendix of reasons common to several requests, the read-across adaptation is rejected

B. Adequacy of studies on the source substance(s)

As explained in the Appendix on Reasons common to several requests, 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 OECD TG 471. Therefore, the following specification must be met:

- The test must 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)

The reported data for the studies you have provided did not include the required fifth strain, *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

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

Therefore, the information requirement is not fulfilled.

In the comments to the draft decision, you acknowledge that the read-across approach has been rejected by ECHA due to the identified above. You specify that you agree to perform the requested study.

Study design

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

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.

You have provided the following information:

i. a short-term toxicity study on aquatic invertebrates according to APHA, 1975 on the

Substance ([redacted], 1979);

ii. an adaptation under Annex XI, Section 1.3. ('QSAR') for short-term toxicity on aquatic invertebrates. In support of your adaptation you provided a predicted 48h-EC50 from ECOSAR.

You have provided no information on long-term toxicity on aquatic invertebrates for the Substance.

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 do 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).
>
> You have provided an estimation of the saturation concentration of the Substance in water predicted using WSKOWWIN (EPISuite). The predicted water solubility is reported as 0.00979 mg/L. You also provided information on structurally similar substances (DEHP with EC number 204-211-0 and DiNP with EC number 271-090-9) which further support that the Substance has low water solubility.
>
> This information indicates that the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must therefore be provided.

On this basis, the information requirement is not fulfilled.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix C.1.

In the comments to the draft decision, you acknowledge that the long-term toxicity testing on aquatic invertebrates must be considered if the substance is poorly water soluble as part of the standard information requirements for a substance registered for 1 tonne or more per year. You specify that you agree to perform the requested study in conjunction with the OECD GD 23.

4. Growth inhibition study aquatic plants

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

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. a study according to an US EPA procedure (1971) on the analogue substance Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate, EC No. 240-920-1 (CAS No. 16883-83-3).

We have assessed this information and identified the following issues:

A. For the reasons explained in the Appendix of reasons common to several requests, your read-across adaptation is rejected.

B. The identity of the test material used in the source study is unclear.

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; ECHA Guidance 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 study i. above, you have identified the test material as substance "*Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate, EC No. 240-920-1 (CAS No. 16883-83-3)*", without further information, including composition.

In the absence of composition information on the test material, the identity of the test material and its impurities cannot be assessed, and you have not demonstrated that the test material is representative for the substance that was intended to be tested. Therefore, the information provided is rejected.

C. *The source study on the selected analogue substance is not reliable*

As explained in the Appendix on Reasons common to several requests, 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 OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test. Therefore, the following specification must be met:

Key parameter to be measured

- the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated. Growth must be expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period;

  For study i. above, you report an effect value (96h-EC50) based on cell number. You have not provided any information on inhibition of growth expressed based on growth rate. Therefore, this study does not provide an adequate coverage of the key parameter foreseen to be investigated in OECD TG 201.

Technical specifications impacting the sensitivity/reliability of the test

- for *Pseudokirchneriella subcapitata* the initial cell density is 5 x 10^3-10^4 cells/mL.

  For study i. above, you report that the initial cell concentration was c.a. 2 x 10^4 cells/mL. Therefore, the initial biomass in the test was too high which may have affected the sensitivity of the test.

Characterisation of exposure

- the concentrations of the test material are measured at least at the beginning and end of the test:

1) at the highest, and
2) at the lowest test concentration, and
3) at a concentration around the expected EC_{50}.

For volatile, unstable or strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required.

- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

For study i. above, you specify that no analytical monitoring of exposure concentration was conducted. Therefore, you have not demonstrated that exposure was satisfactorily maintained during the test and that effect values can be reliably expressed based on nominal concentrations.

Reporting of the methodology and results

- the test conditions are reported (*e.g.*, composition of the test medium);
- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
  microscopic observation performed to verify

For study i. you have not provided the information listed above. In the absence of this information, ECHA cannot verify that the study met the specifications of OECD TG 201, that the validity criteria of the study were met and that the interpretation of the study results are adequate.

Therefore, study i. does not meet the requirements of OECD TG 201.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the low water solubility (estimated to be 0.0098 mg/L using WSKOWWIN) and adsorptive properties (log Kow estimated to be 6.66 based KOWWIN v1.67). 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 multi-constituents/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.

