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Helsinki, 01 December 2022

Addressees
Registrant(s) of JS_117-08-8_Art10 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
19/12/2017

Registered substance subject to this decision ("the Substance")
Substance name: Tetrachlorophthalic anhydride
EC number: 204-171-4

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 ***9 March 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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

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

2. If negative results are obtained in test performed for the information requirement of requirement of Annex VII, Section 8.4.1.: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490);

3. Justification for an adaptation of a Short-term repeated dose toxicity (28 days) based on the results of the Sub-chronic toxicity study (90 days) requested below (Annex VIII, Section 8.6.1.);

4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats.

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

5. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats;

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

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

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

9. 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. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

10. 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 substance-tailored exposure-driven testing

0.2. Information provided

1 You have adapted the following standard information requirement(s) according to Annex XI, Section 3.2 (a) (b) (c) substance-tailored exposure-driven testing:

- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.).

2 However, you have adapted the following standard information requirement(s) without stating particularly which legal basis you refer to.

3 You have provided a justification for your adaptation in Section 7.8.1 and 7.8.2 of your dossier, and you conclude that "….Since the exposure throughout the life cycle of tetrachlorophthalic anhydride might take place only at one use site for an intermediate use and only at the bag discharge station with very short duration per activity (< 15 minutes) and with very strict RMMs and OCs which apply to the substance allocated to the high hazard category, the exposures to the workers are practically negligible. The protection level for a no threshold respiratory sensitizer like tetrachlorophthalic anhydride is very high, the implemented RMMs and OCs are very strict. At this high protection level, the other local and systemic effects shall be well prevented, if any. Also taking into consideration of animal welfare, the developmental toxicity study shall be omitted."

4 ECHA understands that you intend to apply a substance-tailored exposure-driven testing according to Annex XI, Section 3.2. (b) for the endpoints listed above. ECHA notes that option (a) is not applicable since you have not provided quantitative exposure and risk assessment in the registration dossier. Also option (c) is not satisfied since the substance is not incorporated in the article.

0.3. Assessment of the information provided

5 Under Annex XI, Sections 3(1) and (2), testing may be omitted based on the exposure scenario(s) developed in the chemical safety assessment (CSR) by providing an adequate and scientifically supported justification based on a thorough and rigorous exposure assessment.

0.3.1. Strictly controlled conditions not demonstrated

6 Under Annex XI, Section 3(2)(b), it must be demonstrated and documented for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply (see further Guidance on Intermediates (Version 2, December 2010) and Practical Guide 16).

7 You have not provided any evidence of strictly controlled conditions throughout the life cycle as set out in Article 18(4)(a) to (f). You have provided general operational conditions and risk management measures which should be applied for the Substance allocated to the "high hazard" band. You have performed measurements (inhalation exposure level 6-11 µg/m^3) both with air measurements and biomonitoring, but you have not included the

results to the exposure assessment. However, you have included inhalation monitoring results to the sections 7.8.1 and 7.8.2 without any contextual information to describe under which circumstances the measurements (sampling and analysis) were performed.

8 ECHA notes that all the tasks in the exposure scenarios (ES) are not performed under strictly controlled conditions (SCC) and exposure to the Substance is likely in PROCs 8b (bag discharge), 9 (sampling) and 28 (cleaning and maintenance). According to the ECHA Guidance Chapter R.5: Adaptation of information requirements (version 2.1 December 2011), for omitting standard information requirement thorough and rigorous exposure assessment should be performed and it should demonstrate absence of exposure or no significant exposure with a high level of confidence. In fact, the exposure measurements that you have included under both toxicological end points demonstrate that releases occur, and the conditions of use are not under the SCC.

