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Helsinki, 01 June 2023

Addressees
Registrant(s) of 701-314-7_JS_EM_LR as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11/05/2022

Registered substance subject to this decision ("the Substance")
Substance name: Alkenes, C6-11 (branched), hydroformylation products, distn. residues, heavy cracked fraction
EC/List number: 701-314-7

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 ***8 December 2026***.

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

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

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

2. Soil simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

3. Sediment simulation testing also requested below (triggered by Annex VIII, Section 9.2.)

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

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

5. 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.

6. Soil simulation testing (Annex IX, Section 9.2.1.3.; 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.

7. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

8. Identification of degradation products (Annex IX, 9.2.3.; test method: EU C.23./OECD TG 307 or EU C.24./OECD TG 308 or 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.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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

How to comply with your information requirements

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

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

Appeal

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

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

[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.

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Appendix 1: Reasons for the decision

Contents

0. Reasons common to several requests

0.1. Assessment of your adaptation based on Column 2 for the standard information requirements on degradation under Annex IX, Section 9.2

1 Similar considerations are relevant for the application of the information requirements on Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.), Soil simulation testing (Annex IX, Sections 9.2.1.3.), on sediment simulation testing (Annex IX, Sections 9.2.1.4.) and on Identification of degradation products (Annex IX, Sections 9.2.3.) which are therefore addressed here, before addressing endpoint-specific issues in the relevant Appendix.

2 For all of these requirements you have provided an adaptation with justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2. In support of your adaptation, you provided the following justification: "*In accordance with column 2 of REACH Annex IX, The Biodegradation in water and sediments simulation test, (required in Section 9.2.1.2 and 9.2.1.4) does not need to be conducted as the chemical safety assessment according to Annex I does not indicate the need to investigate further the degradation of the substance and its degradation products*."

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

4 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose or ECHA to require biotic degradation testing not covered by the standard information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on Soil simulation testing, Sediment simulation testing and Identification of degradation products required under Annex IX, Sections 9.2.1.2-4 and 9.2.3., Column 1.

5 Therefore, your adaption is rejected.

0.2 Assessment of your adaptation under Annex XI, section 1.2 provided in the comments to the draft decision and update of the registration dossier

6 In the comments to the draft decision and update of the registration dossier you have provided an adaptation by using Annex XI, section 1.2 (weight of evidence (WoE)) for the following information requirements:

- Simulation testing on ultimate degradation in surface water;
- Soil simulation testing;
- Sediment simulation testing;
- Identification of degradation products (triggered by Annex VIII, Section 9.2 and standard information requirement at Annex IX, Section 9.2.3.).

7 In the justification of WoE you refer to the Guidance R.11 and assessment strategies recommended there, and you summarise "*that the fraction, or "block" profiling approach is*

most scientifically appropriate for evaluating the registered substance". To support the adaptation, you have provided following information:

(i) Experimental (standard and enhanced) ready biodegradability studies on the Substance;
- Study according to OECD TG 301F (2010, 60 days "*test with non-adapted and pre-exposed inoculum*");
- Study according to OECD TG 301F (1997; 28 days test).

(ii) Experimental data on ready biodegradability of the "representative constituents" of the Substance and of test materials structurally similar to constituents of the Substance;
- Study according to OECD TG 301F with Alcohols, C8-10-iso-, C9-rich (2015; 28 days test).
- Study according to OECD TG 301F with Alcohols, C8-10-iso-, C9-rich (2012; 28 days test).
- Study according to OECD TG 301B with Isobutylaldehyde bis-(2-ethylhexyl)-acetal (1995; 28 days test).
- Study according to OECD TG 301B with Dioctyl Ether (Capryl Ether; 1,1-oxydioctane) (28 days test; study summary not reported in the registration dossier; you note that "*Reliable guideline studies are reported within the ECHA portal*").
- Study according to OECD TG 301D with Dioctadecyl Ether (1,1-oxydioctane) (28 days test; study summary not reported in the registration dossier; you note that "*Reliable guideline studies are reported within the ECHA portal*").

