~~Confidential~~

Helsinki, 03 November 2023

Addressees
Registrant(s) of JS_Isopropylcyclohexane as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/01/2018

Registered substance subject to this decision ("the Substance")
Substance name: Isopropylcyclohexane
EC/List number: 211-792-4

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 ***10 February 2028***.

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

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

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

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

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

3. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

4. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2.)

5. Soil simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

6. Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

7. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)

8. Bioaccumulation in aquatic species also requested below (triggered by Annex VIII, Sections 9.3.)

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

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

10. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

11. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C.

12. 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.

13. 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.

14. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.23./OECD TG 307 or EU C.24./OECD TG 308 or EU C.25./OECD TG 309)

15. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: EU C.13./OECD TG 305, aqueous exposure /dietary exposure)

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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

How to comply with your information requirements

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

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance

you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

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 related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided:

i. a study on growth inhibition of aquatic plants (1992) with the Substance

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issue[s]:

1.2.1. The provided study does not meet the information requirement

4 To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

5 Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;
b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
c) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*;

6 Characterisation of exposure

e) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided.

7 Your registration dossier provides an OECD TG 201 study showing the following:

8 a)-d) There is no information on specifications a)-d).

9 e) No analytical monitoring was conducted.

10 In the comments to the draft decision, you have attached a copy of a Robust Study Summary (RSS). The RSS includes the information listed in the point above a)-d) as missing in the dossier. You have proposed to update your dossier with the modified RSS. On point e), you stated that due to the properties of the Substance the concentrations of the test material might be overestimated, this would mean that the toxicity of the Substance might be underestimated.

11 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no analytical monitoring was conducted. Therefore, there

is no characterisation of exposure. This point is not addressed in your comments on the draft decision and thus remains, which is sufficient to reject the study.

12 On this basis, the information requirement is not fulfilled.

1.3. Study design and test specifications

13 The Substance is difficult to test due to the low water solubility (0.616 mg/L), adsorptive properties (log Kow 6) and volatility (Henry's Law Constant (H) 123000 Pa m^3/mol). 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.

2. Long-term toxicity testing on aquatic invertebrates

14 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

2.1. Triggering of the information requirement

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

16 In the provided OECD TG 105 (2012), the saturation concentration of the Substance in water was determined to be 616 µg/L.

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

18 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 9.

Reasons related to the information under Annex VIII of REACH

3. Long-term toxicity testing on fish

19 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

3.1. Triggering of the information requirement

20 In the provided OECD TG 105 (2012), the saturation concentration of the Substance in water was determined to be 616 µg/L.

21 Therefore, the Substance is poorly water soluble.

22 In your comments to the draft decision, you state that, under the Column 2 provision, the test must be considered but this does not mean that the long-term study has to be conducted definitely. However, poor water solubility is a reason justifying long-term toxicity study on fish over a short term study and you have provided no reason why the study should not be conducted.

23 On this basis, information on long-term toxicity on fish must be provided

24 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 10.

4. Simulation testing on ultimate degradation in surface water

25 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).

26 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 (Guidance on IRs and CSA, Section 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:

27 it is potentially persistent or very persistent (P/vP) as:

- it is not readily biodegradable (*i.e.* <60/70% degradation in an OECD TG 310;

28 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 has a calculated BCF > 2000.

4.1. Information provided

29 Your registration dossier provides the following:

- the Substance is not readily biodegradable (1% degradation after 28 days in OECD

TG 310);
- the Substance has a high potential to partition to lipid storage (log K_{ow} of 6 based on OECD TG 117);
- the Substance has a calculated BCFof 4225 (supporting QSAR study).

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

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 15 of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Requests 1,2,9,10 of this decision).

31 Under section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that the Substance is not P/vP. In support of your conclusion you provide the following additional information: '*As exposure in the auqatic compartment is negligible due to high volatility of the substance the P-criteria cannot be appropriately applied*'.

32 However, information on physico-chemical parameters is not considered sufficient on its own to conclude that the Substance is not P/vP or that the P/VP criteria is inappropriate under Annex XIII.