In the comments to the draft decision, you acknowledge that the read-across approach has been rejected by ECHA due to the shortcomings identified above. You specify that you agree to perform the requested study in conjunction with the OECD GD 23.

5. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. a study similar to OECD TG 301B on bis(2-ethylhexyl) phthalate, EC No. 204-211-0 (CAS No. 117-81-7) (Saeger & Tucker, 1976);
ii. a study similar to OECD TG 301B ([redacted], 1984) on:
   - bis(2-ethylhexyl) phthalate, EC No. 204-211-0 (CAS No. 117-81-7),
   - 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich, EC No. 271-090-9 (CAS No. 68515-48-0), and
   - 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich, EC No. 271-091-4 (CAS No. 68515-49-1);
iii. a study similar to EPA OTS 795.45 which involves a modified SCAS procedure (similar to OECD 302A) following by a 19d DOC Die-away test (similar to OEDC TG 301A) (O'Grady *et al*., 1985) on:
   - bis(2-ethylhexyl) phthalate, EC No. 204-211-0 (CAS No. 117-81-7),
   - 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich, EC No. 271-090-9 (CAS No. 68515-48-0), and
   - 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich, EC No. 271-091-4 (CAS No. 68515-49-1).

We have assessed this information and identified the following issues:

A. For the reasons explained in the Appendix of reasons common to several requests, your read-across adaptation is rejected

B. The identity of the test materials used in the source studies is unclear.

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; ECHA Guidance 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 all the above studies, you have identified the test material as "commercial grade" of the corresponding substances without further information, including composition.

In the absence of composition information on the test materials, the identity of these test materials and their impurities cannot be assessed, and you have not demonstrated that the test materials are representative for the substances that were intended to be tested. Therefore, the information provided is rejected.

C. *The source studies on the selected analogue substances are not reliable*

As explained in the Appendix on Reasons common to several requests, 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 OECD TG 301 or 310. Therefore, the following specification must be met:

Validity criteria

- The test material is the sole source of added organic carbon.

  For study i., you specify that "*50 mg of yeast extract*" in addition to the test material.

  For study ii., you specify that "*Acetone was used as a solvent for this test*". You have not specified the concentration of added acetone in the test vessels.

  For study iii., you specify that "*Dispersion was achieved using acetone (<200 µl)*".

  Therefore, the test material was not the sole source of added carbon in the test vessels in any of the provided studies. With regard studies ii and iii., Annex III of OECD TG 301, specify that an emulsifier or solvent may be used but it must not be biodegraded. Also a blank run containing the auxiliary substance should be performed. Acetone is known to be a biodegradable solvent and you have not provided the results of a blank run containing the auxiliary substance. Therefore, none of these studies meet the validity criteria of OECD TG 301.

Technical specifications impacting the sensitivity/reliability of the test

- The inoculum is not be pre-adapted to the test material.

  For study i., you have not specified whether or not the inoculum was pre-adapted to the test material.

  For study ii., you state that "*The inoculum was adapted to phthalic acid esters for 2 weeks prior to the start of the test, which is contrary to OECD guidelines*"

  For study iii., you state that "*The acclimated mix from the SCAS test was used as the inoculum in the die-away test*".

Therefore, while this cannot be verified for study i., it can be concluded that the inoculum in study ii. and iii. were acclimated to the test materials leading to conditions that are too favourable compared to a standard ready biodegradability test. As a result, these study do not meet the requirements of OECD TG 301.

Reporting of the methodology and results

- The source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
- The results of measurements at each sampling point in each replicate is reported in a tabular form;

For study i. to iii., you have not specified the inoculum concentration (in cells/mL). Also you have not provided adequate reporting of the study result and therefore an independent assessment of the interpretation of the results of these studies cannot be conducted.

Based on the above, none of these studies meet the requirements of OECD TG 301.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you acknowledge that the read-across approach has been rejected by ECHA due to the shortcomings identified above. You agree to generate further information on ready biodegradability for the Substance.

Study design

Section 3 of the revised introduction to the OECD Guidelines For Testing Of Chemicals[4] states that ready biodegradability tests must be designed so that positive results are unequivocal. It further states that these tests are intended for pure substances but may also be relevant, on a case-by-case basis, to mixtures of structurally similar chemicals (i.e. where constituents are expected to show similar degradation kinetics). However, the results of a positive ready biodegradability test on substances containing different types of constituents (i.e. UVCBs or multi-constituent substances) is not, on its own, adequate to conclude unambiguously whether all constituents are readlily biodegradable.

