~~Confidential~~

Helsinki, 02 November 2023

Addressees
Registrant(s) of JS_MPAAU_282_758_4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
08/01/2021

Registered substance subject to this decision ("the Substance")
Substance name: Methylphosphonic acid, compound with amidinourea (1:1)
EC number/ List number: 282-758-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***7 August 2026***.

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)

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

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

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

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

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

6. 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.

7. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.25/OECD TG 309).

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in

accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

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

Appendix 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Assessment of your adaptation for the long-term aquatic toxicity testing

1 The following considerations are relevant for the information requirements on long-term toxicity testing on aquatic invertebrates (Annex IX, Sections 9.1.5) and on fish (Annex IX, Sections 9.1.6.) and therefore addressed here as Reasons common to both requests.

2 For both of these information requirements you have provided the following information:

- a justification to omit the study which you consider to be based on REACH Annex XI No. 3, as well as REACH Annex IX, Section 9.1., Column 2. In support of your adaptation you provide the following justification: *"(…) study does not need to be conducted as the results of the exposure calculations in the Chemical Safety Assessment do not indicate a relevant exposure to the aquatic environment. Therefore, no need for further testing can be identified."*

3 We have assessed this information and identified the following issues:

4 Annex IX, Section 9.1., Column 2 does not allow omitting to submit information on long-term toxicity to aquatic invertebrates and to fish set out in Column 1 of that section. It must be understood as a trigger for providing further information on aquatic invertebrates and fish if the chemical safety assessment according to Annex I indicates the need (see also Decision of the Board of Appeal in case A-011-2018).

5 We understand that you also claimed adaptation under Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing) and therefore evaluated your adaptation against requirements of this general adaptation rule in REACH.

6 Under Annex XI, Section 3, the information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet the following criteria:

(a) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a PNEC can be derived from available data, which:
      - must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
      - must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in Guidance on IRs and CSA, Section R.10.3;
      - the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1.

0.1.1. Not compliant aquatic toxicity data used for PNEC derivation

7 For the reasons explained under Requests 1, 2, 4, and 5 below, your dossier does not include reliable information on the hazardous properties of the Substance on at least three trophic levels of aquatic organisms.

8 Therefore, you have not demonstrated that an appropriate PNEC for water can be derived and your adaptation is rejected.

0.1.2. Exposure assessment

9 The results of the exposure assessment must show that exposures are always well below the PNEC, i.e. RCRs must always be well below 1. This means that the risks must always be controlled, under every plausible condition of the uses of the Substance. Therefore, every RCR must be low enough to ensure that the risks are always controlled considering the possible sources of variability and uncertainty in the assessment of exposure. ECHA Guidance R.19 on uncertainty analysis provides a framework for carrying out a stepwise, tiered approach to uncertainty analysis: either qualitative, deterministic, or probabilistic.

10 For the exposure scenarios 4 and 5 (identified uses for consumers and professional workers), you have not based your exposure assessment on the generic assumptions recommended in ECHA Guidance R.16 but have used less conservative input parameters (in particular for the release factors). You have not demonstrated that your exposure assessment is always conservative enough and the RCRs always low enough to cover the possible sources of variability and uncertainty. Therefore, exposures cannot be regarded as being always well below the PNEC.

11 Therefore, the CSA indicates the need for long-term aquatic toxicity testing and your proposed adaptation under Annex XI, Section 3.2 is rejected.

0.2. Assessment of your adaptation for the degradation testing

12 Similar considerations are relevant for the application of the Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2), which are therefore also addressed here.

13 You have adapted this information requirement by using Annex XI, Section 3.2. To support the adaptation, you have provided following information:

> "*In accordance with REACH Annex XI, No. 3.2. (Substance-Tailored Exposure-driven Testing), the study does not need to be conducted as the direct and indirect exposure of surface water is unlikely. Exposure to aquatic environment, including surface water and sediment, is considered negligible during manufacturing process, and further processing of the substance MPAAU (CAS 84402-58-4, [redacted]), due to the fact that Risk Management Measures (RMM) are in place for wastewater incineration from manufacturing and processing of MPAAU. During the regular use of MPAAU fixed on technical textile surfaces ([redacted]) also no exposure to the aquatic environment is expected as no washing of such textiles is advised. The registrant shows within the attached Chemical Safety Report (CSR), covering all relevant exposure routes throughout the life cycle of the substance, that there are no unacceptable risks to the aquatic environment as all calculated RCR values are well below 1.*"

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

15 Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(1) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a PNEC can be derived from available data, which:

- must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in Guidance on IRs and CSA, Section R.10.3;
- the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1.

