Helsinki, 07 November 2023

Addressees
Registrant(s) of 91001-64-8_292-835-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
16/09/2014

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C14-18 and C16-18-unsatd., 2-phenoxyethyl esters, maleated
EC number: 292-835-4

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 ***15 May 2028***.

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

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

1. Apply the harmonised classification and labelling of the constituents of the Substance to the Substance for STOT RE (Annex VI, Section 4.) or provide reasons for not classifying.

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

2. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211).

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

3. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210);

4. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; test method: EU C.25./OECD TG 309) at a temperature of 12°C;

5. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

6. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided;

7. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: using an appropriate test method: OECD TG 309, 308 or 307);

8. Bioaccumulation in aquatic species (triggered by Annex VIII, Section 9.3, column 2; in accordance with Annex XIII section 2.1; test method: EU C.13./OECD TG 305, aqueous exposure).

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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

How to comply with your information requirements

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

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4. In addition, the studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in this Appendix.

Appeal

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

Failure to comply

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

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

Appendix 1: Reasons for the 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)

Contents

Reasons related to the information under Annex VI of REACH

Under Article 10(a) of REACH, a technical dossier must contain information specified in Annex VI to REACH.

1. Apply the harmonised classification and labelling of the constituents of the Substance to the Substance for STOT RE (Annex VI, Section 4.)

1 Classification and labelling of the substance, resulting from the application of Title I, II and III of Regulation (EC) No 1272/2008 (CLP), is an information requirement as specified in Annex VI to REACH.

2 Your Substance is a UVCB, which contains [redacted] in its composition to which a harmonised classification applies.

3 According to ECHA's CLP Guidance[2] "*Substances may contain impurities, additives, or other constituents while still meeting the substance definition in CLP. This applies to both mono-constituent, multi-constituent (e.g. reaction masses) and UVCB substances. The classification of such impurities, additives or individual constituents may influence the classification of the substance, in addition to the other hazardous properties. If data on the substance with its components are not available (or for CMRs, see section 1.1.6.1), in principle, the same classification and labelling rules as for mixtures should apply also for such substances".*

4 Under Article 10(1) of CLP, "*Specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance or in a mixture as an identified impurity, additive or individual constituent leads to the classification of the substance or mixture as hazardous*".

5 Further, according to section 3.9.3.4.1. of Annex I to CLP a "*mixture shall be classified as a specific target organ toxicant (specific organ specified) when at least one ingredient has been classified as a Category 1 or Category 2 specific organ toxicant and is present at or above the appropriate generic concentration limit"* triggering classification. The concentration limits for classification of substances/mixtures as STOT RE Category 2 as a result of the presence in their composition of ingredients classified as STOT RE Category 1 are 1.0% ≤ concentration ≤ 10% (Table 3.9.4. of Annex I to CLP).

6 [redacted] is included in Annex VI to CLP as specific organ toxicant category 1 (H372, respiratory system, inhalation).

7 According to your registration dossier, your Substance is a UVCB, which contains [redacted] in its composition at a concentration ranging from [redacted]%, but you have not classified the Substance as STOT RE Category 2 (H372, respiratory system, inhalation) or provided any justification for the non-classification.

8 Based on the above, you are requested to classify your Substance as STOT RE Category 2 (H372, respiratory system, inhalation) or to provide reasons for not classifying. These reasons should be scientifically justified.

9 In your comments on the draft decision you indicate that although [redacted] is listed in the composition of the Substance, it is bound in the UVCB as maleate and should

[2] Guidance on the Application of the CLP Criteria, Section 1.1.7.2

therefore not be considered as influencing the properties of the Substance. You further elaborate on three specific points:

10 – the relevance of the inhalation route of exposure considering the viscosity of the substance and its very low vapour pressure. You point out that the section 3.9.2.2 of the CLP Regulation "*emphasises that only relevant routes of exposure and specific target organ toxicity from repeated exposure should be identified for STOT*";

11 – the scope of the STOT RE classification for [redacted] is limited to the respiratory tract after repeated and prolonged inhalation exposure. You consider that neither acute inhalation exposure nor potential repeated episodes of acute inhalation exposures are relevant for STOT RE classification;

12 – the substance has a very low vapour pressure. You conclude that negligible, if any, repeated inhalation exposure potential to the registered substance is anticipated and that worst-case estimations of exposure based on saturated vapour concentration would still yield exposure levels which are "*orders of magnitude below internally recognised short term as well as long term acceptable exposure limits*".

13 For these reasons, "*based on expert judgment and the weight of evidence, you consider it inappropriate to classify the registered substance as STOT RE 2*".

14 ECHA has assessed the information provided in your comments. According to the information provided in table 1. On Substance identity in the Chemical Safety Report, the composition of the substance includes [redacted]. This explicit reference to [redacted] contradicts your claim that [redacted] is completely bound in the composition of the substance as maleate.

15 Furthermore, Article 5(1) of the CLP Regulation states that "*Manufacturers, importers and downstream users of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I*". Hazard classification according to the CLP Regulation is based on the intrinsic hazardous properties of a substance or mixture and does not take into account exposure considerations. The Section 3.9.2.2 of the CLP Regulation that you refer to in your comments specifies that "*the relevant route or routes of exposure by which the classified substance produces damage shall be identified*". The object of section 3.9.2.2 is therefore different from considering that only hazards associated with relevant routes of exposure based on the conditions of use reported for a Substance need to be considered for classification and labelling purposes.