In Section 1.1. of your dossier you describe the Substance as a mono-constituent substance. In Section 1.2, you describe the manufacturing process as follow: "[redacted]". In section 1.4., you however state that the Substance is "*considered a UVCB substance as the aliphatic alcohol charge for the reaction consists of ~ [redacted]% of a highly isomeric C9 alcohol (commonly to referred to as [redacted]); the remaining aliphatic alcohol charge consists of ~[redacted] % [redacted] and ~[redacted] % [redacted] (n-C8)*". This information indicate that the Substance includes constituent with varying C-chain length as well as varying degree of branching of the C9 fraction. Therefore, the Substance is a complex substance and contains constituents with significant structural differences. For such substance, an investigation of the degradability of carefully selected individual components is required.

In your comments on the draft decision, you specify that, as "*the constituents [redacted] and [redacted] are both considered impurities and the substance is [redacted]% 1,2-Benzenedicarboxylic acid,*

[4] https://www.oecd-ilibrary.org/docserver/9789264030213-en.pdf?expires=1621080812&id=id&accname=guest&checksum=0F3AA0D82468F14859734A13657CB74F

benzyl isononyl alkyl esters", the Substance is considered to be a mono-constituent and not a UVCB. You specify that you will "*update Section 1.4 of the dossier to remove this ambiguity for the future*".

ECHA notes that under Section 1.4. of your registration dossier you report a GC chromatograph for the Substance. Based on this information, 15 peaks corresponding to the isomeric C9 fraction were identified. From that information, it can be concluded that the fraction corresponding to 1,2-Benzenedicarboxylic acid, benzyl isononyl alkyl esters includes different isomeric structures. From the information provided in your dossier it is unlikely that any of these branched isomeric structures amounts individually for over 80% of the Substance. Furthermore, the isomeric composition may vary based on the nature of the aliphatic alcohol used as starting material to the reaction to form phthalate esters. Therefore, the Substance cannot be considered as a mono-constituent substance but should be regarded as a UVCB substance. ECHA therefore maintains that the Substance is a complex substance and that due consideration of the composition of the Substance will be required when selecting the test material for the requested study. If you consider that the analytical information currently included in your registration dossier does not reflect the nature of the Substance, you should update your registration dossier without undue delay and revisit the compositional information and the naming of the Substance accordingly. ECHA will assess any update of your registration dossier after the expiry of the deadline set in this decision.

For the generation of new information on ready biodegradability, you must consider the level of information required for the purposes of classification and labelling and, if applicable, the PBT/vPvB assessment and the exposure assessment/risk characterisation. In order to conclude on ready biodegradability for the constituents of the Substance, you may have to conduct more than one study using selected constituent(s) and/or fraction(s). If you choose to test one (or more) fraction(s) of the Substance, you must provide a justification that the constituents of the chosen fraction(s) are similar enough so that similar degradation kinetics can be assumed. If you decide to conduct a single study in order to prove that all constituents of the Substance are readily biodegradable, you must provide a justification that the selected constituent/fraction can be considered a reasonable worst-case for the Substance as a whole. In all cases, you must provide a justification for the selection of constituent(s) and/or fraction(s) to be tested. Such justification must take due account of difference in degradation kinetics of the constituent(s) and/or fraction(s) of the Substance that may be expected as a result of, for instance, differences in chemical structures and physico-chemical properties of the constituent(s) and/or fraction(s) of the Substance. For this purpose, you may consider using the tools and approaches described in ECHA Guidance R.7.9.1. and R.11.4.2.2.2. However, it should be noted that the results of biodegradation (Q)SAR models are not considered sufficient on their own to conclude on not P/vP in the context of the PBT/vPvB assessment (ECHA Guidance R.11.4.1.1.4.) or rapid degradation in the context of classification and labelling (ECHA Guidance R.7.9.5.1.).

In your comments on the draft decision, you specify that you will conduct "*a OECD 301 or OECD 310 study appropriate to the physico-chemical properties* [of the Substance]". You consider that, as the Substance is considered poorly soluble, "*an Extended Ready Biodegradation Study may be considered as detailed in the R.11 ECHA guidance*".