16 As explained above under sections 0.1.1. and 0.1.2., you have not demonstrated that an appropriate PNEC for water can be derived. Furthermore, you have not demonstrated that your exposure assessment is always conservative enough and the RCRs always low enough to cover the possible sources of variability and uncertainty. Therefore, exposures cannot be regarded as being always well below the PNEC.

17 Therefore, the CSA indicates the need for further degradation investigation and your adaption is rejected.

18 In your comments to the draft decision you explain that an outdated version of the CSR has been attached to the member's dossier. You indicate that it is the CSR document attached to the lead registrant's dossier that is of relevance: *"the exposure considerations, risk management measures and RCR in this* [lead registrant's] *CSR document should therefore be basis of the exposure evaluation by ECHA".* You also mention*: "(…) we will share the corrected CSR with these comments to the Agency."*

19 Please note that the issues specified in sections 0.1 and 0.2 of this Appendix are valid for the CSR attached to the lead registrant's dossier as well. Therefore, the conclusions from ECHA assessment of your adaptations for long-term aquatic toxicity and degradation testing remain relevant for both registrants.

20 The further reasons for the test requests and for the tests design are addressed respectively under section 4 – 6 in the below.

Reasons related to the information under Annex VII of REACH

1. Short-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

22 You have provided the following information:

i. OECD TG 202 study (1995) with the Substance.

1.2. Assessment of the information provided

23 We have assessed this information and identified the following issues:

1.2.1. The provided study does not meet the information requirement

24 To fulfil the information requirement, a study must comply with EU C.2./OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

25 Validity criteria

a) the percentage of immobilised daphnids is ≤ 10% at the end of the test in the controls (including the solvent control, if applicable);
b) the dissolved oxygen concentration is ≥ 3 mg/L in all test vessels at the end of the test;

26 Characterisation of exposure

c) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available.

27 Your registration dossier provides an OECD TG 202 study showing the following:

28 Validity criteria

a) the percentage of immobilised daphnids at the end of the test in the controls was not provided;
b) the dissolved oxygen concentration in controls and/or test vessels at the end of the test was not provided;

29 Characterisation of exposure

c) no analytical monitoring of exposure was conducted.

30 Based on the above, the information on validity criteria of OECD TG 202 is missing. On that basis it is not possible to independently assess the reliability and confirm the validity of the study. There are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the concentrations of the test material throughout the test duration were not analytically verified (monitored).

31 Therefore, the requirements of OECD TG 202 are not met.

32 In your comments to the initial draft decision you agree with the request.

1.3. Study design and test specifications

33 The Substance is difficult to test due to the ionisable properties (the reported dissociation constants are: pKa1 = 2.27, pKa2 = 12.00 based on ACD/Labs Software, v11.02 and pKa1 = 2.12, pKa2 = 7.29 based on data from Hazardous Substances Data Bank of TOXNET). Furthermore, the presence of ionic forms at environmentally-relevant pH is supported by the nature of the Substance (well-soluble, organic salt). 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

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

2.1. Information provided

35 You have provided the following information:

i. OECD TG 201 study (2012) with the Substance.

2.2. Assessment of the information provided

36 We have assessed this information and identified the following issues:

37 To fulfil the information requirement, a study must comply with EU C.3./OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

38 Validity criteria

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

39 Characterisation of exposure

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

provided;

f) the concentrations of the test material are measured at least at the beginning and end of the test:
   i. at the highest, and
   ii. at the lowest test concentration, and
   iii. at a concentration around the expected EC_{50}.

40 Reporting of the methodology and results

g) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);
h) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

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

42 Validity criteria

The information on the above validity criteria a)-d) is missing.

43 Characterisation of exposure

e) the analytical monitoring is indicated, however, the results of analytical monitoring of exposure concentrations throughout the test duration is not reported;

f) there is no information if the concentrations of the test material were analytically verified at the beginning and at the end of the test,

44 Reporting of the methodology and results

g) on the test design, you have not specified the number of replicates, the number of test concentrations and the geometric progression used;
h) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

45 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the information on validity criteria of OECD TG 201 is missing. Furthermore, there is no information whether the concentrations of the test material were analytically verified at the beginning and at the end of the test. In addition, the results of algal biomass determined in each flask at least daily during the test period is not reported. On that basis it is not possible to independently assess the reliability and if the validity criteria of OECD TG 201 are met for the study.