16 The request included in this decision is to classify the Substance as STOT RE 2 via the inhalation route based on the presence in its composition of [redacted], classified as STOT RE Category 1, in concentrations exceeding the threshold for classification set in Table 3.9.4. of Annex I of the CLP Regulation. This request for classification is independent of the potential of the uses of the Substance reported in the registration dossiers to give rise to exposure via the inhalation route. It addresses the intrinsic properties of the Substance. Therefore the justification for not classifying the Substance that you have provided in your comments is not considered as adequate and the information gap remains.

Reasons related to the information under Annex VII of REACH

2. Long-term toxicity testing on aquatic invertebrates

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

2.1. Triggering of the information requirement

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

19 You have provided information in your dossier that indicates the Substance includes constituents that are poorly water soluble. You have indicated that "*Computer modelling ((WSKOWWIN, Version 1.41, U.S. Environmental Protection Agency) indicated a water solubility of much less than 1 mg/L for representative constituents of the test material*." In your comments on the draft decision you provide an additional summary of estimated water solubilities based on QSAR calculations (using WSKow and Water NT modules from EPISuite v.4.11) for 15 representative structures for compounds that you state are '*the most likely reaction products and by-product/residuals of the registered UVCB*' which includes constituents of the Substance. The results indicate water solubilities of <1 mg/L in all cases, and <0.1 mg/L in almost all cases.

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

21 In your dossier you provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance. In your comments on the draft decision you state that '*multi-generational aquatic toxicity studies on the UVCB show no effects at water saturation for algae, invertebrates and fish*'. However, you do not provide any long-term or multi-generational aquatic toxicity studies on invertebrates or fish with the Substance in your comments on the draft decision.

22 The information requirement for long-term testing on aquatic invertebrates is therefore not met by data on the Substance from the dossier or by information provided in your comments.

2.2. Information provided in your comments on the draft decision on technical feasibility and aquatic toxicity predictions

23 In your comments on the draft decision you do not agree to conduct the the long-term toxicity test on aquatic invertebrates for the following reasons:

(1) You state that it is not technically feasible to conduct the test and,

(2) aquatic toxicity predictions for the Substance indicate no concern for T

24 These comments are addressed below.

2.2.1. Assessment of the information provided in your comments on technical feasibility

25 In your comments on the draft decision you do not agree to conduct the long-term toxicity test on aquatic invertebrates because you state that it will be technically not feasible to conduct the test due to the very low water solubility of the Substance and the difficulties with analytically measuring the UVCB in water. You state in your comments that the feasibility of the study will be assessed by first investigating the test solution stability in daphnid media and the ability to detect concentrations below 1 mg/L. You state that if testing is not technically possible, a relevant waiver will be included in the dossier.

26 Under Section 2 of Annex XI, a study may be omitted if it is not technically possible to conduct the study as a consequence of the properties of the substance (Annex XI, Section 2).

27 OECD GD 23 and Guidance on IRs and CSA R.7.8, including Appendix R.7.8-1 and Table R.7.8-3, provide practical guidance on accomplishing testing with difficult to test substances including guidance on approaches that can be used for substances with poor water solubility and UVCBs. In order to demonstrate that OECD TG 211 is technically not feasible, you must provide evidence that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish the testing so that reliable results can be generated.

28 In your comments on the draft decision you have simply stated that the test will not be technically feasible to conduct due to the very low water solubility of the Substance and the difficulties associated with analytically measuring the UVCB in water. ECHA acknowledges that the Substance is difficult to test. However, you do not provide any evidence that you have attempted the approaches outlined in OECD GD 23 and Guidance on IRs and CSA R.7.8, including Appendix R.7.8-1 and Table R.7.8-3. Therefore, you do not provide any evidence that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish the testing.

2.2.1.1. No supporting information provided for Annex XI Section 2 adaptation

29 In your comments on the draft decision you acknowledge that a waiver in accordance with Annex XI, Section 2 is not currently included in the dossier, and you do not provide an adaptation under Annex XI, Section 2 in your comments. You state that the feasibility of the study will be assessed and, if testing is not technically possible, a relevant waiver will be included in the dossier. Since no adaptation under Annex XI is provided in your dossier, or in your comments on the draft decision, no conclusion on the compliance of the proposed adaptation can currently be made.

2.2.2. Assessment of the information provided in your comments regarding aquatic toxicity predictions for the Substance

30 In your comments on the draft decision you provide a summary of the available long-term aquatic toxicity data for the main starting materials/reactants (hereafter referred to as the source substances) that are used in the manufacturing of the UVCB. You state that this information indicates the source substances show '*no concern for T of PBT*'. You further state that the Substance is expected to be less bioavailable than the source substances therefore it also poses no concern for T of PBT.

31 You do not provide detailed justification or supporting documentation to establish that the aquatic toxicity of the Substance can be reliably predicted from the source substances.

2.2.2.1. No supporting information provided for a read-across approach

32 You do not explicitly refer to an adaptation under Annex XI 1.5 in your comments. However, since you seek to predict the long-term aquatic toxicity properties of the Substance based on the long-term aquatic toxicity information available for the source substances, we have assessed this information provided in your comments in the understanding that you intend to use a grouping and read-across approach according to Annex XI, section 1.5 of the REACH Regulation.

33 You propose to predict the long-term toxicity to aquatic invertebrates of the Substance based on studies on the following source substances, which are the starting materials used for the manufacture of the UVCB Substance i.e:

34 [redacted] You have not provided any justification to support the contention that data on the long term aquatic toxicity on invertebrates for these source substances can be used for the prediction of (eco)toxicological properties for the Substance.