ECHA acknowledges that positive results from enhanced screening tests may be used together with other supporting information to conclude that a substance is not P/vP. Acceptable enhancements are limited to extension of the duration of the test (but it should be no longer than 60 days) or an increased in the test vessel size (ECHA Guidance R.7.9.4.1.).

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.).

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. A study according to "*Analysis of data from in vitro cytogenetics assays, UKEMS Sub-committee on guidelines for mutagenicity testing*" with the analogue DINP (McKee, 2000);
ii. A study similar to EPA OPPTS 870.5375 ('In vitro Mammalian Chromosome Aberration Test') with the analogue BBP ([redacted], 1997).
iii. A study similar to EPA OPPTS 870.5385 ('In Vivo Mammalian Cytogenetics Tests: Bone Marrow Chromosomal Analysis') with the analogue BBP ([redacted], 1997);
iv. A study according to OECD TG 474 with the analogue DINP (McKee, 2000);
v. A non-guideline study with the analogue BBP ([redacted], 1997).

We have assessed this information and identified the following issues:

A. For the reasons explained in the Appendix of reasons common to several requests, your read-across adaptation is rejected

B. Adequacy of studies on the source substance(s)

As explained in the Appendix on Reasons common to several requests, 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 OECD TG 473 or 487. Therefore, the following specifications must be met:

- at least 300 well-spread metaphases must be scored per concentration.

The reported data for the studies you have provided did not include the scoring of at least 300 metaphases per concentration. (studies i. and ii.)

The information provided does not cover key parameter required by OECD TG 473/487.

For the data from an *in vivo* cytogenicity test to be considered adequate, the *in vivo* study you submitted has to meet the requirements of OECD TG 474/475, and the specifications/conditions of this test guideline include:

a) At least 200 metaphases must be analysed for each animal for structural chromosomal aberrations including and excluding gaps.
b) The highest dose studied must be the maximum tolerated dose (MTD), i.e. the highest dose that is tolerated without evidence of toxicity (e.g. body weight depression or hematopoietic system cytotoxicity, but not death or evidence of pain, suffering or distress necessitating humane euthanasia). The highest dose can also be a dose that produces toxicity in the bone marrow (e.g. a reduction in the proportion of immature erythrocytes among total erythrocytes in the bone marrow or peripheral blood).

The reported data for the *in vivo* studies you submitted did not include:

a) the analysis of the adequate number of cells (study iii.)
b) a maximum studied dose that is a MTD or induces toxicity (study iv.)
c) a demonstration that the systemic or target tissue (bone marrow) exposure to the Substance or its metabolites. (study v.)

The information provided does not cover specifications/conditions required by OECD TG 474/475.

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) of the corresponding OECD TG.

On this basis, the information requirement is not fulfilled.

In your comments, you acknowledge this read-across approach has been rejected by ECHA due to the shortcomings identified above. You specify that you agree to perform a study according to OECD TG 487.

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.

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.

i. Triggering of the study

Your dossier contains an adaptation for an *in vitro* gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or *in vitro* micronucleus study.

The information for the *in vitro* gene mutation study in bacteria and for the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study provided in the dossier are rejected for the reasons provided in sections A2 and B1.

The result of the requests for information in sections A2 and B1 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.

ii. Assessment of information provided

You have adapted this information requirement under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:

i. A study similar to OECD TG 476 with the analogue BBP ([redacted], 1977);
ii. A study similar to EPA OPPTS 870.5300 ('In vitro Mammalian Cell Gene Mutation Test') with the analogue BBP ([redacted], 1997);
iii. A study similar to EPA OPPTS 870.5900 ('In vitro Sister Chromatid Exchange Assay') with the analogue BBP ([redacted], 1997);

iv. A study similar to EPA OPPTS 870.5915 ('In Vivo Sister Chromatid Exchange Assay') with the analogue BBP ([redacted], 1997);
v. A study similar to EPA OPPTS 870.5450 ('Rodent Dominant Lethal Assay') with the analogue BBP ([redacted], 1997).

We have assessed this information and identified the following issues:

A. For the reasons explained in the Appendix of reasons common to several requests, the read-across adaptation is rejected

B. Adequacy of studies on the source substance(s)

As explained in the Appendix on Reasons common to several requests, 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 OECD TG 476 or 490.

The information provided (studies ii. and iii.) is not an *in vitro gene mutation study in mammalian cells*. The information provided does not cover the key parameter(s) required by the OECD TG 476 or 490.