33 Therefore, the additional information from your PBT assessment is not adequate to conclude that the Substance is not a potential PBT/vPvB substance.

34 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Further, the additional information from your PBT assessment is not adequate to conclude on the PBT/vPvB properties of the Substance.

35 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

36 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 Request 11.

5. Soil simulation testing

37 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).

38 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 (Guidance on IRs and CSA, Section R.11.4.).

39 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

40 Further, the Substance has low water solubility (0.616 mg/L), high partition coefficient (log Kow 6) and high adsorption coefficient (log $K_{oc,soil}$ of 3.1), indicating high potential to adsorb to soil.

41 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.

42 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 Request 12.

6. Sediment simulation testing

43 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).

44 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 (Guidance on IRs and CSA, Section R.11.4.).

45 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

46 Further, the Substance has low water solubility (0.616 mg/L), high partition coefficient (log Kow 6) and high adsorption coefficient (log $K_{oc,soil}$ of 3.1) , indicating high potential to adsorb to sediment.

47 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.

48 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 Request 13.

7. Identification of degradation products

49 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).

50 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 (Guidance on IRs and CSA, Section R.11.4.).

51 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

52 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

53 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 Request 14.

8. Bioaccumulation in aquatic species

54 Under Annex VIII, Section 9.3., Column 2, further information on bioaccumulation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the bioaccumulation properties of the substance.

8.1. Triggering of the information requirement

55 Therefore, this information requirement is triggered in case if for example additional information on bioaccumulation as set out in Annex XIII, point 3.2.2, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

56 As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

57 Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

58 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Request 15.

Reasons related to the information under Annex IX of REACH

9. Long-term toxicity testing on aquatic invertebrates

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

9.1. Information provided

60 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) Justification for data waiving: '*According to Annex IX, 9.1, column 2 of the REACH regulation long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The chemical safety assessment does not indicate a need for long-term tests with aquatic invertebrates.* '.

9.2. Assessment of the information provided

61 We have assessed this information and identified the following issue:

9.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

62 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).

63 Your adaptation is therefore rejected.

64 On this basis, the information requirement is not fulfilled.

65 In the comments to the draft decision, you agree to perform the requested study.

9.3. Study design and test specifications

66 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 and test specifications' under Request 1.

10. Long-term toxicity testing on fish

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

10.1. Information provided

68 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) Justification for data waiving: '*According to Annex IX, 9.1, column 2 of the REACH regulation long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The chemical safety assessment does not indicate a need for long-term tests with fish.*'.

10.2. Assessment of the information provided

69 We have assessed this information and identified the following issue:

10.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

70 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).

71 In the comments to the draft decision you disagree to perform the requested study stating that '*Considering that the registrant intends to carry out a long-term study with aquatic invertebrates the benefit of a long-term study with fish is questionable.*'

72 The hypothetical impact of a long term study with aquatic invertebrates cannot be taken into account and you have provided no identifiable legal basis to your adaptation.

73 Your adaptation is therefore rejected.

74 On this basis, the information requirement is not fulfilled.

10.3. Study design and test specifications

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

76 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 and test specifications' under Request 1.

11. Simulation testing on ultimate degradation in surface water

77 Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

11.1. Information provided

78 You have provided the following information:

(i) Justification under PBT assessment: '*As exposure in the auqatic compartment is negligible due to high volatility of the substance the P-criteria cannot be appropriately applied*';
(ii) Justification for data waiving: '*As no biodegradation (1% within 28 days) was observed in a study on ready biodegradability it is not expected that a significant degradation would occur in a simulation test. The test substance is considered as non-biodegradable in surface water and sediment compartment.*'.

11.2. Assessment of information provided

79 We have assessed this information and identified the following issue:

11.2.1. Your justification to omit the study has no legal basis

80 A registrant may only adapt this information requirement based on the basis of Column 2 or Annex XI to the REACH Regulation.

81 You have not provided any legal basis for your adaptation and it is unclear to which one you would be referring to. In any case, the Substance is identified as potential PBT/vPvB for the relevant information explained under Request 4 above.