(iii) Predictions of degradation potential (ready biodegradability, inherent biodegradability and primary degradation half-lives) by QSAR models (Catalogic, BioWin);

(iv) Assessment of metabolic pathways (predictions by EAWAG BDD-PPS, Catalogic models); and

(v) Results of quantitative exposure and risk assessment which as noted by you "*can help to identify the compartments most likely to experience exposure to the substance*".

8 We have evaluated the provided information and identified following issues:

9 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.

10 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.

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

12 Relevant information that can be used to support a weight of evidence adaptation includes similar information that is produced by the OECD TGs 307, 308 and 309. These test guidelines require the study to investigate and determine the following key elements:

a) the rate of (aerobic and/or anaerobic) transformation of the test material in natural surface water, four soil types and at least two sediments, respectively; and
b) the identity and rates of formation and decline of transformation/degradation products.

0.2.1. Relevance of the information provided

13 ECHA acknowledges that assessment and testing strategies based on use of representative 'fractions' and/or 'constituents', as recommended in Guidance R.11, are relevant for the degradation and persistence assessment for the complex substances containing multiple constituents with diferent chemical structures and/or functional groups.

14 The sources of information (i), (ii) and (iii) provide relevant information on ready biodegradability. While this does not directly determine the key elements mentioned above, as explained in Guidance documents R.7b and R.11, if the substance (its constituents) are readily biodegradable the simulation test will provide little additional information since rapid mineralisation in the environment is already assumed. Also degradation products of the substance (its constituents) will not need to be assessed because any such products can be assumed to be minimal and transient.

15 The source of information (iv) provides relevant information on the identity and rates of formation and decline of transformation/degradation products. However, the source of information (v) does not provide information neither on any of key elements investigated and determined in OECD TGs 307, 308 and 309 nor on ready biodegradability.

16 Furthermore, primary half-lives, which reflect rates of primary transformation, provided in the source of information (iii) are not relevant for the key element (a) investigated in OECD 307, 308 and 309 test guidelines as explained in section 0.2.1.1. below.

0.2.1.1. Relevance of predictions of half-lives by Catalogic 301F kinetic Model (v.13.16)

17 A (Q)SAR model should be associated with a defined endpoint, that can be measured and therefore modelled. The intent of this principle is to ensure transparency in the endpoint being predicted by a given model, since a given endpoint could be determined by different experimental protocols and under different experimental conditions. Furthermore, a (Q)SAR model should be associated with a defined domain of applicability. The need to define an applicability domain expresses the fact that (Q)SARs are reductionist models which are inevitably associated with limitations in terms of the types of chemical structures, physico-chemical properties and mechanisms of action for which the models can generate reliable predictions.

18 In the WoE justification document you reported primary half-lives in surface water, soil and sediment predicted by Catalogic 301F kinetic Model (v.13.16).

19 The Catalogic 301F kinetic Model (v.13.16) predicts degradation under OECD 301F test conditions (as noted in the Catalogic model manual), i.e. under conditions applied in standard ready biodegradability test. As explained in ECHA Guidance on IR and CSA, Chapter R.11, in principle, degradation simulation studies performed in appropriate environmental media and at environmentally realistic conditions are the only tests that can provide a definitive degradation half-life that can be compared directly to the persistence criteria as defined in REACH Annex XIII.

20 Therefore, Catalogic 301F kinetic Model (v.13.16) does not predict half-lives which are estimated as outcome of analysis of the rate of (aerobic and/or anaerobic) transformation of the test material in natural surface water, four soil types and at least two sediments under conditions of OECD TGs 309, 307 and 308, respectively. Therefore, this information is not relevant for the key element (the rate of (aerobic and/or anaerobic) transformation of the test material) investigated in these test guidelines as well as estimated half-lives cannot be compared to the criteria listed in sections 1.1.1 and 1.2.1 of Annex XIII of REACH.

