~~Confidential~~

Helsinki, 23 January 2024

Addressee
Registrant of JS_201-545-9 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11/12/2020

Registered substance subject to this decision ("the Substance")
Substance name: Dicyclohexyl phthalate
EC number: 201-545-9

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 information under request 3 below by ***30 January 2025*** and all other information listed below by ***1 February 2027***.

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

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

1. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F or OECD TG 301B/C/D/F or EU C.29./OECD TG 310)

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

4. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111)

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

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

6. 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.

7. Identification of degradation products (Annex IX, 9.2.3.; test method: OECD TG 308)

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

9. 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)

10. 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 or ISO 22030)

The reasons for the decision 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.

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 requests
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 requests

Contents

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

1.1. Information provided

2 You have provided a short-term toxicity study on daphnids (2000) with the Substance

1.1. Assessment of the information provided

1.1.1. The provided study does not meet the specifications of the test guideline

3 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH) and the requirements of OECD GD 23 if the substance is difficult to test. The Substance is difficult to test as it has low water solubility and adsorptive properties (log Kow of 4.8). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) at least 5 concentrations are tested. If less than 5 concentrations are tested, appropriate justification must be provided;

Reporting of the methodology and results

b) the test procedure is reported (*e.g.,* composition of the test medium, pH adjustment, TOC content and water hardness, loading in number of *Daphnia* per test vessel);
c) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported;
d) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;
e) as explained above the Substance is difficult to test. Therefore, the following additional information must be provided:
   - the results of a preliminary solubility study,
   - a description of the methods used to prepare stock and test solutions, a preliminary stability,
   - if the test material is tested at the saturation concentration, evidence that all reasonable efforts have been taken to achieve a saturation concentration,
   - the results of a preliminary stability study.

4 In the provided study described as short-term toxicity study on daphnids:

Technical specifications impacting the sensitivity/reliability of the test

a) 3 concentrations were tested, and no justification was provided as to why the minimum requirement of 5 test concentrations does not need to be met;

Reporting of the methodology and results

b) on the test procedure, you have not specified the composition of the test medium, if pH adjustment were performed, the hardness of the water and TOC content;
c) the dissolved oxygen and pH measured at least at the beginning and end of the

test are not reported;
d) the analytical method is not described and the results of the analytically determined exposure concentrations are not provided;
e) the Substance is difficult to test, and you have not provided the information listed above under point e).

5 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not justified why the minimum number of test concentrations was not used in the test.
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, as you have not provided the information listed under point b) to e), ECHA is not in a position to assess whether the validity criteria of the test guideline were met, whether the test conducted under conditions that are consistent with the requirement of the OECD TG 202 and OECD GD 23, and to assess the interpretation of the study results.

6 Therefore, the requirements of OECD TG 202 in combination with OECD GD 23 are not met.

7 In the comments to the draft decision, you provide additional information addressing the deficiencies identified under points a) to e). However, as the information 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.

8 On this basis, information requirement is currently not fulfilled.

1.2. Study design and test specifications

9 The Substance is difficult to test due to the water solubility and adsorptive properties (log Kow of 4.8). OECD TG 202 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 202. 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. Growth inhibition study aquatic plants

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

2.1. Information provided

11 You have provided a growth inhibition study on algae (2000) with the Substance.

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the specifications of the test guideline

12 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). The Substance is difficult to test as it has low water solubility and adsorptive properties (log Kow of 4.8). Therefore, the following specifications must be met:

Reporting of the methodology and results

a) the test design is reported (*e.g.*, number of replicates);
b) the test conditions are reported (*e.g.*, composition of the test medium, test temperature, biomass density at the beginning of the test);
c) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported and if exponential growth in the control cultures was observed over the entire test;
d) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
e) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;
f) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;
g) as explained above the Substance is difficult to test. Therefore, the following additional information must be provided:
    - the results of a preliminary solubility study,
    - a description of the methods used to prepare stock and test solutions, a preliminary stability,
    - if the test material is tested at the saturation concentration, evidence that all reasonable efforts have been taken to achieve a saturation concentration,
    - the results of a preliminary stability study.

13 In the provided study described as a growth inhibition study on algae:

Reporting of the methodology and results

a) on the test design, you have not specified the number of replicates;
b) on the test conditions, you have not specified composition of the test medium, test temperature, pH, biomass density at the beginning of the test;
c) the method used to determine algal biomass is not reported numbers over the range of biomass occurring in the test;
d) tabulated data on the algal biomass determined daily for each treatment group and control are not reported;
e) microscopic observations to verify a normal and healthy appearance of the inoculum culture are not reported;
f) on the analytical method adequate information is not reported and the results of the analytically determined exposure concentrations are not provided;
g) the Substance is difficult to test, and you have not provided the information listed above.