Therefore, the information requirement is not fulfilled.

Under Section 8.4.3., Column 2, Annex VIII to REACH, the study may be omitted if adequate data from a reliable *in vivo* mammalian gene mutation test are available. ECHA Guidance[5] clarifies that the *in vivo* study must be a Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay (TGR), performed according to OECD TG 488. This test investigates gene mutations using reporter genes.

You have provided two studies (iv. and v.) that are not performed according to OECD TG 488.

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) of the corresponding OECD TG.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

On this basis, the information requirement is not fulfilled.

In your comments, you acknowledge this read-across approach has been rejected by ECHA due to the shortcomings identified above. You specify that you agree to perform a study according to OECD TG 490.
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.

3. Long-term toxicity testing on fish

[5] ECHA Guidance R.7a, R.7.7.6.3, p. 568

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.

You have provided the following information:

i. a short-term toxicity study on fish according to US EPA 660/3-75-009 on the Substance ([redacted], 1980);
ii. an adaptation under Annex XI, Section 1.5. ('Grouping of substances and read-across'). In support of your adaptation, you have provided the following information:
    a. a study similar to OECD TG 203 on *Pimephales promelas* with the analogue substance Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate, EC No. 240-920-1 (CAS No. 16883-83-3), and
    b. a study similar to OECD TG 203 on *Oncorhynchus mykiss* with the analogue substance Benzyl 2,2,4-trimethyl-1-[(2-methylpropanoyl)oxy]pentan-3-yl benzene-1,2-dicarboxylate, EC No. 240-920-1 (CAS No. 16883-83-3).

You have provided no information on long-term toxicity on fish for the Substance.

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 do 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.

On this basis, the information requirement is not fulfilled.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section C.2.

In the comments to the draft decision, you acknowledge that the long-term toxicity testing on fish must be considered if the substance is poorly water soluble as part of the standard information requirements for a substance registered for 10 tonnes or more per year. You specify that you agree to perform the requested study in conjunction with the OECD GD 23.

4. Soil simulation testing

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301B);

- it is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5);
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier provides the following:

- The Substance has a high potential to partition to lipid storage (predicted Log K_{ow} ranging of 6.66 to 17.2 based on KOWWIN v 1.67). Furthermore, you report that at least some constituents of the Substances are predicted to be B using the BCFBAF (v 3.00).

Furthermore, the information in your dossier is currently incomplete and therefore:

- It is not possible to conclude on ready biodegradability (see Appendix A.5. of this decision)
- It is not possible to conclude on the toxicity of the Substance (see Appendices C.1-2 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (estimated to be 0.0098 mg/L using WSKOWWIN), high partition coefficient (log Kow estimated to be 6.66 based KOWWIN v1.67) and high adsorption coefficient (log K_{oc} predicted to range from 4.3 using the MCI method and 4.0 using the log Kow method), indicating high potential to adsorb to soil.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix C.3.

In your comments, you acknowledge that this information may be required if the results of the ready biodegradability study requested under Appendix A.5 indicates that there is still concern for persistence in the environment for the Substance. If this is the case you specify that you agree to continue the testing strategy as laid out in the R.11 ECHA guidance and perform simulation studies with identification of the transformation products.

5. Sediment simulation testing

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

As already explained in Appendix B.3., the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (estimated to be 0.0098 mg/L using WSKOWWIN), high partition coefficient (log Kow estimated to be 6.66 based KOWWIN v1.67) and high adsorption coefficient (log K_{oc} predicted to range from 4.3 using the MCI method and 4.0 using the log Kow method), indicating high potential to adsorb to sediment.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Appendix C.4.

The comments on the draft decision presented in Appendix B.4. equally applies to this information requirement.

6. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

As already explained under Section B.3., the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

The examination of the available information or adaptations, as well as further information on the selection of the approach to generate this information are addressed in Appendix C.5.

The comments on the draft decision presented in Appendix B.4. equally applies to this information requirement.

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

1. 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.).

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you did not provide any further justification.

We have assessed this information and identified the following issue:

> Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).
>
> Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 211 specifies that for difficult to test substances 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 A.4.

In your comments to the draft decision, you refer to the comments already presented in Appendix A.3. and provided no further comments on this request.

2. 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.).

You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you did not provide any further justification.

We have assessed this information and identified the following issue:

> Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).
>
> Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

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.).