0.2.2. Reliability of the information provided

21 Moreover, the reliability of provided sources of information (ii), (iii), (iv) and (v) is significantly affected by the following deficiencies.

0.2.2.1. Coverage of selected representative structures

22 Information on the degradability of substances is required for hazard assessment (e.g. for classification and labelling), risk assessment and persistence assessments (for PBT/vPvB assessment). For complex mixtures or substances (i.e. UVCB or multi-constituent substances which are composed of constituents expected to show different degradation kinetics) information on degradability of constituents is needed for the hazard (Guidance on the Application of the CLP Criteria, Sections 1.1.6.1 and II.3.1), persistence (Annex XIII) and exposure/risk assessments (e.g. Guidance R.7c, Appendix R.7.13-1).

23 More specifically, according to Annex XIII the identification of PBT/vPvB substances shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation and/or degradation products.[2] As further explained in ECHA Guidance on IR and CSA, Chapter R.11 the assessment based on known constituents can be applied when these constituents are suspected based on available information to represent the worst case of the (v)P, (v)B and T properties of all constituents of the substance and/or of respective fractions of the substance. It is further noted that degree and/or site of branching may have an impact on the PBT properties of constituents.

24 In the WoE justification document you note that "*there is no clear constituent or block of the substance which indicates, through screening level information data that there is evidence of PBT or vPvB properties thereby clearly representing a "worst case" scenario for PBT / vPvB properties for the UVCB substance and as such may be confidently used as a representative constituent for further testing and assessment*". Then you identified "*three groups of structures*" and explain that for the PBT/vPvB assessment "*two to four structures were selected to represent the range of the most abundant structures within the group.*"

25 In the WoE justification document you report 14 representative structures which are used in the WoE approach by predicting degradation potential and pathways, bioaccumulation potential and performing risk assessment for these selected structures. These structures include a number of branched alcohols, ethers and acetals.

26 You do not however provide documentary evidence (e.g. supporting analytical information) that would support that the selected constituents (e.g. considering the degree and sites of branching) represent the worst case for the assessment of (v)P, (v)B and/or T properties of all constituents from various fractions of the Substance.

[2] As also explained in section 2 of Appendix 4 to this decision, there are various assessment and testing strategies recommended and available for the PBT/vPvB assessment including degradation, persistence assessment. For the PBT/vPvB assessment any of constituents of the substance present in concentration ≥ 0.1% (w/w) have to be considered. For complex substances, a single screening or definite test may not be sufficient to rule out concern on the hazard property (e.g. persistence) or to conclude on that property and therefore, considering all the information available to reduce the need for testing multiple tests might be necessary.

27 Without understanding limits of potential variations of relevant constituents and impact of these variations on the (v)P, (v)B and T properties, it is not possible to conclude that the selected single constituents are representative of all constituents of the Substance (of respective "*groups of structures*") and to exclude relevant constituents of higher concern for the PBT/vPvB assessment are present in the Substance, to avoid bias.

28 Therefore, the available information on degradation provided in your registration dossier and in your comments, does not allow to rule out that the Substance, any of its constituents or relevant transformation/degradation products are potentially persistent or very persistent.

0.2.2.2. Lack of documentation of the prediction by EAWAG BDD-PPS model (source of information (iv))

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

- the model prediction(s), including the endpoint.

30 In the WoE justification document and registration dossier you provided predictions of transformation pathways from the EAWAG BBD-PPS model for four representative constituents (source of information (iv)).

31 The information you provided about the prediction lacks the information on selections made in the model before running it, i.e. the degradation pathways displayed are not complete and it is not explained what and why has been pre-selected before running the model. Moreover, it is not explained why the transformation pathways are displayed to a certain level (maximum 7).

32 In absence of such information, ECHA cannot establish that the prediction can be used to meet information requirement on identification of degradation products.