35 We identify the following issues:

36 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 a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summaries of the source studies.

37 You have provided a only a simple table briefly summarising the results of long-term aquatic toxicity studies conducted with the source substances. You have not provided a hypothesis, explanation of the rationale for the prediction, or robust study summaries of the source studies. You have not provided documentation as to why this information is reliable and relevant for the prediction of long-term aquatic toxicity for the Substance.

38 In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substances.

39 Therefore, the information from the source substances submitted in your comments on the draft decision cannot be reliably used as information on long-term aquatic toxicity for the Substance.

2.2.2.2. Assessment of your comments regarding bioavailability

40 You have indicated in your comments that the Substance will have low aquatic toxicity due to low bioavailability and therefore poses no concern for T of PBT.

41 Annex VII section 9.1.1 column 2 states that the requirement for short-term toxicity testing in invertebrates can be adapted if there are factors indicating that short-term aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

42 The Guidance on IRs and CSA R.7.8.5 describes the molecular characteristics that can be used to assess whether aquatic toxicity is unlikely to occur due to the fact that the substance is unlikely to cross biological membranes. The issues that may be considered are those that also indicate low potential for bioaccumulation based on low bioavailability/hindered uptake (as described in Guidance on IRs and CSA R.11-4). The indicators of hindered uptake include large molecular size (Dmax > 17.4 Å and MW > 1100), Log Kow >10, and no chronic toxicity or uptake in mammals.

43 Annex VII section 9.1.1 column 2 is not a valid legal basis for adaptation for long-term toxicity testing on invertebrates. The Substance is poorly water soluble hence long-term aquatic toxicity testing is triggered under Annex VII section 9.1.1 column 2.

44 Furthermore, the Substance has constituents with molecular weights ranging from 100-500 and Log Kows of >4-6 for some constituents and >6.2 for some constituents based on the OECD TG 117. Hence the molecular sizes and Log Kows of the Substance do not meet the molecular characteristics associated with low likelihood to cross biological membranes. In your dossier (IUCLID dossier Section 7.1) you also acknowledge that some absorption and systemic availability of the Substance cannot be entirely discounted because a number of its components have Log Kows ≤ 4.1 and molecular weights of ca. 100 or ca. 370 to <500 and because some dermal absorption after topical administration has been concluded from an irritation response (increased ear thickness) and a dose-related sensitization response attained in a Local Lymph Node Assay (LLNA) in mice. Therefore long-term aquatic toxicity cannot be excluded based on a lack of bioavailability as the Substance has constituents that do not meet the characteristics indicating low potential to cross biological membranes, and there is evidence of uptake and absorption from a skin sensitization study on the Substance. The Substance is therefore expected to be bioavailable and long-term aquatic toxicity cannot be excluded.

45 Finally, the requirement for long-term testing under AVII section 9.1.1 is triggered for poorly water soluble substances and this information requirement does not require a coincident concern for PBT. Nevertheless, the Substance is a potential PBT/vPvB (as described in Request 4) hence further information is required on all PBT criteria to conclude on the PBT/vPvB properties of the Substance.

46 In conclusion, you have not provided adequate evidence that the test is technically not feasible to conduct, nor have you provided information in your dossier or in your comments that meets the information requirement for long-term toxicity on aquatic invertebrates for this poorly water soluble Substance. On this basis, the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

47 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

48 The Substance is difficult to test due to the low water solubility (< 1 mg/L), and due to the adsorptive properties of some major constituents (LogKoc > 5.6). 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. 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 211. 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.

49 For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

50 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is

mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);

- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

Reasons related to the information under Annex VIII of REACH

3. Long-term toxicity testing on fish

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

3.1. Triggering of the information requirement

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

53 As already explained in Request 2, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

54 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance. Therefore, the information requirement is not fulfilled.

3.2. Information provided in your comments on the draft decision regarding technical feasibility and unlikely exposure

55 In your comments on the draft decision you do not agree to conduct the long-term toxicity testing on fish for the following reasons:

(1) You state that it is not technically feasible to conduct the test, and

(2) pelagic organisms are unlikely to be exposed to the Substance.

56 These comments are addressed below.

3.2.1. Assessment of your comments regarding technical feasibility:

57 In your comments on the draft decision you state that the long-term toxicity testing on fish will be technically difficult to conduct due to the very low water solubility of the Substance and the difficulty measuring the UVCB in water. You state that the conduct of the test should be dependent on first investigating the test solution stability in fish media and the ability to detect the Substance. Your comments regarding the technical feasibility of long-term aquatic toxicity testing have already been addressed under Request 2. As already explained under Request 2, you do not provide any evidence that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish long-term aquatic toxicity testing.

58 In your comments on the draft decision you acknowledge that a waiver for long-term fish toxicity testing in accordance with Annex XI, Section 2 is not currently included in the dossier, and you do not provide an adaptation under Annex XI, Section 2 in your comments. You state that the feasibility of the study will be assessed and, if testing is not technically possible, a relevant waiver will be included in the dossier. Since no adaptation under Annex XI is provided in your dossier, or in your comments on the draft decision, no conclusion on the compliance of the proposed adaptation can currently be made.

3.2.2. Assessment of your comments regarding the statement that pelagic organisms are unlikely to be exposed

59 In your comments on the draft decision you state that pelagic organisms are unlikely to be exposed to the Substance via the water phase due to its very low water solubility and relatively high ranges for Log Kow and Log Koc, and because you state that the Substance will be biodegraded and removed during sewage treatment.