14 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, as you have not provided the information listed under point a) to g), ECHA is not in a position to assess whether the validity criteria of the test guideline were met, whether the test conducted under conditions that are consistent with the requirement of the OECD TG 201 and OECD GD 23, and to assess the interpretation of the study results.

15 Therefore, the requirements of OECD TG 201 in combination with OECD GD 23.

16 In the comments to the draft decision, you provide additional information addressing the deficiencies identified under points a) to g). However, as the information 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.

17 On this basis, information requirement is currently not fulfilled.

2.3. Study design and test specifications

18 OECD TG 201 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.

3. Ready biodegradability

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

3.1. Information provided

20 In your dossier you provide:

(i) a study on ready biodegradation from test method equivalent to OECD 301C (1977) with the Substance.

21 In your comments to the draft decision, you explain that you intend to adapt this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the studies already listed under (i) above and the following additional information:

(ii) QSAR predictions using BIOWIN v.4.10 for the Substance;

(iii) QSAR predictions using VEGA v. 1.1.5 model for the Substance.

3.2. Assessment of information provided in your dossier

3.2.1. The provided study does not meet the specifications of the test guideline

22 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301C, the following requirements must be met:

Reporting of the methodology and results

a) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;
b) the test design is reported (for instance, the number of replicates);
c) the test conditions are reported (for instance, DOC content of the dilution water, test temperature, pH);
d) the methods of preparation of test solutions are reported;
e) the results of measurements at each sampling point in each replicate is reported;
f) the determination of the biodegradation using a specific chemical analytical method is reported.

23 In the provided study described as a ready biodegradability study according to OECD TG 301C:

Reporting of the methodology and results

a)-f) you have provided none of the information listed above.

24 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. As you have not provided the information listed above under points a) to f), ECHA is not in a position to assess whether the test was conducted under conditions that are consistent with the test guideline specification, whether the validity criteria were met and to assess the interpretation of the study results.

25 Therefore, the requirements of OECD TG 301C are not met in study (i).

3.3. Assessment of the information provided in your comments to the draft decision

3.3.1. Weight of evidence adaptation rejected

26 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

27 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

28 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

29 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach.

30 However, you have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

31 Beside this critical deficiency, ECHA has also assessed the other aspects of your adaptation.

32 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 9.2.1.1. includes similar information that is produced by the OECD TG 301/310. OECD TG 301/310 require the study to investigate the following key parameter:

- the ultimate aerobic biodegradation (as measured by parameters such as DOC removal, CO2 production and oxygen uptake) of the test material under low inoculum concentration is measured at sufficiently frequent intervals to allow the identification of the beginning and end of biodegradation.

33 The sources of information (i) to (iii) may provide relevant information on the above key parameter.

3.3.1.1. The provided QSAR predictions (ii) to (iii) do not provide reliable information to conclude that the Substance degrades rapidly

34 Guidance on IRs and CSA, Section R.7.9.5.1. specifies that (Q)SARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation. However, when no useful information on degradability is available (either experimentally derived or estimated), (Q)SAR predictions can be used as supporting evidence of that the substance is not rapidly degradable.

35 You provide (Q)SARs predictions to support the conclusion that the Substance is to be regarded as readily biodegradable. However, as explained above, (Q)SARs predictions are not considered to provide sufficient confidence to conclude that a substance degrades rapidly. Therefore, the sources of information (ii) and (iii) cannot be considered as reliable for the purpose of your weight of evidence adaptation.

3.3.1.2. The reliability of the available experimental study (study (i)) cannot be ascertained

36 As explained above under 3.2.1., you have not provided adequate information on study (i) to allow an independent assessment of its reliability and therefore cannot contribute to your weight of evidence adaptation.

37 Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for Ready biodegradability.

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

Reasons related to the information under Annex VIII of REACH

4. Hydrolysis as a function of pH

39 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

4.1. Information provided

40 You have adapted this information requirement by using Column 2 of Annex VIII, Section 9.2.2.1., Column 2. In support of your adaptation, you provided the following justification: "*the study does not need to be conducted because the substance is readily biodegradable*".

4.1. Assessment of the information provided

4.1.1. Ready biodegradability not demonstrated

41 Under Annex VIII, Section 9.2.2.1., Column 2, first indent, the study may be omitted if the substance is readily biodegradable.

42 In your dossier and in your comment to the draft decision, you claim that the information from your dossier provided under ready biodegradation supports the conclusion that the Substance is readily biodegradable.

