~~Confidential~~

Helsinki, 2 May 2022

Addressees
Registrant of JS_formerNONS_413-750-2 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
19/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: A mixture of: esters of C14-C15 branched alcohols with 3,5-di-t-butyl-4-hydroxyphenyl propionic acid; C15 branched and linear alkyl 3,5-bis(1,1-dimethylethyl)-4-hydroxybenzenepropanoate; C13 branched and linear alkyl 3,5-bis(1,1-dimethylethyl)-4-hydroxybenzenepropanoate
EC number: 413-750-2

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***10 May 2024***.

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

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

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

2. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

3. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

4. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

5. Long-term toxicity testing on terrestrial invertebrates (Annex IX, Section 9.4.4.; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220 or EU C.39/OECD TG 232)

6. Long-term toxicity on 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)

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

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

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

Appendix 1: Reasons for the decision

Contents

Reasons for the decision(s) related to the information under Annex IX of REACH

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

1 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

1.1. Information provided to fulfil the information requirement

2 You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the Substance.

3 ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

4 ECHA agrees that a PNDT study in a first species is necessary.

1.2. Specification of the study design

5 You proposed testing in the rat as a first species. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

6 You did not specify the route for testing. The oral route of administration is the most appropriate to investigate reproductive toxicity (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

1.3. Outcome

7 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Soil simulation testing

8 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

9 Substances with a log K_{oc} > 4 are considered to have a high potential for adsorption to soil (Guidance on IRs and CSA, Section R.7.9.4.3.).

10 The Substance has a low water solubility (0.33 mg/L based on EU Method A.6) and high adsorption coefficient (log K_{oc} > 5 based on EU Method A.8) and therefore has high potential for adsorption to soil.

2.1. Information provided to fulfil the information requirement

11 You have submitted a testing proposal for an Aerobic and Anaerobic Transformation in soil test (test method: OECD TG 307 / EU C.23). in support of your testing proposal, you provided the following justification: "*In accordance with Chapter R.11: PBT/vPvB assessment, Figure R.11—3: Integrated Assessment and Testing Strategy for persistence assessment – maximising data use and targeting testing, it is considered appropriate to assess this endpoint without the need to assess via the OECD 309 study. The substance is not readily biodegradable but shows a propensity towards inherent biodegradation. The log K_{oc} was above 5.0 for the test substance at a temperature of 20°C and K_{oc} is set at > 100,000. The substance therefore has a propensity to absorb to sludge, soil and sediment*

based on the available information. It is considered appropriate therefore to conduct this test as part of hazard assessment to preclude the possibility of "P"".

12 Your registration dossier does not include any information on aerobic and anaerobic transformation in soil.

13 ECHA agrees that an appropriate degradation simulation study in soil is needed.

2.2. Test selection and study specifications

14 The proposed Aerobic and Anaerobic Transformation in soil test (test method: OECD TG 307/ EU C.23) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).

15 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section 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.

16 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

17 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

18 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section 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) (Guidance on IRs and CSA, Section 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.

19 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 307; Guidance on IRs and CSA, Section R.11.4.1.).

2.3. Outcome

20 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

3. Sediment simulation testing

21 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.

22 Substances with a log K_{oc} > 4 are considered to have a high potential for adsorption to sediment (Guidance on IRs and CSA, Section R.7.9.4.3.).

23 For the reasons already explained under Appendix 1.2 the Substance is considered to have a high potential for adsorption to sediment and information on Sediment simulation testing must be provided.

3.1. Information provided to fulfil the information requirement

24 You have submitted a testing proposal for an Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (test method: OECD TG 308/ EU C.24).

25 Your registration dossier does not include any information on aerobic and anaerobic transformation in aquatic sediment systems.

26 ECHA agrees that an appropriate degradation simulation study in sediment is needed.

3.2. Test selection and study specifications

27 The proposed Aerobic and Anaerobic Transformation in Aquatic Sediment Systems test (test method: OECD TG 308/ EU C.24) is appropriate to cover the information requirement for degradation/biodegradation (Guidance on IRs and CSA, Section R.7.9.4.1).

28 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section 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.

29 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.

30 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Section R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

31 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 (Guidance on IRs and CSA, Section 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) (Guidance on IRs and CSA, Section 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.

32 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; Guidance on IRs and CSA, Section R.11.4.1.).

3.3. Outcome

33 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Identification of degradation products

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

35 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for soil simulation testing (OECD TG 307) and sediment simulation testing (OECD TG 308). In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to further investigate the effects on degradation.

4.1. Information provided to fulfil the information requirement

36 You have provided no information on the identity of transformation/degradation products for the Substance.

37 Therefore, ECHA concludes that an appropriate identification of degradation products study is needed.

4.2. Test selection and study specifications

38 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 1.2. and 1.3. 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.

39 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (Appendices 1.2. and 1.3.) 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).

40 You may also use other appropriate and suitable test method(s) to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated.

4.3. Outcome

41 Under Article 40(3)(c) of the REACH Regulation, you are requested to carry out the additional test with the Substance, as specified above.