60 You do not refer to any legal basis for adaptation in this comment. However, we understand that you may consider this a justification to omit the long-term fish toxicity study based on on exposure considerations according to Annex XI, Section 3 of REACH regulation.

61 However you provide no supporting information with this comment.

62 ECHA identifies the following issues for completeness:

63 From the comments on the draft decision ECHA understands that you intend to adapt this information requirement under substance-tailored exposure-driven testing according to Annex XI, Section 3.2(a).

64 ECHA has therefore evaluated your adaptation under Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing).

65 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 3.2.(a),(b) or (c). In particular:

66 3.2 (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.;

(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 ECHA Guidance R.10.3.

(iii) the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

67 In the comments on the draft decision, you state that pelagic organisms are unlikely to be exposed to the Substance via the water phase due to its very low water solubility and relatively high ranges for Log Kow and Log Koc, and because the Substance will be biodegraded and removed during sewage treatment. You do not provide an exposure assessment in your dossier or in your comments on the draft decision. You state in the CSR that environmental exposure was not assessed since the substance is not classified for environmental hazards. You have therefore not provided a rigorous exposure assessment in accordance with Annex I, Section 5 to support an adaptation under Annex XI Section 3, as required by Annex XI s.3.2(i).

68 Furthermore, the use pattern of the substance includes uses by professional workers in the following products types:

- PC 9a: Coatings and paints, thinners, paint removers
- PC 18: Ink and toners

69 These product categories are associated with the following process categories/techniques for workers:

- PROC 10: Roller application or brushing;
- PROC 11: Non industrial spraying;
- PROC 13: Treatment of articles by dipping and pouring

70 These uses of the Substance are associated with the following environmental release categories:

- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

71 Releases of the Substance to the environment from widespread uses by professional workers cannot be controlled to the same degree as uses in controlled industrial settings. Based on the above use pattern, direct or indirect releases to the environment can be expected.

72 Annex XI Section 3(a)(ii) stipulates that the PNEC used in the risk assessment must be based on reliable data from at least three trophic levels.

73 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do not give a true measure of toxicity for this type of substances and the long-term tests are required for a reliable hazard assessment, including PNEC derivation. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7., Section R.7.8.5).

74 In your registration dossier, you provide the following aquatic toxicity studies for the Substance: algal growth inhibition, short-term toxicity to fish and short-term toxicity to aquatic invertebrates. Furthermore, you provide a water solubility data that confirms the water solubility of the Substance is <1 mg/L.

75 Short-term aquatic toxicity tests are considered inadequate to assess the hazards of poorly water soluble substances and long-term aquatic toxicity testing is therefore required for this Substance. Currently, there are no reliable long-term aquatic toxicity test results available for aquatic invertebrates and for fish (Requests 2 and 3). Therefore, reliable data from at least three trophic levels is not available for the derivation of a reliable PNEC. Therefore you do not provide a reliable data from three trophic levels to support an adaptation under Annex XI Section 3, as required by Annex XI s.3.2(ii).

76 Therefore your adaptation under Annex XI Section 3 is rejected.

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

3.3. Study design and test specifications

78 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.).

79 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 2.

4. Simulation testing on ultimate degradation in surface water

80 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

4.1. Triggering of the information requirement

81 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301F);
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5).

82 Your registration dossier provides the following:

- the Substance is not readily biodegradable (35% degradation after 28 days in OECD TG 301F);
- the Substance has a high potential to partition to lipid storage (Log K_{ow} >4-6 for some constituents and above 6.2 for some constituents based on OECD TG 117).

83 Furthermore:

- it is not possible to conclude on the toxicity of the Substance, see Requests 2 and 3 of this decision.

84 Based on the above, the available information on the Substance indicates that it is a potential PBT/vPvB substance.

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

86 Your registration dossier does not include any information on aerobic and anaerobic transformation in surface water. Therefore, the information requirement is not fulfilled.

4.2. Information provided in your comments on the draft decision

87 In your comments on the draft decision you request that all requirements for simulation and bioaccumulation studies are removed from the decision because; (a) you consider the Substance is not P, (b) you consider that the testing is not appropriate as the Substance has very low water solubility and because exposures are not expected, (c) you expect there will be technical feasibility issues and, (d) you propose an alternative testing approach. You further state that if all the simulation tests are not removed then at least the surface water study (OECD TG 309) should be removed. To support this position you provide the following:

a) A weight of evidence assessment concluding that the Substance is not persistent according to Annex XI 1.2. (weight of evidence).

b) You provide an adaptation for the surface water study under Annex IX 9.2.1.2 column 2 stating that the substance is highly insoluble in water and that direct or indirect exposure of the aquatic environment is unlikely.

c) You state that the surface water study is not relevant to the Substance based on the very low water solubility and that it will be technically not possible to

conduct the study which ECHA understands to be an adaptation under XI section 2 (technically not possible).

d) You provide a proposed alternative tiered testing strategy starting with enhanced ready biodegradation studies and further assessments of water solubility prior to conducting the simulation studies. You state that based on the results of the water solubility studies the most soluble constituent could be identified and the simulation testing conducted on this constituent. You state that if it is concluded the surface water study is not technically feasible to conduct you will consider conducting the soil simulation study (OECD TG 307) and the sediment simulation study (OECD TG 308).

