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Helsinki, 08 December 2023

Addressee(s)
Registrant(s) of JS-PEOP-DEOP as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
22 November 2016

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of potassium ethyl octylphosphonate and diethyl octylphosphonate
EC/List number: 939-595-5

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 ***15 March 2027***.

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

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

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.1./OECD TG 203);

2. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18/OECD TG 106);

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

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

5. Bioaccumulation in aquatic species, also requested below (triggered by Annex VIII, Section 9.3., Column 2.).

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

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

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

8. 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.

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

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

The reasons for the request(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.

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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 request(s)
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 request(s)

Reasons related to the information under Annex VIII of REACH

1. Short-term toxicity testing on fish

1 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

1.1. Information provided

2 You have provided a short-term toxicity study on fish (1987) with the Substance.

1.2. Assessment of the information provided

3 To fulfil the information requirement, a study must comply with OECD TG 203 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Key parameter measured

a) the concentration of the test material leading to the mortality of 50% of the juvenile fish at the end of the test is estimated.

Validity criteria

b) mortality in the control(s) is ≤ 10% (or one fish, if fewer than 10 control fish are tested) at the end of the test;

c) the dissolved oxygen concentration is ≥ 60% of the air saturation value in all test vessels throughout the exposure;

d) the analytical measurement of test concentrations is conducted.

Technical specifications impacting the sensitivity/reliability of the test

e) at least 5 concentrations are tested.

Reporting of the methodology and results

f) the test procedure and methods used to prepare stock and test solutions is reported;

g) the test conditions including results of at least daily measurements of dissolved oxygen, pH, salinity (if relevant) and temperature measured daily in each test vessel are reported. The results of hardness and TOC determinations at the beginning of the exposure in the dilution water are reported;

h) mortalities and sub-lethal effects (*e.g.* with regard to equilibrium, appearance, ventilator and swimming behaviour) are reported. The frequency of observations includes at least 2 observations within the first 24 hours and at least two observations per day from day 2 to 4.

4 In the study provided:

Key parameter measured

a) the concentration of the test material leading to the mortality of 50 % of the juvenile fish at the end of the test was not estimated. You report only an LC50 between 10 and 100 mg/L.

Validity criteria

b) you did not report whether the mortality in the control(s) was <10% at the end of the test;

c) you did not report whether the dissolved oxygen concentration was maintained ≥ 60% of the air saturation value;

d) no analytical measurement of test concentrations was conducted.

Technical specifications impacting the sensitivity/reliability of the test

e) only 3 concentrations were tested.

Reporting of the methodology and results

f) the methods used to prepare stock and test solutions is not reported;

g) test conditions including the dissolved oxygen, pH and TOC are not reported;

h) tabulated data on mortalities and sub-lethal effects (e.g. with regard to equilibrium, appearance, ventilator and swimming behaviour) are not reported.

5 Based on the above,

- the information provided does not cover the key parameter(s) required by the OECD TG 203 (point a above);
- the validity criteria of OECD TG 203 are not met (point d above);
- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically only 3 concentrations were tested (point e above) resulting in uncertainties estimating the LC50.
- the reporting of the study is not sufficient (points f-h above) to conduct an independent assessment of its reliability. In particular the points described under g-h above are needed to establish that the study meets the validity criteria.

6 On this basis, the specifications of OECD TG 203 are not met and the information requirement is not fulfilled.

1.3. Study design

7 The Substance is difficult to test due to the low surface tension of the Substance (26.6 - 26.8 mN/m according to OECD 115). Furthermore, the Substance is potentially adsorptive (adsorptive properties are to be confirmed with the request 2). The OECD TG 203 specifies that, for difficult to test substances, you must consider the approach described in the 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 the OECD TG 203. 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 solutions.

8 In your comments to the draft decision, you agree that the study provided does not meet the current standards of an OECD TG 203 study. Instead of performing a new OECD TG 203 study as requested, you propose to perform a long-term toxicity study in fish (OECD TG 210, see request 7 of this decision). You consider that this information can be used to adapt the information requirement of short-term toxicity to fish.

9 Annex VIII, Section 9.1.3., Column 2 specifies that the short-term toxicity study does not need to be conducted if a long-term aquatic toxicity study on fish is available.

