~~Confidential~~

Helsinki, 24 November 2022

Addressees
Registrants of Amines, C10-14-tert-alkyl as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/05/2021

Registered substance subject to this decision ("the Substance")
Substance name: Amines, C10-C14-tert-alkyl
EC/List number: 701-175-2

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 ***29 November 2027***.

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

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

1. 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.)

5. Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.)

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

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

7. 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.

8. 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.

9. 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.

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

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

12. Long-term toxicity testing on terrestrial invertebrates (triggered by Annex IX, Section 9.4.1., column 2; test method: EU C.33/OECD TG 222 or EU C.32/OECD TG 220 or EU C.35/OECD TG 232)

13. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

14. Long-term toxicity on terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

The reasons for the requests 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

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

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

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VIII of REACH

1. Simulation testing on ultimate degradation in surface water

1 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).

1.1. Triggering of the information requirement

2 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 301D),
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

3 Your registration dossier provides the following:

- the Substance is not readily biodegradable (22% degradation after 28 days in OECD TG 301D);
- the Substance is an ionisable surfactant and therefore high potential for bioaccumulation cannot be excluded based on available information;

4 Furthermore, the information in your dossier is currently incompliant and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 11 of this decision), and
- it is not possible to conclude on the toxicity of the Substance see Request 6 of this decision).

5 In your comments to the draft decision, you disagree that the "*Substance potentially meets the T criterion of PBT*" and you state that "*Both the chronic fish study (OECD TG 210) and the alga growth study (OECD TG 201) provided in the dossier have NOEC values >0.01 mg/L. Further, the Substance has not been classified as either carcinogenic, mutagenic, as a reproductive toxicant, or STOT RE 1 or 2*".

6 ECHA acknowledges that the currently available information does not qualify the Substance to be regarded as T. However, as already explained above, it is not yet possible to conclude on the toxicity of the Substance as the information requirement detailed under Request 6 is not met.

7 Under section 2.3 of your IUCLID dossier and section 8 of your CSR ('PBT assessment'), you conclude that the Substance is not P/vP or B/vB. In support of your conclusion you provide the following additional information:

i. you consider that the limited degradation observed in the available ready

biodegradability study "*was a function of some degree of toxicity of the test material to the activated sludge microorganisms*". You consider "*that numerous have shown that when these aliphatic amines are tested for biodegradability at test concentrations at environmentally realistic concentrations (i.e., mg/L) which are typically below the toxicity threshold, that biodegradation does occur*". You also refer to other publications which you consider supportive of "*the biodegradability of branched aliphatic hydrocarbons*". You refer to the QSAR predictions provided under section 5.2 of your IUCLID dossier for a single putative isomer of the substance. You consider that the results of Biowin 2, 3 and 6 support that the whole substance is expected to biodegrade fast. You consider that taken together this information support that the substance is not persistent.

In your comments to the draft decision, you agree that the available data do not demonstrate that the Substance failed to meet the readily biodegradability criteria due to inoculum toxicity. You also agree with a preliminary conclusion of potentially P, and that additional studies are needed.

ii. you consider that the log Kow value determined for the Substance (i.e., 2.9) supports a low potential for bioaccumulation of the Substance. You refer to the equation by [redacted] (1979) and [redacted] (1998), which both use log Kow as the sole input parameter, and consider these QSAR support low bioaccumulation potential in both fish and earthworms. Based on this information you conclude that the Substance does not meet the B/vB criteria.

In your comments to the draft decision, you agree that log Kow is not a valid descriptor for assessing the bioaccumulation potential of ionizable substances. You propose a stepwise approach to clarify the B potential of the Substance as further described under Request 11.

1.2. Assessment of the information in relation to the triggering

8 ECHA has identified the following issues with your justification:

a) As specified in paragraph 25 of OECD TG 301, if in a toxicity test, containing both the test substance and a reference compound, less than 35% degradation (based on total DOC) or less than 25% (based on total ThOD or ThCO2) occurred within 14 days, the test substance can be assumed to be inhibitory. Further, as specified in Annex II of OECD TG 301, if inhibition due to toxicity is to be avoided, the test substance concentrations used in ready biodegradability testing should be less than 1/10 of the EC50 values (or less than EC20 values) obtained in toxicity testing (e.g., OECD TG 209).