9 Therefore, the use of the Substance under strictly controlled conditions is not demonstrated.

10 In addition, minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

11 Based on the above, your adaptations are rejected.

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Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

12 An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

13 You have provided:

(i) an *in vitro* gene mutation study in bacteria (OECD TG 471), with the Substance (1985)

1.2. Assessment of the information provided

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

14 To fulfil the information requirement, a study must comply with the OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101);

15 In study (i) described as an *in vitro* gene mutation study on bacteria:

a) the test was performed with the strains S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (i.e., the strain *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101) is missing);

16 The information provided does not cover the specification required by the OECD TG 471.

17 Therefore, the information requirement is not fulfilled.

1.3. Specification of the study design

18 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

Reasons related to the information under Annex VIII of REACH

2. In vitro gene mutation study in mammalian cells

19 An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

2.1. Triggering of the information requirement

20 Your dossier contains a negative result for an *in vitro* cytogenicity study in mammalian cells and inadequate data for gene mutation study in bacteria.

21 The *in vitro* gene mutation study in bacteria provided in the dossier is rejected for the reasons provided in request 1.

22 The result of the request 1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

~~23~~ Consequently, you are required to provide information for this information requirement, if the *in vitro* gene mutation study in bacteria provides a negative result.

2.2. Information provided

24 You have adapted this information requirement by using a Grouping of substances and read-across approach and provided the following information:

(i) *in vitro* gene mutation study in mammalian cells (OECD TG 476), with the source substance phthalic anhydride (EC 201-607-5) (2010);

25 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

26 Furthermore, ECHA understands that you have provided the following *in vivo* study to adapt this information requirement by using Annex VIII, Section 8.4.3., column 2. To support the adaptation, you have provided the following information:

(ii) Drosophila sex-linked recessive lethal (SLRL) assay (1985) with the Substance

2.3. Assessment of the information provided

27 We have assessed this information and identified the following issue(s):

2.3.1. Read-across adaptation rejected for study (i)

28 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

29 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

30 We have identified the following issue(s) with the prediction of toxicological properties:

2.3.1.1. Missing supporting information to compare the properties of the substances

31 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

32 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance cause the same type of effect. In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance.

33 For the source substance, you provide the study used in the prediction in the registration dossier. Apart from that study, your registration dossier does not include any robust study summaries or descriptions of data for the Substance that would confirm that both substances cause the same type of effects.

34 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

2.3.2. The provided adaptation does not meet the criteria of Annex VIII, Section 8.4.3., column 2

35 Under Annex VIII, Section 8.4.3., column 2, the study may be omitted if adequate data from a reliable in vivo mammalian gene mutation test are available. The Guidance on IRs and CSA, Section R.7.7.6.3. clarifies that the in vivo study must be a Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay (TGR), performed according to the OECD TG 488. This test investigates gene mutations using reporter genes.

36 The study (ii) is described as a Drosophila SLRL assay. This test detects the occurrence of mutations, both point mutations and small deletions, in the germ line of an insect. However, since this study was conducted in insects it does not investigate gene mutation in mammalian cells as the TGR.

37 Therefore, the requirements of Annex VIII, Section 8.4.3., column 2 are not met and your adaptation is rejected.

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

2.4. Specification of the study design

39 To fulfil the information requirement for the Substance, either the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Short-term repeated dose toxicity (28 days)

40 A short-term repeated dose toxicity study (28 days) is an information requirement under Annex VIII, Section 8.6.1. This information may take the form of a study record or a valid adaptation in accordance with either a specific adaptation rule under Column 2 of Annex VIII or a general adaptation rule under Annex XI.

3.1. Information provided

41 You have provided:

(i) A sub-chronic oral toxicity study in rat (OECD TG 408), with the Substance (1993);
(ii) A sub-chronic oral toxicity study in mouse (OECD TG 408), with the Substance (1993).

3.2. Assessment of the information provided

42 We have assessed this information and identified the following issue(s):

3.2.1. Study not reliable

43 Under Annex VIII, Section 8.6.1, Column 2, Paragraph 1, Indent 1, the study may be omitted if a reliable sub-chronic (90 days) or chronic toxicity study is available or proposed by the registrant, provided that appropriate species, dosage, solvent and route of administration are used.