88 We have assessed the information provided in your comments on the draft decision and identified the following issues:

4.2.1. In regard to your weight of evidence approach concluding inherent biodegradability and therefore not P

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

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

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

92 You indicate in your comments that you have provided a weight of evidence to support the argument that the Substance is inherently biodegradable and therefore not persistent, hence simulation studies should not be required. In support of your adaptation you provide the following:

(i) Results of one experimental study on the Substance (OECD TG 301F) showing 35% degradation in 28 days which you state demonstrates the Substance '*is inherently biodegradable and not persistent'*.

(ii) A statement that the Substance '*is composed of natural fatty acids and other constituents that are readily biodegradable*'.

(iii) A reference to a US EPA 2022 document which you indicate states that >40% degradation in a ready biodegradability test '*probably represents nearly complete ultimate biodegradation*'.

Based on these sources of information you state there is sufficient evidence to conclude the Substance is not P.

93 Regarding the statement (i) that the results of OECD TG 301F can be used to conclude the Substance is inherently biodegradable and not persistent:

94 The Guidance on IRs & CSA R.7.9.4 & R.7.9.5 in Chapter R.7b; and Table 11.2 and Figure 11.3, and R.11.4.1.1.1 from Chapter R.11, provide guidance on the screening level information that can be used to assess the inherent biodegradability and P/vP properties of

a substance. Conclusions on inherent biodegradability may be based on inherent biodegradability tests (i.e. OECD TG 302 tests) or enhanced ready biodegradability studies as long as certain testing conditions, as specified in Chapter R.7b, are met. For example, >70% degradation in a Zahn-Wellens test (OECD TG 302B) within 7 days, or >70% degradation within 14 days in a MITI II test (OECD TG 302C) indicate inherent biodegradability and hence unlikely P/vP. A result showing >60% ultimate biodegradability (ThOD, CO2 evolution) or >70% ultimate biodegradability (DOC removal) in an enhanced ready biodegradability test indicates inherent biodegradability and hence unlikely P/vP.

95 You do not provide any results from inherent biodegradability tests or enhanced ready biodegradability tests. You have based your assessment of inherent biodegradability on the results of ready biodegradability testing showing 35% degradation in 28 days (OECD 301F) a result that indicates the Substance is potentially P/vP. The OECD 301F study is relevant to the assessment of the biodegradability of the Substance since it indicates that the Substance is not readily biodegradable, however, the results of this study cannot be used to conclude on inherent biodegradability or the P/vP properties of the Substance.

96 Annex XIII Section 3.2 lists the information considered in the assessment of P/vP properties when screening information indicates the substance may have PBT/ vPvB properties. Annex XIII Section 3.2.1 (a-c) states that the results (i.e. degradation half-life) from water, soil and sediment simulation studies must be used to compare against the P/vP criteria stipulated in Annex XIII Sections 1.1.1 and 1.2.1 (e.g. substance fulfils the P criteria if degradation half-life >40 days in fresh or estuarine water). In your dossier, and in your comments, you do not provide simulation studies with the Substance under relevant environmental conditions hence it is not possible to conclude on P/vP properties of the Substance.

97 Regarding the statement (ii) that the Substance is mostly composed of fatty acids and other constituents that are all readily biodegradable:

98 The results of the OECD TG 301F study (35% degradation) provides evidence that the Substance is not composed of constituents that are all readily biodegradable. Furthermore, as already addressed under Request 2, you have not provided adequate evidence or justification that the properties of the Substance can be reliably predicted from the source substances used to manufacture the Substance which are fatty acids and [redacted]. This line of evidence is therefore unreliable.

99 Regarding your reference (iii) to a US EPA 2022 document which you provide as evidence that >40% degradation in a ready biodegradability test '*probably represents nearly complete ultimate biodegradation*':

100 The US EPA 2022 document is an interim guidance document that is relevant to the selection of specific input parameters for multi-media models including waste water treatment (WWT) models. This guidance is designed to be used when degradation half-lives for compartments are unavailable, and other ways must be found to obtain the required model inputs. The US EPA cautions the user that there remain substantial scientific uncertainties in the suggested estimation methods and that the methods in the guidance remain largely unvalidated. US EPA acknowledges that among the assumptions is that intermediate results from a ready or inherent test can be used to derive intermediate half-lives, and it is unclear that this is reasonable and that the specific numbers suggested as cut-points (e.g., 40% of theoretical ultimate degradation in the ready test) were selected '*based on judgment and may not be the best for present purposes*'. This interim guidance document therefore does not provide reliable nor relevant evidence for the purpose of concluding on P/vP properties of the Substance according to REACH Annex XIII.

101 In conclusion, in your weight of evidence, you provide one experimental study of relevance to the assessment of the biodegradability of the Substance which indicates the Substance

is a potential P/vP substance. Your other lines of evidence are general comments which are considered unreliable and not relevant to concluding on the P/vP properties of the Substance.

102 It is therefore not possible to conclude based on any single source of information alone, or considered together, whether or not the Substance has or has not the particular dangerous property foreseen to be investigated in the requested simulation studies.

103 Your weight of evidence adaptation is therefore rejected.

4.2.2. Regarding your adaptation to omit the surface water study based on your proposed use of the adaptation possibility under Annex IX 9.2.1.2 column 2 (highly insoluble) and your statement that direct or indirect exposures are unlikely

104 You propose to use the adaptation possibility under Annex IX 9.2.1.2 column 2 first indent (highly insoluble) and you state that direct and indirect exposure is unlikely. It should be noted that the likelihood of exposures is not an adaptation possibility under Annex IX 9.2.1.2 column 2. In addition, Annex IX 9.2.1.2 column 2 is not an adaptation possibility at Annex VIII when testing is triggered based on AVIII column 2 due to potential PBT/vPvB concern.