10 The information on long-term toxicity to fish is yet to be generated and currently not available in your registration dossier. Therefore, no conclusion on the compliance can currently be made and the data gap remains. You remain responsible to submit this information in an updated registration dossier by the deadline set in the decision.

2. Adsorption/desorption screening

11 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

2.1. Information provided

12 You have adapted this information requirement by using Column 2 of Annex VIII, Section 9.2.2.1. To support the adaptation, you have provided the following information:

(i) "Waiving according to "column 2" in Annex VIII and IX of REGULATION (EC) No 1907/2006. The study need not to be conducted because based on the physicochemical properties the substance can be expected to have a low potential for adsorption (Log Kow < 3)."

2.2. Assessment of the information provided

13 Under Annex VIII, Section 9.3.1, Column 2, first indent, the study may be omitted if the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient). In order to adapt this information requirement based on low octanol-water partition coefficient (log K_{ow}), lipophilicity must be the sole characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

14 You claim that the Substance has a low octanol-water partition coefficient and has therefore low potential for adsorption/desorption.

15 You have not provided any relevant evidence or argument that the Substance can be expected to have a low potential for adsorption.

16 In sections 4.10 and 4.21 of your dossier, you report surface tension of 26.6 - 26.8 mN/m (OECD TG 115) and dissociation constant of 6.85 - 6.95 (OECD TG 112) for the Substance.

17 The information in your dossier indicates that the Substance is ionisable and a surface active. Therefore, other mechanisms than lipophilicity may drive adsorption.

18 You have not demonstrated that lipophilicity is the sole characteristic driving adsorption potential and that log K_{ow} is not a valid descriptor for assessing the adsorption potential of the Substance.

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

20 In your comments to the draft decision, you agree with the shortcomings of the provided adaptation. You indicate that you plan to explore ways to address this information requirement. However, in your comments to the draft decision you have not provided any new scientific information that could address the information requirement/the deficiencies. Therefore, the data gap remains and the information requirement is not fulfilled.

2.3. Study design

21 To fulfil the information requirement, the test method(s) according to the OECD TG 121 and the OECD TG 106 are in general appropriate. You must ensure that the Substance is within the applicability domain of the chosen test method. Because the OECD TG 121 is not applicable for surface active substances, the OECD TG 106 is the appropriate method for the Substance considering its surface active properties.

3. Simulation testing on ultimate degradation in surface water

22 Under Annex VIII, Section 9.2., Column 2, further information on degradation 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 degradation of the substance.

3.1. Triggering of the information requirement

23 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (i.e. <60% degradation in an OECD 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - for some groups of substances (e.g. organometals, substances that are present in their ionised form(s) at environmentally relevant conditions (e.g. pH 4-9), surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid, i.e. bioaccumulation cannot be waived on the basis of low log K_{ow} alone for such substances;
- it meets the T criteria set in Annex XIII: STOT RE 1 or 2.

24 Your registration dossier provides the following:

- the Substance is not readily biodegradable (32% degradation after 60 days in a study according to the OECD TG 301B);
- some of the constituents of the Substance are present in their ionised form at environmentally relevant conditions (pH 4-9) based on the reported dissociation constant (6.85 - 6.95; OECD TG 112) and are surface active based on the reported surface tension (26.6 - 26.8 mN/m; OECD TG 115), and therefore high potential for bioaccumulation cannot be excluded based on available information;
- the Substance meets the T criteria on the basis of your self-classification as STOT RE 2 (kidney).

25 Furthermore, it is not possible to conclude on the degradation and bioaccumulation potential of the Substance (see requests 8 and 10 of this decision).

26 Under section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that the Substance is not B/vB nor T. You base your conclusion on the following:

- low log Kow (2.23) indicates that the Substance does not bioaccumulate;
- the "calculated BCF is < 2000 L/kg", and
- the substance is not T based on: the result of 3 aquatic acute toxicity tests, the substance does not meet the criteria for CMR classification, and the substance has no STOT classification.

27 However,

- you do not provide any documentation why the Log K_{ow} is relevant to determine B potential of the Substance. As described above, high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;
- you refer to a BCF calculation in your B assessment but do not provide any documentation for the calculation in order to demonstrate its reliability;
- you indicate self-classification as STOT RE 2 (kidney) in section 2.1 of your IUCLID dossier.