82 In your comments to the draft decision, you agree to the lack of legal basis.

11.2.2. Intention to adapt without full adaptation.

83 In the comments to the draft decision, you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH regulation.

84 You indicate that you plan to explore ways to address this information requirement and address the P criteria in a weight of evidence approach using in silico data and try to experimentally test the abiotic degradation of chemicals in the atmosphere. However, the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intentions, you have not provided any new scientific information addressing the information requirement.

85 We further note that the standard information requirement is on persistence in water, not in air.

11.2.3. The provided adaptation does not meet the criteria of Annex IX, Section 9.2.1.2., Column 2

86 In the comments to the draft decision, you propose to adapt this standard information requirement based on Column 2 of Annex IX, Section 9.2.1.2 to REACH.

87 Under Annex IX, Section 9.2.1.2., Column 2, first indent, the study can be omitted in case the Substance is highly insoluble.

88 There is no cut off value for solubility in the REACH Regulation. Since any substance may be persistent, what is most important is what can be assessed in a study, i.e., it is necessary to demonstrate that it is not reasonably possible to develop an analytical method with sufficient sensitivity to meet the test guideline requirements taking into account the specific technical limitations of the OECD TG 309 which include, in particular:

- for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and
- the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

89 Consequently, a substance has an insolubility too high for conducting a simulation testing on ultimate degradation in surface water in accordance with OECD TG 309 if the LOQ of a sensitive analytical method is not at least ten times lower to the water solubility of the substance.

90 You indicate that the Substance has ‘extremely low solubility’ and, based on a Mackay level I model calculation, distributes < 0.01% in the hydrosphere.

91 You have not assessed the solubility of the Substance, provided no information on the limit of quantification and no explanation how information on distribution based on the volatility of the Substance is relevant for assessing whether the Substance is highly insoluble.

92 Therefore, you have not demonstrated that the Substance is highly insoluble and your adaptation is rejected.

11.2.4. Technical infeasibility

93 In the comments to the draft decision, you propose to adapt this information requirement based on Annex XI, Section 2 to the REACH Regulation. You present arguments on the Substance being difficult to test (due to highly volatilisation) and stating that a valid OECD TG 309 study cannot be performed as the Substance is not in the applicabilithy domain (due to the highly volatilisation of the Substance).

94 OECD TG 309 set a threshold of volatility in connection with its applicability domain: Henry's law constant <100 Pa m^3/mol or 0.01 atm m^3/mol.

95 The Substance has a Henry's law constant of 123000 Pa m^3/mol.

96 The information provided provided as part of your comments addresses the incompliances identified above and fulfills the information requirement. However, as the adaptation is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set in the decision.

97 On this basis, the information requirement is not fulfilled.

11.3. Study design and test specifications

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

99 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "*total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances*". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

100 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, 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 (NER - summary 2019 (europa.eu)).

101 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 309; Guidance on IRs and CSA, Section R.11.4.1.).

12. Soil simulation testing

102 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.

103 The Substance has low water solubility (0.616 mg/L), high partition coefficient (log Kow 6) and high adsorption coefficient (log $K_{oc,soil}$ of 3.1) and therefore has high potential for adsorption to soil.

12.1. Information provided

104 You have provided the following information:

(i) Justification for data waiving: '*As no biodegradation (1%) was observed in a study on ready biodegradability it is not expected that significant degradation would occur in a soil degradation test. The test substance is considered as non-biodegradable in surface water, sediment and soil compartment.*';

12.2. Assessment of information provided in your registration dossier

105 We have assessed this information and identified the following issue:

12.2.1. Your justification to omit the study has no legal basis

106 A registrant may only adapt this information requirement based on the basis of Column 2 or Annex XI to the REACH Regulation.

107 You have not provided any legal basis for your adaptation and it is unclear to which one you would be referring to. In any case, the Substance is identified as potential PBT/vPvB for the relevant information explained under Request 4 above.