43 However, for the reasons explained under request 3, the information on ready biodegradability is rejected.

44 Therefore, you have not demonstrated that the Substance is readily biodegradable and your adaptation is rejected.

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

Reasons related to the information under Annex IX of REACH

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

47 You have provided a chronic toxicity test on aquatic invertebrates study (2000) with the Substance.

5.2. Assessment of the information provided

5.2.1. The provided study does not meet the specifications of the test guideline

48 To fulfil the information requirement, a study must comply with the OECD TG 211 and the requirements of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The Substance is difficult to test as it has low water solubility and adsorptive properties (log Kow 4.8). Therefore, the following specifications must be met:

Reporting of the methodology and results

a) the test conditions are reported (*e.g.* test medium composition, the TOC/DOC concentration of the test medium);
b) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided
c) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are reported,
d) the full record of the daily production of living offspring during the test by each parent animal is provided,
e) the number of deaths among the parent animals (if any) and the day on which they occurred is reported,
f) as explained above the Substance is difficult to test. Therefore, the following additional information must be provided:
    - the results of a preliminary solubility study,
    - a description of the methods used to prepare stock and test solutions, a preliminary stability,
    - if the test material is tested at the saturation concentration, evidence that all reasonable efforts have been taken to achieve a saturation concentration,
    - the results of a preliminary stability study.

49 In the provided study described as a *long-term toxicity study on daphnids:*

Reporting of the methodology and results

a)-f) you have provided none of the information listed above.

50 Based on the above, the reporting of the study is not sufficient to conduct an independent assessment of its reliability. As you have not provided the information listed above under points a) to f), ECHA is not in a position to assess whether the test was conducted under conditions that are consistent with the test guideline specification, whether the validity criteria were met and to assess the interpretation of the study results.

51 In the comments to the draft decision, you provide additional information addressing the deficiencies identified under points a) to f). However, as the information 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.

52 Therefore, the requirements of OECD TG 211 are currently not met, and the information requirement is not fulfilled.

5.3. Study design and test specifications

53 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.

6. Sediment simulation testing

54 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.

55 The Substance has a high partition coefficient (log K_{ow} 4.8) and high adsorption coefficient (log $K_{oc,soil}$ 3.6-4.1) and therefore has high potential for adsorption to sediment.

6.1. Information provided

56 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.4. To support the adaptation, you have provided following justification: "*the study does not need to be conducted because the substance is readily biodegradable*".

6.2. Assessment of the information provided

6.2.1. Ready biodegradability not demonstrated

57 Under Column 2 of Annex IX, Section 9.2.1.4., the study may be omitted if the Substance is readily biodegradable.

58 You claim that the information from your dossier supports the conclusion that the Substance is readily biodegradable.

59 However, for the reasons explained under request 3, the information on ready biodegradability is rejected.

60 Therefore, you have not demonstrated that the Substance is readily biodegradable, and your adaptation is rejected.

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

6.3. Study design and test specifications

62 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.

63 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.

64 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 308.

7. Identification of degradation products

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

7.1. Information provided

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

67 Therefore, the information requirement is not fulfilled.

7.2. Study design and test specifications

68 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.

69 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

70 You must obtain this information from the degradation study requested in request 6.

71 To determine the degradation rate of the Substance, the requested study according to OECD TG 308 (request 6) must be conducted at 12°C and at a test material application rate 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).

8. Bioaccumulation in aquatic species

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

8.1. Information provided

73 In your dossier, you have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). To support the adaptation, you have provided the following information:

(i) a prediction from QSAR based on CAESAR (2013)
(ii) a prediction from QSAR based on BCFBAF ([redacted])(2013)

74 In your comments to the draft decision, you explain that you intend to adapt this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the study already listed under (i) and (ii(and the following additional information:

(iii) QSAR predictions using VEGA Arnot Gobas model v. 1.1.5 for the Substance,
(iv) QSAR predictions using BCF model (KNN/Read-Across) v1.1.0 for the Substance,

75 In addition to QSAR information from the models VEGA and KNN, you provided the documentation in your comments for models (i) to (iv) including QMRF and QPRF.

8.2. Assessment of the information provided in your dossier

8.2.1. Assessment of (Q)SAR information

76 Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

(3) the prediction needs to be derived from a scientifically valid model,
(4) the substance must fall within the applicability domain of the model,
(5) results need to be adequate for the purpose of risk assessment or classification and labelling, and
(6) adequate and reliable documentation of the method must be provided.