5. Long-term toxicity testing on terrestrial invertebrates

42 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 (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

43 Under Annex IX, Section 9.4., column 2, for substances that have a high potential to adsorb to soil or that are very persistent, long-term toxicity testing must be considered instead of short-term. Guidance on IRs and CSA, Section R.7.11.5.3. clarifies that a substance is considered to be very persistent in soil if it has a half-life >180 days. In the absence of specific soil data, high persistence is assumed unless the substance is readily biodegradable.

44 Based on the information from your registration dossier the Substance has a high potential to adsorb to soil and is potentially very persistent:

- the Substance is considered to be potentially highly persistent in soil as it is considered not readily biodegradable based on OECD 301C and F studies;
- the Substance is considered to have high adsorption potential to soil as you report a Log K_{OC} value of above 5 based on OECD TG 121.

45 Therefore, information on long-term toxicity to terrestrial invertebrates must be provided.

5.1. Information provided to fulfil the information requirement

46 Your registration dossier includes a short-term toxicity study on terrestrial invertebrates based on OECD TG 207 on the Substance (1997) but no information on long-term toxicity to terrestrial invertebrates.

47 Therefore, the information requirement is not fulfilled.

5.2. Test selection and study specifications

48 The Earthworm Reproduction Test (test method: EU C.33/OECD TG 222), Enchytraeid Reproduction Test (test method: EU C.32/OECD TG 220) and the Collembolan Reproduction Test in Soil (test method: EU C.39/OECD TG 232) are appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (ECHA Guidance R.7.11.3.1).

5.3. Outcome

49 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X of the REACH Regulation. The information requirement for Effects on terrestrial organisms at Annex IX covers short-term toxicity to invertebrates (Section 9.4.1.), effects on soil micro-organisms (Section 9.4.2.) and short-term toxicity to plants (Section 9.4.3.). However, you have provided a testing proposal for effects on soil micro-organisms only. Therefore, under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

6. Long-term toxicity to terrestrial plants

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

51 As already explained under Appendix 1.5., the Substance is considered to be potentially highly persistent in soil and has high adsorption potential to soil.

52 Therefore, information on long-term toxicity to terrestrial plants must be provided.

6.1. Information provided to fulfil the information requirement

53 Your registration dossier includes a study according to OECD TG 208 on the Substance (1997). The study was conducted on three plant species.

54 ECHA has assessed this information and identified the following issue:

55 ISO 22030 and OECD TG 208 are both considered adequate to meet the information requirement for long-term toxicity on terrestrial plants. If a similar number of species is tested, ISO 22030 is expected to be more sensitive as it provides additional reproduction endpoints that are not covered by the OECD TG 208. However, if a higher number of species is used in the OECD 208, this test is expected to provide more relevant results in the majority of cases due to the better coverage of inter-species sensitivity. Based on a statistical analysis (Monte Carlo analysis), it was found that the OECD TG 208 can be considered of equal or greater sensitivity to the ISO 22030 when six or more species are tested. At the opposite, when fewer species are tested, the OECD TG 208 does not qualify as a long-term test due to the expected lower sensitivity when compared to the ISO 22030.

56 The study available in your dossier was conducted with only three species.

57 Therefore, this study does not provide sufficiently broad species selection to be considered a long-term test and the information requirement is not fulfilled.

6.2. Test selection and study specifications

58 The Terrestrial Plant Test (EU C.31./OECD TG 208, with at least six species) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

59 The OECD TG 208 (EU C.31.) 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.

6.3. Outcome

60 Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X of the REACH Regulation. The information requirement for Effects on terrestrial organisms at Annex IX covers short-term toxicity to invertebrates (Section 9.4.1.), effects on soil micro-organisms (Section 9.4.2.) and short-term toxicity to plants (Section 9.4.3.). However, you have provided a testing proposal for effects on soil micro-organisms only. Therefore, under Article 40(3)(c), you are requested to conduct the additional test with the Substance, as specified above.

7. Effects on soil micro-organisms

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

7.1. Information provided to fulfil the information requirement

62 You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) with the following justification: "The log K_{oc} was above 5.0 for the test substance at a temperature of 20°C and K_{oc} is set at > 100,000. The substance therefore has a propensity to absorb to sludge, soil and sediment based on the available information. Assessment of other terrestrial organisms indicates that the substance is not harmful to organisms; however, there is no data for this endpoint. The registrant therefore considered it prudent to assess this endpoint, given the uses and the data available to confirm that there is no risk to soil micro-organisms".

63 Your registration dossier does not include any information on effects on soil microorganisms.

64 ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

7.2. Test selection and study specifications

65 The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (Guidance on IRs and CSA, Section R.7.11.3.1.).

7.3. Outcome

66 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

ECHA received your testing proposal(s) on 19 July 2021 and started the testing proposal evaluation in accordance with Article 40(1).

ECHA held a third-party consultation for the testing proposal(s) from 30 September 2021 until 15 November 2021. ECHA did not receive information from third parties.

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

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

ECHA did not receive any comments within the commenting period.

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

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

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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[2].

1.2. 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 particular on the distribution of carbon chain length and degree of branching.

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

2. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, 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.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

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