44 The study (i) is described as an oral sub-chronic toxicity study. The study (ii) is also described as an oral sub-chronic toxicity study.

45 However, we have identified the following issue(s) with the studies:

46 The study (i) is not reliable as no NOAEL was identified. At lowest dose tested in this study, 94 mg/kg body weight/day, the following adverse effects were observed: microscopic kidney lesions in males and females. At higher doses (750 and 1500 mg/kg bw/day) dose-dependent increases in kidney weights and in the incidence and severity of renal tubule necrosis and/or dilation were observed.

47 The study (ii) is not reliable as based on the information from studies (i) and (ii), the mouse seems not to be the most sensitive species. In this study, no significant adverse effects were seen at any dose, up to 1500 mg/kg per day (top dose) whereas effects were seen at lower doses in the study (i) performed in the rat.

48 Therefore the rat is considered a more sensitive species than the mouse for this Substance.

49 The selection of the doses used in study (i) prevented the identification of a NOAEL for the most sensitive species, which is rat. On this basis, the study (i) is not considered reliable to fulfil the information requirement.

3.3. Specification of the study design

50 Annex VIII, Section 8.6.1., Column 2 provides that an experimental study for this information requirement is not needed if a reliable sub-chronic (90 days) or chronic toxicity study is available.

51 The present decision requests the registrants concerned to generate and submit a reliable sub-chronic toxicity study (90 days) (see request 5). According to Annex VIII, Section

8.6.1., Column 2 and to prevent unnecessary animal testing, a short-term toxicity study (28 days) does not therefore need to be conducted.

52 Because you still must comply with the information requirement in Annex VIII, Section 8.6.1., you are requested to submit a justification for the adaptation provided in Column 2 of that provision.

4. Screening for reproductive/developmental toxicity

53 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

4.1. Information provided

54 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing.

4.2. Assessment of the information provided

55 We have assessed this information and as explained in Reasons common to several requests section, the adaptation according to Annex XI, Section 3.2 is rejected.

56 Therefore, the information requirement is not fulfilled.

4.3. Specification of the study design

57 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

58 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

Reasons related to the information under Annex IX of REACH

5. Sub-chronic toxicity study (90-day)

59 A sub-chronic toxicity study (90 day) with the most appropriate route of administration is an information requirement under Annex IX, Section 8.6.2.

60 Annex IX, 8.6.2 column 2 sets the conditions whereby testing by the inhalation route are more appropriate than testing by the default oral route of administration.

61 Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

62 According to the ECHA Guidance on IRs and CSA, Section R.1.2.3.4, the oral route is the default route of administration for repeated-dose toxicity because it is assumed to maximise systemic availability of most substances. However, on a case-by-case basis, the appropriateness of other routes of administration should also be assessed. Testing by the inhalation route is the default route for gases and the preferred route for liquids of high to very high vapour pressure at ambient temperature (>25 kPa or boiling point below 50°C) for which inhalation is usually the predominant route of human exposure. For liquids of lower vapour pressure and for dusts (including nanomaterials), testing by the inhalation route is appropriate if human inhalation exposure is likely taking into account the possibility of exposure to aerosols, particles or droplets of an inhalable size (aerodynamic diameter below 100 µm).

63 Furthermore, characterisation of the relative bioavailability of a substance after exposure via the inhalation route compared to the default oral route is essential in order to determine the extent of the systemic exposure to the test item after inhalation exposure and to assess the adequacy of the information generated for the purpose of hazard identification.

64 According to the information provided in the dossier, the Substance is a solid in the form of prisms or needle and a mass median diameter is 110.0 µm (spherical volume) and 105.0 µm (cubical volume) with the vapour pressure of 1.65E-05 Pa at 25°C. As there is no spraying application under the conditions of use, the potential for exposure to aerosols or particles of an inhalable size is not likely. In addition, there is no information in your dossier on the relative bioavailability of the Substance after exposure via the inhalation route compared to the default oral route.