28 In your comments to the draft decision, you agree that the Substance meets the criteria for T, as it is classified as STOT RE 2.

29 You further provide predictions of BCF using EpiSuite(v4.11, i.e. BCFBAF), CompTox Chemicals Dashboard (T.E.S.T) and OPERA(2.6) for the two main constituents Potassium ethyl octylphosphonate and diethyl octylphosphonate. BCF values are indicated to be in the range of 4.07 – 157.4. You conclude that since this is below 2000 L/kg, the Substance would not meet the criteria of being B/vB.

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

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

3.1.1.1. The substance is outside the applicability domain of the model

31 Under Guidance on IRs and CSA R.6.1.5.3., a prediction is within the applicability domain of the model, when, among others, the substance and the structures selected for the prediction fall within the descriptor, structural, mechanistic and metabolic domains.

32 Your registration dossier provides the following information:

(i) The main constituents of the Subsance's composition are potassium ethyl octylphosphonate (EC 268-740-9) and diethyl octylphosphonate (EC 213-941-9).

33 The following information is also available for the selected structure(s) used as input for the prediction:

(ii) The Substance is a surfactant (surface tension = 26.6.-26.8 mN/m)
(iii) One of the main constituents, potassium ethyl octylphosphonate, is fully ionised (anion) at environmental relevant pH 4-9

34 The selected structure(s) used as input for the prediction are outside the applicability domain of the models BCFBAF and OPERA because the models predict bioaccumulation in fish lipids based on log K_{ow}. For surface active and ionised substances the mechanisms of

bioaccumulation may however be other than passive diffusion to lipids. Therefore, the prediction relying on log K_{ow} as a descriptor can underestimate the bioaccumulation potential of the Substance.

3.1.1.2. The prediction is not adequate due to low reliability

35 Under Guidance on IRs and CSA R.6.1.3.4. a prediction is adequate for the purpose of classification and labelling and/or risk assessment when the model is applicable to the chemical of interest with the necessary level of reliability. Guidance on IRs and CSA R.6.1.5.3. specifies that, among others, the following conditions must be met:

- the model predicts well substances that are similar to the substance of interest, and
- reliable input parameters are used, and
- the prediction is consistent with other information available (e.g. for related endpoint(s)).

36 As already specified under 3.1.1.1 the Substance's main constituents are potassium ethyl octylphosphonate (EC 268-740-9) and diethyl octylphosphonate (EC 213-941-9). Both contain phosphonate as a functional group in their molecular structure.The prediction(s) for the selected structure(s) used as input are not reliable because there are no phosphonates in the training sets of any of the BCF models used.

37 Therefore, you have not demonstrated that the prediction for the Substance is adequate for the purpose of classification and labelling and/or risk assessment.

38 Based on the above, a conclusion on bioaccumulation properties of the Substance cannot be made.

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

40 Moreover, the additional information you provided in your comments to the draft decision are not sufficient to conclude on the B/vB properties of the Substance and the PBT/vPvB concern therefore remains.

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

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

3.2. Information requirement not fulfilled

43 The information provided, its assessment and the specifications of the study design are addressed under request 8.

4. Identification of degradation products

44 Under Annex VIII, Section 9.2., Column 2, further information on degradation 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 degradation of the substance.

45 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

46 As already explained in request 3, the Substance is a potential PBT/vPvB substance.

47 Your considerations submitted in your comments to the draft decision in this regard are addressed in request 3.

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

4.1. Information requirement not fulfilled

49 The information provided, its assessment and the specifications of the study design are addressed under request 9.

5. Bioaccumulation in aquatic species

50 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.

51 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.

52 As already explained in request 3, the Substance is a potential PBT/vPvB substance.

53 Your considerations submitted in your comments to the draft decision in this regard are addressed in request 3.

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

5.1. Information requirement not fulfilled

55 The information provided, its assessment and the specifications of the study design are addressed under request 10.

Reasons related to the information under Annex IX of REACH

6. Long-term toxicity testing on aquatic invertebrates

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

6.1. Information provided

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

(i) "Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006 (CSA does not indicate need for further investigations)"

6.2. Assessment of the information provided

58 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

59 Your adaptation is therefore rejected and the information requirement is not fulfilled.

6.3. Study design

60 OECD TG 211 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.

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

7. Long-term toxicity testing on fish

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

7.1. Information provided

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

(i) *"Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006 (CSA does not indicate need for further investigations)"*

7.2. Assessment of the information provided

64 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

65 Your adaptation is therefore rejected and the information requirement is not fulfilled.

7.3. Study design

66 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.).