OECD TG 210 specifies that for difficult to test substances 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 A.4.

In your comments to the draft decision, you refer to the comments already presented in Appendix B.3. and provided no further comments on this request.

3. Soil simulation testing

Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

The Substance has low water solubility (estimated to be 0.0098 mg/L using WSKOWWIN), high partition coefficient (log Kow estimated to be 6.66 based KOWWIN v1.67) and high adsorption coefficient (log K_{oc} predicted to range from 4.3 using the MCI method and 4.0 using the log Kow method), indicating high potential to adsorb to soil.

You have provided an adaptation under Annex IX, Section 9.2.1.3., Column 2 with the justification: "the substance is readily biodegradable".

We have assessed this information and identified the following issue:

> For the reasons explained in Appendix A.5., the information requirement on ready biodegradability is not fulfilled. Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

The results of the ready biodegradability test requested in this decision will determine whether the Substance includes non-readily biodegradable (and hence potentially P/vP) constituent(s)/fraction(s). If the information requested under Appendix A.5. shows that all constituent(s)/fraction(s) are readily biodegradable then no simulation study needs to be conducted. However, if negative results are obtained, (a) simulation study(ies) will be required. In such case, the test material(s) to be used in the simulation study(ies) must correspond the non-readily biodegradable constituent(s)/fraction(s) identified in the ready biodegradability test(s).

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; ECHA Guidance R.11.4.1.).

In your comments to the draft decision, you refer to the comments already presented in Appendix B.4. and provided no further comments on this request.

4. Sediment simulation testing

Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

The Substance has low water solubility (estimated to be 0.0098 mg/L using WSKOWWIN), high partition coefficient (log Kow estimated to be 6.66 based KOWWIN v1.67) and high adsorption coefficient (log K_{oc} predicted to range from 4.3 using the MCI method and 4.0 using the log Kow method), indicating high potential to adsorb to sediment.

You have provided an adaptation under Annex IX, Section 9.2.1.4., Column 2 with the justification: "the substance is readily biodegradable".

We have assessed this information and identified the following issue:

> For the reasons explained in Appendix A.5., the information requirement on ready biodegradability is not fulfilled. Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

Study design

The results of the ready biodegradability test requested in this decision will determine whether the Substance includes non-readily biodegradable (and hence potentially P/vP) constituent(s)/fraction(s). If the information requested under Appendix A.5. shows that all constituent(s)/fraction(s) are readily biodegradable then no simulation study needs to be conducted. However, if negative results are obtained, (a) simulation study(ies) will be required. In such case, the test material(s) to be used in the simulation study(ies) must correspond the non-readily biodegradable constituent(s)/fraction(s) identified in the ready biodegradability test(s).

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; ECHA Guidance R.11.4.1.).

In your comments to the draft decision, you refer to the comments already presented in Appendix B.4. and provided no further comments on this request.

5. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

You have provided no information on identification of degradation products for the Substance.

On this basis, the information requirement is not fulfilled.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation studies requested in Appendices C.3. and C.4. or by some other measure. If any other method is used for the identification of the

transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (Appendices C.3. and C.4.) must be conducted at 12°C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (*e.g.* 10 times).

In your comments to the draft decision, you refer to the comments already presented in Appendix B.4. and provided no further comments on this request.

6. Long-term toxicity on terrestrial invertebrates

Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

Based on the information from your registration dossier, the Substance is considered to have high adsorption potential to soil as you report predicted log Kow above 5 for the Substance.

Therefore, the Substance has a high potential to adsorb to soil. On this basis, information on long-term toxicity on terrestrial invertebrates must be provided.

You have adapted this information requirement under Annex IX, Section 9.4., Column 2 with the following justification: "*In the absence of such studies the guidance states that the PNEC soil may be calculated using the equilibrium partitioning method. However, as the aquatic PNEC is greater than the water solubility of the test substance toxicity is not expected, and a PNEC soil is not calculated*."