65 Based on this information, ECHA considers that the oral route is the most appropriate route of administration, and data in the registration dossier generated via the inhalation route is not considered to reliably inform on the systemic toxicity of the Substance after repeated exposure. Therefore, only the data generated via the oral route and included in the dossier is addressed in the following.

5.1. Information provided

66 You have provided:

(i) a sub-chronic oral toxicity study in rat (OECD TG 408), with the Substance (1993);
(ii) a sub-chronic oral toxicity study in mouse (OECD TG 408), with the Substance. (1993)

5.2. Assessment of the information provided

5.2.1. Study provided fails to identify a NOAEL

67 Under Annex IX, Section 8.6.2., Column 2, Paragraph 5, Indent 1, further studies may be required in case of failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects.

68 The study (i) is described as a sub-chronic oral toxicity study in rat. At lowest dose tested in this study, 94 mg/kg body weight/day, the following adverse effects were observed: microscopic kidney lesions in males and females. At higher doses (750 and 1500 mg/kg bw/day) dose-dependent increases in kidney weights and in the incidence and severity of renal tubule necrosis and/or dilation were observed.

69 In study (ii), described as sub-chronic oral toxicity study in mouse, no significant adverse effects were seen at any dose, up to 1500 mg/kg per day (top dose). Therefore the rat is considered a more sensitive species than the mouse for this Substance.

70 You have failed to identify a NOAEL for the most sensitive species, which is rat.

71 Without a NOAEL you do not have an adequate starting point for the risk assessment of the Substance. Therefore, an additional study is required to meet the information requirement.

5.3. Specification of the study design

72 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, and considering the guidance on IRs and CSA, Section R.7.5.6.3.2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance for the reasons listed above.

73 According to the OECD TG 408, the rat is the preferred species.

74 Your dossier studies conducted both in rats (study i) and mice (study ii). More severe effects were observed in rats compared to the mices. In order to not underestimate toxicity, ECHA considers that the study should be conducted in rats.

75 Doses selected for your study should be chosen in a way that allows to identify a NOAEL.

76 Therefore, the study must be performed in rats according to the OECD TG 408 with oral administration of the Substance.

6. Pre-natal developmental toxicity study in one species

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

6.1. Information provided

78 You have adapted this information requirement by using Annex XI, Section 3. (substance-tailored exposure-driven testing).

79 You have also provided a prenatal developmental toxicity study (OECD TG 414) as supporting study (1984) (study i).

6.2. Assessment of the information provided

80 We have assessed this information and identified the following issue(s):

6.2.1. Adaptation according to substance-tailored exposure-driven testing fails

81 As explained in Reasons common to several requests section, the adaptation according to Annex XI, Section 3.2 is rejected.

82 Therefore, the information requirement is not fulfilled.

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

83 To fulfil the information requirement, a study must comply with OECD TG 414 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the dams are examined for any structural abnormalities, weight and histopathology of the thyroid gland, thyroid hormone measurements, gravid uterus weight, and uterine content;

84 In study (i) described as a pre-natal developmental toxicity study:

a) data on the examination of the dams, including incidence and severity, are missing; in particular, the following investigations are missing:
   - macroscopical examination of organs for any structural abnormalities or pathological changes (special attention to reproductive organs) at necropsy,
   - Gravid uteri + cervix weights, thyroid gland weight at necropsy,
   - T4, T3 and TSH measurements

85 The information provided does not cover the specification(s) required by the OECD TG 414.

86 Therefore, the information requirement is not fulfilled.

6.3. Specification of the study design

87 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

88 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

89 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

7. Long-term toxicity testing on aquatic invertebrates

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

7.1. Information provided

91 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 justification: "According to column 2 of REACH Annex IX, long-term testing shall be proposed by the registrant if the Chemical Safety Assessment (CSA) indicates the need to investigate further the effects on aquatic organisms. As the CSA resulted in a PEC/PNEC-ratio below 1, the risk towards aquatic organisms is sufficiently controlled based on the available data and no chronic tests are required."