105 As explained in Guidance on IRs and CSA R.11.4, testing to conclude on potential PBT/vPvB concern triggered at Annex VIII cannot be omitted unless the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. Annex XI Section 3.2(b) requires that the Substance is used throughout the lifecycle under strictly controlled conditions, and (c) requires that the Substance not released during the lifecycle.

106 You have not provided an adaptation under Annex XI section 3.2 (b) or (c) and you do not provide a rigorous exposure assessment demonstrating that the Substance is used throughout the lifecycle under strictly controlled conditions, or that the Substance not released during its lifecycle. Furthermore, as already explained under Request 3, the use pattern of the Substance, which includes widespread uses by professional workers, indicates that releases of the Substance to the environment can be expected to occur. Therefore, direct or indirect exposures of the aquatic environment can be expected.

107 Your adaptation is therefore rejected.

4.2.3. Regarding adaptations to omit the surface water study based technical feasibility considerations and on the relevance of the surface water study

108 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance.

109 Guidance on IRs and CSA R.11.4.1.1.1 states that the OECD TG 309 is the preferred test to start persistency assessment. If another test is selected, or it is proposed to omit the surface water study, this should be justified, based on the following:

- Aquatic testing is not technically feasible i.e. it can be demonstrated that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated. Appropriate analytical methods should have a suitable sensitivity and be able to detect relevant changes in concentration (including that of metabolites). Generally, when water solubility of a substance is very low (typically below 1 µg/L),

testing on sediment (OECD TG 308) and/or soil (OECD TG 307) may be needed instead of a pelagic test (OECD TG 309);

- The aquatic compartment is not considered relevant at all, and there are compartment specific concerns for the sediment and soil compartments, including indications from available data (e.g. literature) suggesting that persistence is likely to occur in a different environmental compartment (i.e. in soil or sediment).

110 We have assessed your comments and note the following issues:

- Based on the information in the dossier the water solubility of the Substance is <1 mg/L for some constituents and <0.01 mg/L for other constituents. The available information indicates that some constituents of the UVCB have water solubilities >1µg/L and indicates that conduct of the surface water simulation study is technically feasible. You do not provide any evidence to demonstrate that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated. According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. Any technical difficulties to perform the test and the considered solutions must be clearly documented. However, your claim is not supported by any substance-specific justification or any documented evidence.

- The aquatic compartment is considered to be a relevant environmental compartment since, by default, the water compartment receives significant amount of emissions directly or indirectly, and transports/distributes the substance through e.g. deposition and run-off (unless based on the fate and release(s) of the substance, it is considered that the water compartment is not a relevant environmental compartment at all). Once entering water, a substance may stay there for very long time and be spread over long distances before it reaches other environmental compartments (via environmental transport, partitioning and distribution processes) such as sediments or (via air) the soil compartment. In addition, particularly for lower water solubility substances which tend to be adsorptive, the OECD TG 309 (with a default concentration of suspended solids of 15 mg dw/L) minimizes potential NER formation. If NER is formed at significant levels in the OECD TGs 307 and 308 studies, this can be difficult to interpret and compare with degradation half-lives criteria of Annex XIII to the REACH Regulation (ECHA Guidance R.11.4.1.1.1). You have not demonstrated that the water compartment is not a relevant compartment at all. For these reasons, based on the information provided in the dossier and in your comments, the conditions for omitting the surface water study are not fulfilled and the information from the OECD TG 309 is relevant for the Substance.

111 Your adaptation under Annex XI section 2 is therefore rejected.

4.2.4. Regarding your proposed alternative testing strategy using additional biodegradability screening and water solubility testing

112 You propose to conduct enhanced ready biodegradability testing, and additional water solubility testing, on the Substance prior to conducting any simulation testing.

113 You state that you may use the results of the additional water solubility testing to select the most soluble constituent for simulation testing. Guidance on IRs & CSA, Section R.

11.4.1 states that regardless of whether full substance identification is possible or not for the whole composition, the registrant should make efforts for carrying out a PBT/vPvB assessment for all constituents, impurities and additives present in concentrations above 0.1% (w/w). Section R.11.4.2.2 provides further insight into how to carry out PBT/vPvB assessment for fractions of the substance. Where representative constituents, or groups/blocks of constituents, are selected for PBT/vPvB testing these should represent the worst case for PBT-properties. The approaches chosen must be adequately documented and justified.

114 Your comments on the draft decision do not provide any new data on the biodegradation of the Substance. Your proposed strategy relies essentially on data which is yet to be generated, therefore it cannot yet contribute to conclusions on the compliance of the registration dossier.

115 Furthermore, in regards to the sequence of testing: As stated in Appendix 4 (Section 2) of this decision you are advised to consider the intrinsic properties of the Substance, and its identified uses and release patterns, when determining the sequence of simulation degradation testing. You may therefore choose to conduct simulation studies starting with the worst case scenarios for persistence, with appropriate justifications. In cases where the substance is adsorptive, and releases to surface water are expected to be limited, starting with simulation testing in the sediment/soil compartments may be justified. However, based on the information provided in the dossier, and in your comments on the draft decision, the water compartment cannot be considered as not relevant at all and still warrants investigations in an OECD TG 309, as indicated above. The deadline in this decision allows adequate time for sequential testing.