0.2.2.3. Lack of documentation of the prediction by Catalogic 301F kinetic Model (v.13.16) (source of information (iii))

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

- the relationship between the modelled substance and the defined applicability domain,
- the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

34 In the WoE justification document you provided predictions of degradation percentage in 60 days by Catalogic 301F kinetic Model (v.13.16) for representative constituents (source of information (iii)).

35 However, you have not provided information about the prediction listed above. In absence of such information, ECHA cannot establish that the prediction is reliable for the use in the weight of evidence.

36 Thus, based on deficiencies noted under section 0.2.2 above, sources of information (ii), (iii), (iv) and (v) do not provide sufficient reliable information on degradability of the Substance (i.e. its constituents).

0.2.3. Contradiction of the information provided with the conclusion of weight of evidence

37 Finally, information provided under lines of evidence (i) and (iii) contradicts with the conclusion of weight of evidence made by you.

38 As noted above, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. In order to provide sufficient weight to conclude on the corresponding information requirement provided results should be also consistent and support the conclusion of WoE.

39 In the WoE justification document you conclude that "*Experimental, QSAR, and other relevant evidence for the registered substance, and its representative & analogue constituents convincingly support ultimate and primary degradability in water, soil, & sediment compartments which do not exceed the bright line criteria for persistent (P) or very persistent (vP) as outlined in Annex XIII.*" Furthermore, you report experimental (screening level) degradation studies on the Substance and predictions of ready biodegradation potential for representative constituents by QSAR models (Catalogic 301F Kinetic Model (v.13.16) and BIOWIN (v.4.1.0).

40 You indicate that mineralisation of 33-51% in 28-60 days of the Substance has been detected in the ready biodegradability study with whole Substance, i.e. below ready biodegradability criterion of 60% in 28 days. Furthermore, QSAR predictions for representative constituents reported in the WoE justification document indicate that a number of representative constituents, mainly acetals, are predicted to be not readily biodegradable. E.g. representative structures 12-14 (acetals with carbon range between 24 and 30) are predicted as 'likely not readily biodegradable' by predictions of US EPA BioWin 3 and 4 Models (v.4.1.0).

41 This indicates that at least some of constituents of the Substance are not readily biodegradable and therefore, they screen as P/vP which contradicts with your conclusion that neither of constituents is P/vP.

0.2.4. Conclusion on weight of evidence

42 In summary, as explained above, the source of information (v) does not provide information relevant for key elements investigated and determined in OECD TGs 307, 308 and 309 or on ready biodegradability, and primary half-lives provided in the source of information (iii) are not relevant for the key element (a) investigated in OECD 307, 308 and 309 test guidelines. Furthermore, the sources of information (ii) to (v) do not provide sufficient reliable information on key elements investigated and determined in OECD TGs 307, 308 and 309 or on ready biodegradability. Finally, information provided under lines of evidence (i) and (iii) contradicts with the conclusion of weight of evidence made by you. Therefore, your adaptation is rejected.

43 While it has been already concluded that information provided under line of evidence (v) is neither relevant nor reliable, it should be further noted that for substances satisfying the PBT and vPvB criteria of Annex XIII a hazard assessment of long-term effects and the estimation of the long-term exposure cannot be carried out with sufficient reliability (Annex I, Section 4.0.1). As explained in section 1 below, the information from your dossier currently does not allow excluding that the Substance (its constituents and or degradation products) may be PBT/vPvB. Therefore, it is not possible yet to conclude on reliability of quantitative risk characterisation based on hazard and exposure predictions for the constituents of the Substance which is used to support the conclusion that simulation testing in sediment and soil can be omitted.