46 In your comments to the initial draft decision you provide information on the validity criteria a) - d). You also mention that analytical monitoring of exposure concentrations was conducted and that results of algal biomass determination are available in the study report. Furthermore, you provide missing details on the test design.

47 However, information on results of analytical monitoring of exposure concentrations throughout the test duration and on results of algal biomass determined in each flask at least daily during the test period were not reported in the comments and are not available in the registration dossier, so the independent assessment of reliability of the study is not possible. Also, the information provided or mentioned in your comments is currently not available in your registration dossier. Therefore, the data gap remains.

48 On this basis, the registration information requirement is not fulfilled.

2.1. Study design and test specifications

49 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' in section 1.3 above.

Reasons related to the information under Annex VIII of REACH

3. Adsorption/ desorption screening

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

3.1. Information provided

51 You have adapted this information requirement by using Column 2 of Annex VIII, Section 9.3.1, first indent. To support the adaptation, you have provided following information: "*the study does not need to be conducted because the substance has a low octanol water partition coefficient and the adsorption potential of this substance is related to this parameter.*"

3.2. Assessment of the information provided

52 We have assessed this information and identified the following issues:

53 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 (logKow). To adapt this information requirement based on low log Kow value, 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.

54 Guidance on IRs and CSA, Section R.7.1.15.4 explains that a *measured* adsorption coefficient is usually needed for ionising substances, since it is important to have information on pH-dependence (cationic substances in particular generally adsorb strongly).

55 You justified the adaptation by stating that the Substance has a low octanol-water partition coefficient (logKow = - 2.7). However, the dissociation constants values provided in your dossier: pKa1 = 2.27, pKa2 = 12.00 (ACD/Labs Software, v11.02) and pKa1 = 2.12, pKa2 = 7.29 (Hazardous Substances Data Bank of TOXNET) indicate the ionisable properties of the Substance. Furthermore, the presence of ionic forms in the environmentally relevant pH range is supported by the nature of the Substance (well-soluble, organic salt).

56 Based on the ionisable properties of the Substance, logKow is not a valid descriptor for assessing the adsorption potential of the Substance and measured adsorption coefficient value is needed to meet the endpoint data requirements. On that basis your adaptation is rejected.

57 In your comments to the initial draft decision you agree with the request.

3.3. Study design and test specifications

58 To fulfil the information requirement for the ionic Substance at the 100 tonnes per year band, the batch equilibrium method (test method OECD TG 106) would be the most appropriate (Guidance on IRs and CSA, Section R.7.1.15.4).

Reasons related to the information under Annex IX of REACH

4. Long-term toxicity testing on aquatic invertebrates

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

4.1. Information provided

60 You have adapted this information requirement, and in support of the adaptation you have provided following information: *"Exposure considerations according to REACH Annex XI No. 3, as well as REACH Annex IX (9.1.5) column 2. - In accordance with REACH Annex XI No. 3 and Annex IX (9.1.5) column 2, the long term aquatic invertebrates study does not need to be conducted as the results of the exposure calculations in the Chemical Safety Assessment do not indicate a relevant exposure to the aquatic environment. Therefore, no need for further testing can be identified."*

61 In your comments to the draft decision you further state: *"(…) opportunities are available to registrants to minimise animal testing that need to be considered. Article 13(4) of REACH stipulates that toxicological and ecotoxicological tests shall be carried out in compliance with EU Directive 86/609/EEC on animal protection. (…) experiments on live animals shall not be performed if the results can be obtained by another scientifically satisfactory method. (…) Considering Annex XI Section 3 of Regulation (EC) No 1907/2006 (REACH), testing in accordance with Sections 8.6 and 8.7 of Annex VIII, Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report (3.1)."*

4.2. Assessment of the information provided

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

63 The minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI or Annex IX, Section 9.1.5., column 2. In case of a data gap ECHA has no administrative discretion whether or not to require the information required by the REACH Regulation.

64 As explained in the section 0. above (Reasons common to several requests) your adaption is rejected. On this basis, the information requirement is not fulfilled.