In the key and supporting ready biodegradability study conducted with a non-adapted inoculum either no toxicity control is reported or it showed >25 % degradation based (based on total ThOD or ThCO2) within 14 days. In Section 6.1.7 of your IUCLID dossier, your report a study according to OECD TG 209 on the Substance. The 30min-EC50 was determined to be 62.5 mg/L. In the key and supporting studies conducted according to OECD TG 301D, the substance was tested at a concentration of 2 mg/L.

Therefore, the results of available ready biodegradability studies do not demonstrate that the fact the Substance failed the ready biodegradability criteria due to inoculum toxicity. Further, the observation of inoculum toxicity in a ready biodegradability study is not a valid basis to exclude that the substance might be P/vP.

b) Results obtained from biodegradation (Q)SAR models are only regarded as screening information on P/vP properties (Annex XIII, Section 3.1.). QSAR predictions can also be used as part of a Weight-of-Evidence approach to support that the substance is not rapidly degradable and therefore potentially P/vP (Guidance on IRs and CSA, Section R.11.4.). However, as further explained in Guidance on IRs and CSA, Section R.11.4.1.1.4., such information is not considered sufficient on its own to conclude on non-persistence and must be supported by additional information (e.g., test data information, read-across). In every case, it must be verified that the QSAR model and predictions are reliable and applicable to the substance.

Under Section 5.2.1. of your dossier, you provide QSAR predictions based using Biowin for a single C12 isomer for the Substance. Based on this information, you conclude that the Substance as a whole is rapidly biodegradable and therefore does not meet the P/vP criteria. You have not provided adequate and reliable documentation in the form of a (Q)SAR Model Reporting Format document (QMRF) and a (Q)SAR Prediction Reporting Format document (QPRF). Your dossier does not contain any relevant additional information (e.g., test data information, read-across) to support your conclusion.

In the absence of adequate documentation, the reliability of the QSAR predictions cannot be subject to an independent assessment. Furthermore, you have not justified why the selected structure used for the prediction allows reaching a robust conclusion for the Substance. Finally, you have not provided any additional information in supporting the weight of evidence that the Substance does not meet the P/vP criteria.

c) For the reasons further explained under Request 11, considering the properties of the Substance, log Kow is not a valid basis to exclude that the Substance may be B/vB.

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

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

1.3. Information provided to fulfil the requirement

11 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2. You also provided a justification based on exposure considerations.

12 The examination of the proposed adaptations, as well as the selection of the requested test and the test design are addressed in Request 7.

2. Soil simulation testing

13 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).

2.1. Triggering of the information requirement

14 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.).

15 As already explained in Request 1, the Substance is a potential PBT/vPvB substance.

16 Further, the Substance has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to soil.

17 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.

2.2. Information provided to fulfil the requirement

18 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2. You also provided justifications based on exposure considerations.

19 The examination of the proposed adaptations, as well as the selection of the requested test and the test design are addressed in Request 8.

3. Sediment simulation testing

20 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).

3.1. Triggering of the information requirement

21 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.).

22 As already explained in Request 1, the Substance is a potential PBT/vPvB substance.

23 Further, the Substance has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to sediment.

24 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.

3.2. Information provided to fulfil the requirement

25 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.2., Column 2. You also provided justifications based on exposure considerations.

26 The examination of the proposed adaptations, as well as the selection of the requested test and the test design are addressed in Request 9.

4. Identification of degradation products

27 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

28 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.).

29 As already explained in Request 1, the Substance is a potential PBT/vPvB substance.

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

4.2. Information provided to fulfil the requirement

31 You have provided no information nor an adaptation for this information requirement.

32 Further information on the selection of the approach to generate this information are addressed in Request 10.

5. Bioaccumulation in aquatic species

33 Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

5.1. Triggering of the information requirement

34 This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (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.).

35 As already explained in Request 1, the Substance is a potential PBT/vPvB substance.

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

5.2. Information provided to fulfil the requirement

37 You have provided an adaptation under Column 2 of Annex IX, Section 9.3.2.

38 The examination of the proposed adaptation, as well as the selection of the requested test and the test design are addressed in Request 11.

Reasons related to the information under Annex IX of REACH

6. Long-term toxicity testing on aquatic invertebrates

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

6.1. Information provided

40 You have omitted this information requirement based on the following justification: "The risk characterization shows that the PEC/PNEC aqua ratio for the aquatic environment is <1, indicating no need for further information and testing".

41 ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3 ('by using substance-tailored exposure-driven testing') using the provisions specified under Section 3.2(a).