0.3 Other issues raised in the comments to the draft decision

44 While you did not submit an adaptation referring to technical impossibility under Annex XI, Section 2, in the comments to the draft decision you note that "*from an experimental perspective, available high tier tests designed to be environmentally relevant using low concentrations of test substance often result in technical limitations associated with identifying degradation/transformation products. Thus, even if the simulation studies requested by the ECHA were performed by the registrant, it is uncertain that they would provide reliable and complete information on degradation products.*"

45 ECHA acknowledges your comment, however there is no documentary evidence (e.g. results of preliminary testing, details of analytical method development and limitations encountered etc.) provided which would justify that the identification of degradation products by the requested test method(s) is not technically feasible. As explained in section 8.3 below, there are possible adaptations allowed to the design of tests performed according to OECD TGs 307, 308 and 309 to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products.

Reasons related to the information under Annex VIII of REACH

1. Simulation testing on ultimate degradation in surface water

46 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).

47 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 (ECHA Guidance 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.* <60/70% degradation in an OECD 301), and
- 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).

48 Your initially evaluated registration dossier provided the following:

- The Substance is not readily biodegradable which is indicated by the supporting experimental ready biodegradability study provided in the registration dossier (33% degradation after 28 days in OECD TG 301F).

49 The key experimental study provided in the registration dossier (OECD TG 301F) cannot change this conclusion.

50 Indeed, the specifications of the OECD TG 301 include that the inoculum is not be pre-adapted to the test material. ECHA Guidance R.7b, section R.7.9.4.1 explains that use of pre-adapted inoculum is not deemed acceptable enchancement from the regulatory perspective for vPvB/PBT assessment, for classification and labelling and for exposure assessment.

51 In the key study, however, the inoculum was pre-adapted to the test material.

52 Thus, at least some constituents screen as P/vP and therefore, the Substance is potentially P/vP. Information provided in the comments to the draft decision and update of the registration dossier are addressed in the section 0.2 above and is not sufficient to conclude on (not) persistence of constituents of the Substance.

- The Substance has a high potential to partition to lipid storage as most of its constituents have log Kow > 4.5. Furthermore, ECHA Guidance R.11, section R.11.4.1.2.6 notes that "*an indication of a biomagnification potential (BMF and/or TMF > 1) can on its own be considered as a basis to conclude that a substance meets the B or vB criteria*". Non-standard guideline experimental dietary bioaccumulation study reported in the dossier resulted in the biomagnification factor (BMF) of 1.43 (dimensionless) for the Substance. Thus, the Substance is potentially B/vB.

53 In the comments to the draft decision and update of the registration dossier you have provided predictions of bioconcentration factors (BCFs) by QSAR models (Arnot-Gobas (BCFBAF, Episuite) and CAESAR (VEGA)) for 14 representative constituents of the

Substance and predicted degradation products. ECHA has assessed provided information and identified following issues:

54 A) Coverage of selected representative structures

55 As explained in the section 0.2.2.1. above, without understanding limits of potential variations of relevant constituents and impact of these variations on the (v)P, (v)B and T properties, it is not possible to conclude that the selected single constituents are representative of all constituents of the Substance (of respective "*groups of structures*"). Therefore, it is not possible to exclude that constituents of higher concern for bioaccumulation assessment specifically and for the PBT/vPvB assessment in general are present in the Substance.

56 B) Lack of documentation of the prediction

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

- the relationship between the modelled substance and the defined applicability domain.

58 The information you provided about the prediction lacks the information on the relationship between the modelled substance (constituents) and the defined applicability domain. Therefore, reliability of the prediction cannot be established which does not allow to consider this prediction for the PBT/vPvB assessment.

59 Therefore, the available information on bioaccumulation provided in your registration dossier and in your comments, does not rule out that the Substance, any of its constituents or relevant transformation/degradation products are potentially B/vB.

60 Based on the above, the available information on the Substance indicates that the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

61 The examination of the available information or adaptations, of comments to the draft decision, as well as the selection of the requested test and the test design are addressed respectively in Request 5 below.

2. Soil simulation testing

62 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).

63 As explained in the reasons for Request 1, the Substance is a potential PBT/vPvB substance.

64 The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has high adsorption coefficient (log K_{OC} > 4.0) reported for the most of its constituents, indicating high potential to adsorb to soil.