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

4.3. Study design and test specifications

117 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.

118 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.).

119 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.

120 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.

121 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)).

122 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.).

5. Soil simulation testing

123 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

5.1. Triggering of the information requirement

124 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

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

126 Further, the Substance has high adsorption coefficient (log $K_{oc,soil}$ above 5.6), indicating high potential to adsorb to soil.

127 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

128 Your registration dossier does not include any information on aerobic and anaerobic biodegradation in soil. Therefore, the information requirement is not fulfilled.

5.2. Information provided in your comments on the draft decision

129 In your comments on the draft decision you seek to adapt this information requirement as follows:

(i) You seek to adapt this information requirement using Column 2 of Annex IX, Section 9.2.1.3. To support the adaptation, you have provided following information: "the study does not need to be conducted because direct and indirect exposure of soil is unlikely"

(ii) ECHA understands that you also seek to adapt this information requirement by using Annex XI, Section 2 (testing not technically possible). To support the adaptation, you have provided the following infromation: "*There is no certainty that a sufficient level of sensitivity can be reached…putting the feasibility of the*

test into question. A radiolabeled material would be needed …however… the synthesis of a representative UVCB will not be feasible."

130 We have assessed your comments and note the following issues:

131 Annex IX, Section 9.2.1.3., Column 2 is not an adaptation possibility at Annex VIII when testing is triggered based on AVIII column 2 due to potential PBT/vPvB concern. As explained in Guidance on IRs and CSA R.11.4, testing to conclude on potential PBT/vPvB concern triggered at AVIII cannot be omitted unless the process and use conditions of the substance meet the conditions as specified in Section 3.2(b) or (c) of Annex XI, and subsequently the substance is considered as if it is a PBT or vPvB in the registration dossier. Annex XI Section 3.2(b) requires that the Substance is used throughout the lifecycle under strictly controlled conditions, and (c) requires that the Substance not released during the lifecycle.

132 You have not provided an adaptation under Annex XI section 3.2 (b) or (c) and you do not provide a rigorous exposure assessment demonstrating that the Substance is used throughout the lifecycle under strictly controlled conditions, or that the Substance not released during its lifecycle. Based on the use pattern of the Substance an adaptation under Annex XI Section 3.2 (b) or (c) would not be accepted.

133 In any case, exposure is not unlikely based on the information provided in your technical dossier. The use pattern of the substance includes uses by professional workers in the following products types:

- PC 9a: Coatings and paints, thinners, paint removers
- PC 18: Ink and toners

134 These product categories are associated with the following process categories/techniques for workers:

- PROC 10: Roller application or brushing;
- PROC 11: Non industrial spraying;
- PROC 13: Treatment of articles by dipping and pouring

135 These uses of the Substance are associated with the following environmental release categories:

- ERC8c: Widespread use leading to inclusion into/onto article (indoor)
- ERC8f: Widespread use leading to inclusion into/onto article (outdoor)

136 Releases of the Substance to the environment from widespread uses by professional workers cannot be controlled to the same degree as uses in controlled industrial settings. Based on the above use pattern, direct or indirect releases to the environment, including exposure of soils, cannot be excluded.

137 Your CSA does not contain an exposure assessment and you have not provided documentation regarding the releases of the Substance to environmental compartments during the life cycle of the Substance.

138 Consequently, information provided in the dossier indicates potential release to the environment and you have not demonstrated with the appropriate documentation that there is no release to the environment at any stage in the life cycle of the substance.

139 Based on the information in your technical dossier an adaptation under Annex XI Section 3.2 (b) or (c) would not be accepted.Furthermore, since the use pattern of the Substance indicates that direct or indirect releases to the environment can be expected the requirements for an adaptation under Annex IX 9.2.1.3 column 2 are also not met.

(iii) The provided adaptation (ii) does not meet the criteria of Annex XI, Section 2. (testing not technically possible)

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

141 You claim that there is no certainty that sufficiently sensitive analytical methods suitable for the Substance can be developed and that a radiollabeled test material cannot be prepared.

142 However, your claim is not supported by any substance-specific justification and documented evidence.

143 The OECD TG 307 provides no particular restriction regarding the testing of UVCB substances nor does it require mandatory use of radiolabelled test materials.

144 You do not provide any considerations with regards to the feasibility of the study using non-radiolabelled test material.

145 Therefore, your adaptation under Annex XI, Section 2 is rejected.

146 Furthermore, in your comments on the draft decision you state that simulation testing is not required as the Substance is not P, you then propose to generate additional data via screening tests (enhanced biodegradability testing, technical feasibility investigations) prior to conducting simulation testing. As already explained above under Request 4, the Substance is a potential P/vP Substance and your proposed additional testing strategy relies essentially on data which is yet to be generated, therefore it cannot yet contribute to conclusions on the compliance of the registration dossier.

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

5.3. Study design and test specifications

148 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.

149 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

150 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 307.

151 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options

to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

152 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

6. Sediment simulation testing

153 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

6.1. Triggering of the information requirement

154 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

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

156 Further, the Substance Substance has high adsorption coefficient (log $K_{oc,soil}$ above 5.6), indicating high potential to adsorb to sediment.

157 Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

158 Your registration dossier does not include any information on aerobic and anaerobic biodegradation in sediment. Therefore, the information requirement is not fulfilled.