108 In your comments to the draft decision, you agree with this issue.

12.3. Additional information provided in your comments to the draft decision

12.3.1. Intention to submit a weight of evidence adaptation

109 In the comments to the draft decision, you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH regulation.

110 You indicate that you plan to explore ways to address this information requirement and address the P criteria in a weight of evidence approach using *in silico* data and try to experimentally test the abiotic degradation of chemicals in the atmosphere. However, the information in your comments is not sufficient for ECHA to make an assessment, because while you have described your intentions, you have not provided any new scientific information addressing the information requirement.

12.3.2. The provided adaptation does not meet the criteria of Annex IX, Section 9.2.1.3., Column 2

111 In the comments to the draft decision, you also propose to adapt this standard information requirement based on Column 2 of Annex IX, Section 9.2.1.3.

112 Under Section 9. 2.1.3, Column 2, second indent of Annex IX to REACH, the study may be omitted if direct and indirect exposure of soil is unlikely. Therefore, it must be demonstrated

that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

113 To support your adaptation, your registration dossier provides: Regardless of the high log Kow and log Koc indicating a high potential for adsorption, the high volatility of the substance leads to a nearly complete volatilisation. In a Mackay Level I model calculation the main target compartment of Isopropylcyclohexane is the atmosphere with a distribution of 99.6 %, followed by soil and sediment with just 0.19% each and the hydrosphere with < 0.01 %. Therefore, in accordance with Annex IX section 9.2.1.2 /3 /4 the OECD 307 and OECD 308 studies are waived since direct and indirect exposure of soil and sediment is unlikely.

114 In your chemical safety assessment, you report the following uses: process solvent industrial, laboratory reagent, transfer of substance or mixture (charging and discharging) at dedicated facilities.

115 You have not demonstrated for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply.

116 The uses provided in the dossier indicate potential releases to the environment and contradict your statement of unlikely direct and indirect exposure.

117 Therefore your adaptation is rejected.

118 Therefore, the arguments provided in your comments are not appropriate to adapt the information requirement.

12.3.3. No demonstration of technical infeasibility

119 In the comments to the draft decision, ECHA understands that you submitted an adaptation under Section 2 of Annex XI of REACH by argueing that a valid OECD 307 study cannot be performed because of the volatility of the Substance.

120 We have assessed this information and identified the following issue:

121 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 307, more specifically on the technical limitations of a specific method, shall always be respected.

122 The OECD TG 307 provides in particular that this test is applicable to all chemical substances (non-labelled or radiolabelled) for which an analytical method with sufficient accuracy and sensitivity is available. It is applicable to slightly volatile, non-volatile, water-soluble or water-insoluble compounds. The test should not be applied to chemicals which are highly volatile from soil (e.g. fumigants, organic solvents) and thus cannot be kept in soil under the experimental conditions of this test.

123 On this basis and in the absence of a threshold above which volatility justifies that the substance falls outside of its applicability domain, an adaptation under Annex XI Section 2 must then take into account the availability of an analytical method with sufficient accuracy and sensitivity as well as the possibility to keep the substance in soil under experimental conditions in light of of the volatility of the corresponding substance.

124 You claim that due to the Substance being highly volatile, valid simulation studies on biodegradation in soil (OECD 307) cannot be performed as the Substance cannot be kept in sediment as well as soil under the experimental conditions of these tests. You have not provided any supporting evidence or information.

125 You have not substantiated your claim that the Substance cannot be kept in sediment or soil under the experimental conditions of these tests. For example, you did not perform any

pre-testing to clarify the feasibility of the study when study design and conditions are adapted following the instructions of the respective test guideline to the testing of substances with potential for volatility (e.g. using biometer-type system, closed vessels with minimised headspace etc.) and did not report results of such pre-testing in support of your justification.

126 Therefore, your adaptation is rejected.

127 Therefore, the arguments provided in your comments are not appropriate to adapt the information requirement.

128 On this basis, the information requirement is not fulfilled.

12.4. Study design and test specifications

129 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.

130 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).

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

132 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.

133 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.).

13. Sediment simulation testing

134 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.