65 Therefore, the CSA indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil represents a relevant environmental compartment.

66 The examination of the available information or adaptations, of comments to the draft decision, as well as the selection of the requested test and the test design are addressed respectively in Request 6 below.

3. Sediment simulation testing

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

68 As explained in the reasons for Request 1, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation.

69 The Substance has high adsorption coefficient (log K_{oc} > 4.0) reported for the most of its constituents, indicating high potential to adsorb to sediment. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

70 The examination of the available information or adaptations, of comments to the draft decision, as well as the selection of the requested test and the test design are addressed respectively in Request 7 below.

4. Identification of degradation products

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

72 As already explained in the reasons for Request 1, the Substance is a potential PBT/vPvB substance. Therefore, the CSA indicates the need for further degradation investigation.

73 The examination of the available information or adaptations, of comments to the draft decision as well as further information on the selection of the approach to generate this information are addressed in the reasons for Request 8 below.

Reasons related to the information under Annex IX of REACH

5. Simulation testing on ultimate degradation in surface water

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

5.1. Information provided

75 Initially, you have provided an adaptation with justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2.

76 In the comments to the draft decision and update of the registration dossier you have further provided an adaptation by using Annex XI, section 1.2 (weight of evidence).

5.2. Assessment of the information provided

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

78 As explained in the Appendix on Reasons common to several requests, and sections 0.1 and 0.2 thereof in particular, your adaptions are rejected.

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

5.3. Specification of the study design

80 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.

81 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.).

82 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.

83 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.

84 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.).

6. Soil simulation testing

85 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

86 As already explained in Section 2, the Substance has high potential to adsorb to soil.

6.1. Information provided

87 Initially, you have provided an adaptation with justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2.

88 In the comments to the draft decision and update of the registration dossier you have provided an adaptation by using Annex XI, section 1.2 (weight of evidence).

6.2. Assessment of the information provided

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

90 As already explained in above sections 0.1 and 0.2 of the Appendix on Reasons common to several requests, your adaptions are rejected.

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

6.3. Specification of the study design

92 Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

93 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).

94 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

95 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 (ECHA Guidance 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) (ECHA Guidance 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.

96 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; ECHA Guidance R.11.4.1.).

7. Sediment simulation testing

97 Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

98 As already explained in the reasons for Request 3, the Substance has high potential to adsorb to sediment.

7.1. Information provided

99 Initially, you have provided an adaptation with justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2.

100 In the comments to the draft decision and update of the registration dossier you have provided an adaptation by using Annex XI, section 1.2 (weight of evidence).

7.2. Assessment of the information provided

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

102 As explained in sections 0.1 and 0.2 of the Appendix on Reasons common to several requests, your adaptions are rejected.

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

7.3. Specification of the study design

104 Simulation degradation studies must include two types of investigations (ECHA Guidance 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.

105 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.

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

107 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 (ECHA Guidance 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) (ECHA Guidance 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.

108 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; ECHA Guidance R.11.4.1.).

8. Identification of degradation products

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

8.1. Information provided

110 Initially, you have provided an adaptation with justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2. In the comments to the draft decision and update of the registration dossier you have provided an adaptation by using Annex XI, section 1.2 (weight of evidence).

8.2. Assessment of the information provided

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

112 As explained in sections 0.1 and 0.2 of the Appendix on Reasons common to several requests, your adaptions are rejected.

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

8.3. Specification of the study design

114 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.

115 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 1 and 5) 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).

116 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308/307 (Requests 2-3 and 6-7) 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).

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 07 April 2021.

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

You have provided comments during the decision-making phase which were found address the incompliance with Annex X, Section 8.7.2., identified in the draft decision. Therefore the original request for a pre-natal developmental toxicity study (test method: OECD TG 414) was removed.

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

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

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

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]

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 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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). 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.

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

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