6.2. Information provided in your comments on the draft decision

159 In your comments on the draft decision you state that simulation testing is not required as the Substance is not P, you then propose to generate additional data via screening tests (enhanced biodegradability testing, water solubility testing, technical feasibility investigations) prior to conducting simulation testing. You indicate that you expect technical difficulties in conducting the simulation tests.

160 As explained above under Request 4, the Substance is a potential P/vP Substance and your proposed additional testing strategy relies essentially on data which is yet to be generated, therefore it cannot yet contribute to conclusions on the compliance of the registration dossier.

161 Your comments regarding the potential problems expected with technical feasibility of conducting the simulation tests are not supported by any substance-specific justification or documented evidence. You do not provide any evidence to demonstrate that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing in surface water so that reliable results can be generated. According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. As already addressed under Request 4, any technical difficulties to perform the test and the considered solutions must

be clearly documented. However, your claim is not supported by any substance-specific justification or any documented evidence.

162 Hence, your adaptation to omit simulation tests based on potential technical feasibility issues under Annex XI, Section 2 is rejected.

163 On this basis, the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

6.3. Study design and test specifications

164 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.

165 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

166 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

167 In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

168 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 308; Guidance on IRs and CSA, Section R.11.4.1.).

7. Identification of degradation products

169 Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

7.1. Triggering of the information requirement

170 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (Guidance on IRs and CSA, Section R.11.4.).

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

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

173 Your registration dossier does not include any information on degradation products identity. Therefore, the information requirement is not fulfilled.

7.2. Information provided in your comments on the draft decision

174 In your comments on the draft decision you state that the identification of degradation products is not required as the Substance is inherently biodegradable and not P. You also indicate that it is not technically feasible to identify and characterise the degradation products of the Substance.

175 As already explained above under Request 4, the Substance is a potential P/vP Substance, and you do not provide any evidence to demonstrate that it has been impossible, with allocation of reasonable efforts, to develop suitable analytical methods and other test procedures to accomplish testing so that reliable results can be generated.

176 On this basis, the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

7.3. Study design and test specifications

177 You must obtain this information from the degradation studies requested in requests 4-6.

178 To determine the degradation rate of the Substance in OECD TG 309 (request 4) the test 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).

179 To determine the degradation rate of the Substance in the requested studies according to OECD TG 308 and 307 (requests 5 and 6) the tests must be conducted at 12°C and at test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

180 Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation studies requested in Requests 4, 5 and 6 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

8. Bioaccumulation in aquatic species

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

8.1. Triggering of the information requirement

182 Therefore, this information requirement is triggered if 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. As already explained in Request 4, the Substance is a potential PBT/vPvB substance.

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

184 Your registration dossier does not include any information on bioaccumulation. Therefore, the information requirement is not fulfilled.

8.2. Information provided in your comments on the draft decision

185 In your comments on the draft decision you state that bioaccumulation testing is not needed as you consider that the Substance is inherently biodegradable (hence you conclude not P), has low potential to cross biological membranes, and because direct and indirect exposure of the aquatic compartment is unlikely. Based on this you seek to adapt the information requirement based on Annex IX 9.3.2, column 2 whichstates that bioaccumulation testing under Annex IX need not be conducted if the Substance has a low potential for bioaccumulation based on Log Kow (e.g. <4.5) and/or low potential to cross biological membranes, or if direct and indirect exposure of the aquatic environment is unlikely. You further state that if bioaccumulation continues to be requested in the decision you will conduct the studies for potential persistence first before concluding on the need for bioaccumulation testing.

186 Annex IX 9.3.2, column 2, is not a valid legal basis to adapt the information requirement for bioaccumulation testing under Annex VIII, Section 9.3, column 2. Furthermore, the Substance does not meet the requirements for an adaptation under Annex VIII, Section 9.3, column 2 for the following reasons:

- As already addressed under Request 4 the Substance is a potential PBT/vPvB Substance and has high potential for bioaccumulation based on Log Kow (>4-6 for some constituents, and >6 for other constituents).
- In addition, as already addressed under Request 2, the potential for the Substance to cross biological membranes cannot be excluded based on current information.
- In addition, exposure cannot be excluded as you do not provide a rigorous exposure assessment, or any other detailed justification or evidence, to establish that direct and indirect exposure of the aquatic environment is unlikely. The use pattern of the Substance (including uses by professional workers) indicates that environmental releases can be expected.

187 Furthermore, as already explained under Request 4 the information requirements for PBT/vPvB assessment, including simulation and bioaccumulation tests, cannot be adapted under Annex XI section 3 unless the requirements of Annex XI Section 3.2 (b) and (c) are met (i.e. that throughout the life-cycle the Substance is used 'as if it is a PBT/vPvB' and that strictly controlled conditions apply). You provide no evidence that the requirements of

Annex XI Section 3.2 (b) and (c) are met. Furthermore, the the use pattern of the Substance (including uses by professional workers) indicates that strictly controlled conditions cannot apply throughout the lifecycle.

188 Your adaptation under Annex IX, 9.3.2, column 2 is therefore rejected, and an adaptation under Annex XI section 3 would not be accepted.On this basis, the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

189 To determine the sequence of testing for PBT/vPvB properties refer to Appendix 4, section 2.1.

8.3. Study design and test specification

190 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.

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

192 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 (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

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

The compliance check was initiated on 08 December 2021.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. Additionally, it has been exceptionally extended by 12 months from the standard deadline normally set 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 your comments into consideration and did not amend the requests.

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).

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[3].

(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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as

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

far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

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[4].

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 in Appendix 1.

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