135 The Substance low water solubility (0.616 mg/L), high partition coefficient (log Kow 6) and high adsorption coefficient (log $K_{oc,soil}$ of 3.1) and therefore has high potential for adsorption to sediment.

13.1. Information provided

136 You provided the following information:

(i) Justification for data waiving: '*As no biodegradation (1% within 28 days) was observed in a study on ready biodegradability it is not expected that a significant degradation would occur in a simulation test. The test substance is considered as non-biodegradable in surface water and sediment compartment.*'.

13.2. Assessment of information provided

137 We have assessed this information and identified the following issue[s]:

13.2.1. Your justification to omit the study has no legal basis

138 A registrant may only adapt this information requirement based on the basis of Column 2 or Annex XI to the REACH Regulation.

139 You have not provided any legal basis for your adaptation and it is unclear to which one you would be referring to. In any case, the Substance is identified as potential PBT/vPvB for the relevant information explained under Request 4 above.

140 In the comments to the draft decision, you indicate your intention to adapt this information requirement and provided the same adaptations for soil and sediment simulation testing.

141 As already explained under Request 12, these adaptations are rejected.

142 On this basis, the information requirement is not fulfilled.

13.3. Study design and test specifications

143 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.

144 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.

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

14. Identification of degradation products

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

14.1. Information provided

147 You have provided following information:

(i) Substance is not PBT/vPvB, further information on degradation is not needed;

14.2. Assessment of information provided

148 We have assessed this information and identified the following issue[s]:

14.2.1. Your justification to omit the study has no legal basis

149 This information requirement may be adapted only on the basis of Column 2 or Annex XI to the REACH Regulation.

150 You have not provided any legal basis for your adaptation and it is unclear to which one you would be referring to. In any case, the Substance is identified as potential PBT/vPvB for the relevant information explained under Request 4 above.

151 On this basis, the information requirement is not fulfilled.

14.3. Study design and test specifications

152 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 Requests 4-6 and 11-13 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.

15. Bioaccumulation in aquatic species

153 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

15.1. Information provided

154 We understand that you have adapted this information requirement by using Column 2 of Annex IX, Section 9.3.2. To support the adaptation, you have provided following information:

(i) an adaptation based on the chemical safety assessment (CSA) with the following justification: `*…low concentration levels are expected in the aquatic compartment.*`.

15.2. Assessment of information provided

155 We have assessed this information and identified the following issue[s]:

15.2.1. The provided adaptation does not meet the criteria of Annex IX, Section 9.3.2., Column 2

156 Under Section 9.3.2., Column 2, second indent of Annex IX to REACH, the study may be omitted if direct and indirect exposure of the aquatic compartment is unlikely. Therefore, it

must be demonstrated that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

157 To support your adaptation, your registration dossier provides a justification: 'Due to low water solubility and very high volatility from surface waters, low concentration levels are expected in the aquatic compartment. Hence an aquatic bioaccumulation study is scientifically unjustified'.

158 You have provided no justification to substantiate your claim that information on physico-chemical parameters sufficient on its own to conclude that direct and indirect exposure of the aquatic compartment is unlikely.

159 Furthermore the QSAR data indicate that the Substance is likely to be B and it might be even vB.

160 Therefore your adaptation is rejected.

161 On this basis, the information requirement is not fulfilled.

162 In the comments to the draft decision, you agree to perform the requested study.

15.3. Study design and test specifications

163 Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (Guidance on IRs and CSA, Section R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:

- a stable and fully dissolved concentration of the test material in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

164 This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

165 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

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

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 November 2021.

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

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

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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.

Following the Board of Appeal's decision in case A-001-2022 ECHA revised the study design specifications for meeting the information requirement for simulation testing on ultimate degradation in surface water (Annex VIII, column 2, section 9.2 and/or Annex IX, first column, section 9.2.1.2).

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 Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 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].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

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

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess 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[3].

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

2. General recommendations for conducting and reporting new tests

2.1. 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 Guidance on IRs & CSA, Sections R.7.9, 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.