6.2. Assessment of the information provided

6.2.1. The Substance screens as PBT/vPvB and therefore the conditions of Annex XI, Section 3.2(a) cannot be demonstrated with sufficient reliability

42 Under Annex XI, Section 3.2(a), 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 if it can be demonstrated that all the following conditions are met:

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

43 However, for substances satisfying the PBT and vPvB criteria of Annex XIII, 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 a result, for such substances, PNEC and PECs cannot be derived with sufficient reliability to demonstrate that, the ratio between PECs and the PNEC are always well below 1 (conditions (a)(ii) and (iii) above). Consequently, such information cannot be used to demonstrate that no significant exposure occurs in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5 (condition (a)(i) above).

44 In section 10 of tour CSR, you report that the total releases to the environment per year for all life cycle stages are 2.05E3 kg/year, 2.7E3 kg/year and 2.27E3 kg/year for the water, air and soil compartment, respectively. Further as already explained under Request 1, the substance screens as PBT/vPvB

45 ECHA notes that the above information indicates that exposure of the environment does occur. In addition, for the reasons explained above, the information from your dossier, currently does not allow excluding that the Substance may be PBT/vPvB. Therefore, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable mean to demonstrate the absence of significant exposure of the environment. Therefore, the conditions set out to justify substance-tailored exposure-driven testing under Annex XI, Section 3.2(a) (i) to (iii) are not met.

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

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

6.3. Study design and test specifications

48 The Substance is difficult to test due to the high adsorption potential (ionisable under relevant environmental pH, log Koc > 4 based on OECD TG 121, surface tension < 60 mN/m based on EU method A.5). 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 solution.

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.

7. Simulation testing on ultimate degradation in surface water

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

7.1. Information provided

52 You have provided the following information:

i. a 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: you consider that the limited degradation observed in the available ready biodegradability study was "*due to toxicity issues to the microbial biomass at the concentrations necessary to comply with the guideline requirements*". You consider studies *"have shown that when these aliphatic amines are tested for biodegradability at test concentrations at environmentally realistic concentrations (i.e.,mg/L) which are typically below the toxicity threshold, that biodegradation does occur*". You also refer to other publications which you consider supportive of "*the biodegradability of branched aliphatic hydrocarbons*". You refer to the QSAR predictions provided under section 5.2 of your IUCLID dossier for a single putative isomer of the substance. You consider that the results of Biowin 2, 3 and 6 support that the whole substance is expected to biodegrade fast. You consider that taken together this information support that the substance is not persistent.

ii. You also state that "*all PEC/PNEC ratios are <1*". In relation to that statement, ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3 ('by using substance-tailored exposure-driven testing') using the provisions specified under Section 3.2(a).

7.2. Assessment of information provided

7.2.1. Annex IX, Section 9.1., Column 2 (see point i. above) is not a valid basis to omit the study

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

54 Therefore, your adaption is rejected.

7.2.2. The Substance screens as PBT/vPvB and therefore the conditions of Annex XI, Section 3.2(a) cannot be demonstrated with sufficient reliability (point ii. above)

55 For the reasons already explained under Request 6, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable mean to demonstrate the absence of significant exposure of the environment. Therefore, the conditions set out to justify substance-tailored exposure-driven testing under Annex XI, Section 3.2(a) (i) to (iii) are not met. Therefore, your adaption is rejected.

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

57 In your comments to the draft decision, you raise concerns about the technical feasibility of the requested study. In particular you state that "*According to OECD 309, the simulation tests are only applicable to non-volatile (< 1 Pa. m3 /mol) or slightly volatile (< 100 Pa. m3 /mol) substances, but not to highly volatile chemicals*". You then explain that "*Using tert-undecanamine (SMILES: CC(C)(C)CCCCCCCN; C11H25N) as an indicative substance and the vapour pressure and water solubility determined for EC 701-175-2, the Henry's Law constant is estimated to be 13.1 Pa.m³/mol (bond estimate method) or 23.7 Pa.m³/mol*

(group estimate method) in EpiSuite. Using CC(C)(C)CCCCCCCCCN (C13H29N), the Henry's Law constant is estimated to be 23 Pa.m³/mol (bond estimate method) or 47.2 Pa.m³/mol (group estimate method) in EpiSuite".

58 ECHA understands that you may intend to submit an adaptation under Annex XI, Section 2. Such adaptation should take into account the limitations of the corresponding method referred to in Article 13(3). ECHA notes that the information you report on Henry's Law constant indicates that the Substance is to be regarded as slightly volatile and therefore as falling in the applicability domain of the OECD TG 309. In the absence of a valid justification and of adequate experimental evidence, you have currently not demonstrated that the OECD TG 309 is not technically feasible.