67 The OECD TG 210 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 1.

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

8. Simulation testing on ultimate degradation in surface water

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

8.1. Information provided

70 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2. To support the adaptation, you have provided the following information:

(i) "*Waiving according to "column 2" in Annex VIII and IX of REGULATION (EC) No 1907/2006 (CSA does not indicate need for further investigations). "*

8.2. Assessment of the information provided

71 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.2., Column 1.

72 Therefore, your adaption is rejected.

73 In your comments to the draft decision, you provide justification as to why this information requirement is not triggered under Annex VIII, i.e. why there is no PBT/vPvB concern for the Substance. However, as explained above, simulation testing on ultimate degradation in surface water is a standard information requirement under Annex IX to REACH (Section 9.2.1.2.). In your comments to the draft decision, you have not provided any information to address the issues raised above.

74 Therefore, the information requirement is not fulfilled.

8.3. Study design

75 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.

76 You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (Guidance on IRs and CSA, Section R.11.4.1.1.3.).

77 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.

78 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.

79 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)).

80 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.).

9. Identification of degradation products

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

9.1. Information provided

82 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2, with the same argumentation as specified under request 8.

9.2. Assessment of the information provided

83 As explained under request 8, your adaptation is rejected.

84 In your comments to the draft decision, you provide justification as to why this information requirement is not triggered under Annex VIII, i.e. why there is no PBT/vPvB concern for the Substance. However, as explained above, Identification of abiotic and biotic degradation products is a standard information requirement under Annex IX to REACH (Section 9.2.3.). In your comments to the draft decision, you have not provided any information to address the issues specified under request 8 which apply equally to the present standard information requirement.

85 Therefore, the information requirement is not fulfilled.

9.3. Study design

86 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.

87 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.

88 You must obtain this information from the degradation study requested in request 8.

89 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 8) must be conducted at 12°C and at a test concentration < 100 µg/L. 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, e.g. 20°C) and at higher application rate (i.e. > 100 µg/L).

10. Bioaccumulation in aquatic species

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

10.1. Information provided

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

(i) "*Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006. The study need not to be conducted because the substance has a low potential for bioaccumulation. The Log Kow is < 3.*"

10.2. Assessment of the Information provided

92 Under Section 9.3.2., Column 2, first indent of Annex IX to REACH, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes.

93 A low log K_{ow} (i.e. log K_{ow} < 3) on its own may be used to show low potential for bioaccumulation only if the potential for bioaccumulation of the substance is solely driven by lipophilicity. This excludes, for example, situations where the substance is surface active or ionisable at environmental pH (pH 4 – 9).

94 Your registration dossier provides an adaptation stating that the log K_{ow} is < 3 without further explanation.

95 As explained under request 2, The Substance is ionisable and a surface active.

96 The log K_{ow} is not a valid descriptor of the bioaccumulation potential of the Substance and your adaptation is rejected.

97 Therefore, the information requirement is not fulfilled.

98 Your considerations submitted in your comments to the draft decision in regard to fulfilling this information requirement by using QSAR prediction are addressed in request 3.

10.3. Study design

99 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.

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

101 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).
Guidance for monomers and polymers; ECHA (2023).
Guidance on intermediates; ECHA (2010).
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 02 May 2022.

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.

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

Following the comments on the draft decision a clerical error was identified and corrected in request 2.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment. No amendments were proposed by the Member States.

ECHA takes note that you updated your registration dossier on 06 November 2023. The updated dossier does not contain any new substantial information as set out in the notification letter to the draft decision which was notified to you on 20 April 2023. In the updated dossier, you essentially provided the same information that had already been submitted in your comments on the draft decision and which has been fully addressed by ECHA. Therefore, the updated dossier does not affect the information requests contained in this decision.

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

Appendix 3: Addressee(s) 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 (https://echa.europa.eu/practical-guides).

(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.

With that detailed information, ECHA can confirm 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 (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.

2.2 Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach", (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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