4.3. Study design and test specifications

65 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' in section 1.3 above.

5. Long-term toxicity testing on fish

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

5.1. Information provided

67 You have adapted this information requirement, and in support of your adaptation, you provide the following information: "Exposure considerations according to REACH Annex XI No. 3 as well as REACH Annex VIII (9.1.3) in connection with Annex IX (9.1.6) column 2. - In accordance with REACH Annex XI No. 3 and Annex VIII (9.1.3) in connection with Annex IX (9.1.6) column 2, the long term aquatic fish study does not need to be conducted as the results of the exposure calculations in the Chemical Safety Assessment do not indicate a relevant exposure to the aquatic environment. Therefore, no need for further testing can be identified."

68 In your comments to the draft decision you further state: *"(…) opportunities are available to registrants to minimise animal testing that need to be considered. Article 13(4) of REACH stipulates that toxicological and ecotoxicological tests shall be carried out in compliance with EU Directive 86/609/EEC on animal protection. (…) experiments on live animals shall not be performed if the results can be obtained by another scientifically satisfactory method. (…) Considering Annex XI Section 3 of Regulation (EC) No 1907/2006 (REACH), testing in accordance with Sections 8.6 and 8.7 of Annex VIII, Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report (3.1)."*

69 In your comments you also advance that *"[b]ased on the current results, fish is not the most sensitive species. We therefore disagree to conduct this vertebrate study, because it is not necessary for concluding on the aquatic toxicity of the substance*".

5.2. Assessment of the information provided

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

71 As already mentioned in section 4.2 above, the minimisation of vertebrate animal testing is not on its own a legal ground for adaptation. In case of a data gap ECHA has no administrative discretion whether or not to require the information required by the REACH Reguation.

72 As explained in section 0. above (Reasons common to several requests) your adaption is rejected. On this basis, the information requirement is not fulfilled.

73 With regard to the additional argument about the most sensitive species we finally note that at present no compliant information on short-term toxicity to aquatic invertebrates is provided in the IUCLID dossier. Therefore, no conclusion on the sensitivity of aquatic species can currently be made, as there is no reliable information on the hazardous properties of the Substance on at least three trophic levels. ECHA Guidance on IR and CSA, Chapter R.7b (Section R.7.8.5.3) further highlights that there should be compelling evidence to suggest that the fish value is likely to be at least a factor of about 10 less sensitive than invertebrates or algae to conclude that there are no further requirements for long-term fish toxicity testing.

5.3. Study design and test specifications

74 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.).

75 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' in section 1.3 above.

6. Simulation testing on ultimate degradation in surface water

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

6.1. Information provided

77 You have adapted this information requirement by using Annex XI, Section 3.2. To support the adaptation, you have provided following information: "*In accordance with REACH Annex XI, No. 3.2. (Substance-Tailored Exposure-driven Testing), the study does not need to be conducted as the direct and indirect exposure of surface water is unlikely. Exposure to aquatic environment, including surface water and sediment, is considered negligible during manufacturing process, and further processing of the substance MPAAU (CAS 84402-58-4, [redacted]), due to the fact that Risk Management Measures (RMM) are in place for wastewater incineration from manufacturing and processing of MPAAU. During the regular use of MPAAU fixed on technical textile surfaces ([redacted]) also no exposure to the aquatic environment is expected as no washing of such textiles is advised. The registrant shows within the attached Chemical Safety Report (CSR), covering all relevant exposure routes throughout the life cycle of the substance, that there are no unacceptable risks to the aquatic environment as all calculated RCR values are well below 1.*"

6.2. Assessment of the information provided

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

79 As explained in section 0. above (Reasons common to several requests) your adaption is rejected.

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

81 In your comments to the initial draft decision you agree with the request.

6.3. Study design and test specifications

82 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.

83 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.).

84 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.

85 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.

86 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)).

87 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.).

7. Identification of degradation products

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

7.1. Information provided

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

90 Therefore, this information requirement is not met.

91 In your comments to the initial draft decision you agree with the request.

7.2. Study design and test specifications

92 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.

93 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.

94 You must obtain this information from the degradation study requested in Request 6.

95 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 6) 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).

References

The following documents may have been cited in the decision.

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

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

Guidance on data-sharing; ECHA (2017).

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

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

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

The compliance check was initiated on 16 November 2021.

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

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

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

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

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

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

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

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

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

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[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