We have assessed this information and identified the following issue:

> For the reasons explained in Appendices A.4. C.1-2, the information requirements on aquatic toxicity are not met. Therefore, you have not demonstrated that no effects up to the water solubility of the Substance are to be expected. Therefore, your adaptation is rejected.
>
> Furthermore, ECHA Guidance R.7.11.5.3. specifies that as the use of the EPM method provides only an uncertain assessment of risk, and while it can be used to modify the standard data-set requirements of Annex IX and X, it cannot alone be used to obviate the need for generating information on effects on terrestrial organisms. In general, where there is no toxicity L(E)C50 in the standard acute toxicity tests at >10 mg/l, or no effects in chronic toxicity at the limit of water solubility, or the screening assessment based on EPM shows no concern, then a single short-term soil test on a suitable species would be adequate to meet the requirements of Annex IX. Where the substance is highly adsorptive, e.g. where the log Kow/Koc >5 (such as the Substance) and/or the substance is very persistent in soil, this single test must be a long-term test.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision, you specify that you "*propose a tiered testing approach by which the aquatic studies are completed first to establish which is the most*

sensitive trophic level and to allow the derivation of PNECs for aquatic and terrestrial risk assessment. This will be followed with either an OECD 222 Earthworm Reproduction Test or an OECD 208 Seedling Emergence and Growth study (on 6 species) depending on the most sensitive trophic level in the aquatic tests. Further risk assessment and appraisal of the data would then determine if further studies are still required or if the risk can be adequately controlled and mitigated".

Study design

ECHA Guidance R.7.11.3.1. specifies that the earthworm reproduction test (OECD TG 222), the Enchytraeid reproduction test (OECD TG 220), and the Collembolan reproduction test (OECD TG 232) are appropriate to cover the information requirement for long-term toxicity testing on terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol since this decision is dependent upon species sensitivity and substance properties. However, when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

7. Effects on soil micro-organisms

Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

You have adapted this information requirement under Annex IX, Section 9.4., Column 2 with the following justification: "*the effects on soil microorganisms study does not need to be conducted as the chemical safety assessment according to Annex I has not indicated a need to investigate further the effects of the substance and/or degradation products on terrestrial organisms*." While, the content of your justification is not explicit we understand that, similar to the justification provided for other terrestrial toxicity endpoints, you consider that "*the aquatic PNEC is greater than the water solubility of the test substance toxicity is not expected, and a PNEC soil is not calculated*."

However, for the reasons already explained under Appendix C.6., your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In your comments on the draft decision, you "*accept that the Equilibrium Partitioning Method does not adequately cover soil microorganisms.* You specify that you agree to perform the requested study

Study design

ECHA Guidance R.7.11.3.1. specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

8. Long-term toxicity on terrestrial plants

Short-term toxicity plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

As explained in Appendix C.6., the Substance has a high potential to adsorb to soil. On this basis information on long-term toxicity on terrestrial plants must be provided.

You have adapted this information requirement under Annex IX, Section 9.4., Column 2 with the following justification: "*In the absence of such studies the guidance states that the PNEC soil may be calculated using the equilibrium partitioning method. However, as the aquatic PNEC is greater than the water solubility of the test substance toxicity is not expected, and a PNEC soil is not calculated*."

However, for the reasons already explained under Appendix C.6., your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In your comments to the draft decision, you refer to the comments already presented in Appendix C.6.

Study design

ECHA Guidance R.7.11.3.1. specifies that the Plant Test: Seedling Emergence and Seedling Growth Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 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 must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

Appendix D: 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[6].

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:

a) the boundary composition(s) of the Substance,
b) 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

a) 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.
b) 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,
c) The reported composition must also include other parameters relevant for the property to be tested, in this case the distribution of the carbon chain length of the alkyl substituents as well as information on branching of the alkyl chain.

This information is needed for ECHA to 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[7].

[6] https://echa.europa.eu/practical-guides
[7] https://echa.europa.eu/manuals

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

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

B. 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 F: Procedure

The information requirement for Bioaccumulation in aquatic species, preferably fish (Annex IX, Section 9.3.2.) is not addressed in this decision. This is because the results from the biodegradation simulation studies are needed to conclude whether the Substance or relevant constituent(s)/fraction(s) of the Substance is (are) P/vP and to decide whether a bioaccumulation study is needed to conclude on the PBT/vPvB properties of the Substance. In such case, the results of the requested biodegradation simulation studies will also inform on the most relevant test material to conduct the bioaccumulation study.

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 15 July 2020.

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

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

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

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

Appendix G: List of references - ECHA Guidance[8] 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)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[10]

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

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

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

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

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[11]

[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[11] 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.

OECD (2006), Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, https://doi.org/10.1787/9789264030213-en.

Appendix H: 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.