77 With regard to these conditions, we have identified the following issue:

8.2.1.1. Lack of documentation of the prediction (QPRF)

78 Guidance on IRs and CSA R.6.1.6.3 states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others:

- the identities of close analogues, including considerations on how predicted and experimental data for those close analogues support the prediction.

79 For the predictions (i) and (ii), you did not provide sufficient information about the prediction and, in particular, with regard to how well the model performs on close analogues (i.e., phthalate substances having cyclic substituents).

80 In your comments to the dossier, you provide additional information addressing the deficiencies identified above, with both a QMRF and a QPRF including data on the analogues used to support the predictions. ECHA considers that this information addresses the deficiencies identified in the draft decision. However, as this information is not available in your dossier, the data gap remains.

8.3. Assessment of the information provided in your comments to the draft decision

81 While the deficiencies identified for the QSARs predictions (i) and (ii) currently available in your registration dossier remain for the reason listed above, ECHA has assessed this

information together with the additional predictions (iii) and (iv) provided as part of a weight of evidence in your comments.

82 ECHA considers that these sources of information together, through a reasoned justification, provide sufficient relevant and reliable information that would enable to fulfil the information requirement.

83 However, as the information 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.

8.4. Study design and test specifications

84 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.

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

86 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).

9. Long-term toxicity on terrestrial invertebrates

87 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.

9.1. Triggering of the information requirement

88 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.

89 The Substance has a high partition coefficient (log K_{ow} 4.8) and high adsorption coefficient (log $K_{oc,soil}$ 3.6-4.1) and therefore has high potential for adsorption to soil.

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

91 In your comments to the draft decision, you disagree that the information on long-term toxicity on terrestrial invertebrates is triggered. You refer to uncertainties related to the Koc,soil value included in your dossier. You explain that you intend to first perform a test

to obtain a new soil adsorption coefficient estimate for the Substance before deciding whether to conduct a short-term or long-term toxicity study on terrestrial invertebrates.

92 As indicated in your comments, this strategy relies essentially on data, which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

9.2. Information provided

93 You have provided the following justification for omitting the study: "*Long term terrestrial toxicity testing is not proposed by the registrant as the chemical safety assessment shows that the substance does not pose any risk to the terrestrial compartment being the predicted exposure concentrations (PECs) lower than the predicted no effect concentrations (PNECs)*". While you have not specified an explicit legal basis for your adaptation, ECHA assumes that you intend to adapt this information under Annex IX, Section 9.4., column 2 and has assessed the information provided on that basis.

9.3. Assessment of the information provided

9.3.1. Screening assessment based on the Guidance on IRs and CSA, Section R.7.11.16 (integrated testing strategy for Effects on Terrestrial Organisms) is not applicable for the Substance.

94 Under Annex IX, Section 9.4., column 2, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focussed on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

95 The following information indicates that Substance falls into the soil hazard category 4 (HC4):

- the Substance is considered very toxic to aquatic organisms as the lowest long-term NOEC for the Substance is < 0.1 mg/L for fish,
- as already explained above, the Substance is considered to have high potential to adsorb to soil.

96 As specified in the Guidance on IRs and CSA, Table R.7.11-2, for such substance, the screening assessment based on EPM is not recommended as the intrinsic properties of the Substance indicate a high hazard potential to soil organisms. Therefore, long-term toxicity tests as set out under Annex X, Section 9.4. (invertebrates and plants) must be provided.

97 Therefore, the information requirement is not fulfilled.

9.4. Study design and test specifications

98 The test method EU C.33/OECD TG 222 is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section R.7.11.3.1).

10. Long-term toxicity on terrestrial plants

99 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.

10.1. Triggering of the information requirement

100 For the reasons already explained under Section 14.1., information on long-term toxicity on plants must be provided for the Substance.

10.2. Information provided to fulfil the information requirement

101 You have provided the same justification as in Section 14.2 to omit the study.

10.3. Assessment of the information provided

102 For the reasons already explained under Section 14.3.1., your adaptation is rejected. Therefore, the information requirement is not fulfilled.

103 In your comments to the draft decision, you provided the same considerations as already described in Section 9.1. ECHA's reply equally applies to this information requirement.

10.4. Test selection and study specifications

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

105 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.

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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are 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 07 December 2021.

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

You have provided comments during the decision-making phase which were found to address the incompliances identified in the draft decision and you included this information in documentation with your comments. ECHA took into account your comments and amended the draft decision by removing the following requests:

- Water solubility (Annex VII, Section 7.7.)
- Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1.)
- Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.)
- Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)
- Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.)

ECHA consequently has amended the deadline from 45 to 36 months.

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 3: Addressee 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 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.

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

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(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 variation in compositions reported by all members of the joint submission,
- 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.

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

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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

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