7.2. Assessment of the information provided

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

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

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

94 Your adaptation is therefore rejected.

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

7.3. Study design and test specifications

96 The Substance is difficult to test since it is hydrolytically unstable (hydrolysis half-life in purified water is below 5 minutes at room temperature within a pH range of 9 to 4). OECD TG 211 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. Considering that the Substance is rapidly hydrolysable, it is important to take into account the relative toxicities of the parent test chemical and hydrolysis products to determine the appropriate test design and test media preparation methods for the Substance. Taking the rapid hydrolysis of the parent substance into account, it may be difficult to achieve and maintain the desired exposure concentrations of the Substance or its hydrolysis products. Therefore, you must monitor the test concentration(s) of the Substance, or its hydrolysis products, throughout the exposure duration and report the results.

8. Long-term toxicity testing on fish

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

8.1. Information provided

98 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 justification: "According to column 2 of REACH Annex IX, long-term testing shall be proposed by the registrant if the Chemical Safety Assessment (CSA) indicates the need to investigate further the effects on aquatic organisms. As the CSA resulted in a PEC/PNEC-ratio below 1, the risk towards aquatic organisms is sufficiently controlled based on the available data and no chronic tests are required."

8.2. Assessment of the information provided

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

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

100 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment

according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

101 Your adaptation is therefore rejected.

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

8.3. Study design and test specifications

103 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.).

104 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design and test specifications' under Request 7.

9. Simulation testing on ultimate degradation in surface water

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

9.1. Information provided

106 You have adapted this information requirement by referring to Section 1 of Annex XI. To support the adaptation, you have provided the following justification: "In accordance with section 1 of REACH Annex XI, a simulation test to investigate biodegradation in water and sediment does not need to be conducted. A simulation test should provide data on biodegradation under specified environmentally relevant conditions. The non-degradation (0 % degradation after 28 days) in a study according to OECD Guideline 301 series provides sufficient information to confirm the slow degradation in the environment without the need for a further simulation test. No additional information would be obtained through that test."

9.2. Assessment of information provided

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

9.2.1. Your justification to omit the study does not refer to any adaptation possibility

108 Adapting the information requirement in accordance with the general rules for adaptation set out in Annex XI requires identifying clearly the specific legal basis of the adaptation invoked and complying with relevant conditions listed in the corresponding section of Annex XI. In all cases, adequate and reliable documentation must be provided, including relevant justification and study records.

109 You have not indicated any specific legal basis/section of Annex XI of REACH (e.g. 1.1. Use of existing data, or 1.2. Weight of Evidence, or 1.5. Grouping of substances and read-across approach) that you consider as a reason to adapt this information requirement.

110 In addition, no relevant justification nor documentation (e.g. study record) is provided for this endpoint in the IUCLID dossier.

111 You solely refer to the results of ready biodegradability studies, which inform on ultimate degradation and cannot be used to conclude on degradation in water as investigated in an OECD TG 309 study.

112 Therefore, you have not demonstrated that this information can be omitted.

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

9.3. Study design and test specifications

114 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.

115 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.).

116 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.

117 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. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

118 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.).

10. Identification of degradation products

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

120 You have provided information on the identity of the hydrolysis products, but no information on the identity of further transformation/biodegradation products for the Substance.

121 Therefore, this information requirement is not met.

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

10.1. Study design and test specifications

123 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You must obtain this information from the degradation study requested in Request 9.

124 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 9) 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 June 2021.

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

ECHA took into account your comments and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 24 to 30 months from the date of adoption of the decision. You justified your request based on the information you have received from two testing laboratories in relation with the toxicological studies on vertebrate animals requested in this decision.

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.

On this basis, ECHA has extended the deadline 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: 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;

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

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].

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