59 which might support omitting the respective endpoints according to REACH Annex XI.

7.3. Study design and test specifications

60 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.

61 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.).

62 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.

63 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.

64 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.).

8. Soil simulation testing

65 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.

66 The has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to soil.

8.1. Information provided

67 You have provided the following information:

i. a 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: "*further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation*".
ii. You also state that "*all PEC/PNEC ratios are <1"*. In relation to this statement, ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3 ('by using substance-tailored exposure-driven testing') using the provisions specified under Section 3.2(a).
iii. You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.4. To support the adaptation, you have provided following statement: "*Soil simulation testing does not need to be conducted as direct and indirect exposure of the soil is unlikely*".

8.2. Assessment of information provided

8.2.1. Annex IX, Section 9.1., Column 2 (see point i. above) is not a valid basis to omit the study

68 Annex IX, Section 9.2., Column 2 provides that "further" biodegradation testing must be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. That provision allows a registrant to propose, or ECHA to require, biotic degradation testing not covered by the information on degradation listed under Annex IX, section 9.2., Column 1. Therefore, this provision cannot be used as a justification for omitting the submission of information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.3, Column 1.

69 Therefore, your adaption is rejected.

8.2.2. The Substance screens as PBT/vPvB and therefore the conditions of Annex XI, Section 3.2(a) cannot be demonstrated with sufficient reliability (point ii. above)

70 For the reasons already explained under Request 6, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable mean to demonstrate the absence of significant exposure of the environment. Therefore, the conditions set out to justify substance-tailored exposure-driven testing under Annex XI, Section 3.2(a) (i) to (iii) are not met. Therefore, your adaption is rejected.

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

8.2.3. The information from your dossier in reference to point iii. above indicate likely exposure to the sediment compartment

72 Under Annex IX, Section 9.2.1.4., column 2, second indent, the study may be omitted if direct and indirect exposure of soil is unlikely.

73 In section 10 of your CSR, you report release to soil (2.27E3 kg/year).

74 Therefore, the information from your dossier does not indicate unlikely direct and indirect exposure to the soil compartment and your adaptation is rejected.

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

76 In your comments to the draft decision, you raise concerns about the technical feasibility of the requested study. In particular you state that "*Also, although the OECD TG 307 and 308 do not specify acceptable ranges for the Henry's Law constant, the guidelines state that they should not be applied to chemicals that are highly volatile from soil and water, respectively. The above mentioned estimates of the Henry's Law constant and the measured vapour pressure (23 Pa at 25°C) demonstrate that EC 701-175-2 is volatile, and is therefore not appropriate to undertake such studies. Additionally, the Koc values in sediment and soil (>4.0) and the ionizable behavior suggest tendency for adsorption of the substance to sediment and soil particles, making extraction challenging as well as meeting required recoveries and analytical repeatability. Finally, the UVCB nature of the Substance makes the synthesis of a Rasenberg material extremely difficult. The Registrants welcome any comments the Agency may have for the most appropriate positioning of the radiolabel*".

77 ECHA understands that you may intend to submit an adaptation under Annex XI, Section 2. Such adaptation should take into account the limitations of the corresponding method referred to in Article 13(3). ECHA notes that the vapour pressure indicated by you (i.e., 23 Pa at 25°C) is not indicative of high volatility. Further as already explained under Request 7, the information you report on Henry's Law constant indicates that the Substance is to be regarded as slightly volatile and therefore within the applicability domain of the OECD TG 307. The formation of non-extractable residues dues to the adsorptive properties of the Substance is not in itself a valid reason to omit the study. Therefore, in the absence of a valid justification and of adequate experimental evidence, you have currently not demonstrated that the OECD TG 307 is not technically feasible.

78 On the most appropriate positioning of the radiolabel, ECHA Guidance on IRs and CSA, Section R.7.9.4.1. explains that "[o]*ne should ensure that the 14C label is located in the most recalcitrant part of the molecule*". Therefore, the optimal position of the radiolabel will very much depend on the test material selected by you to conduct the requested study.

8.3. Study design and test specifications

79 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.

80 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).

81 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.

82 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.

83 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.).

9. Sediment simulation testing

84 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.

85 The Substance has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to sediment.

9.1. Information provided

86 You have provided the following information:

i. a 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: you consider that the limited degradation observed in the available ready biodegradability study was "*due to toxicity issues to the microbial biomass at the concentrations necessary to comply with the guideline requirements*". You consider studies *"have shown that when these aliphatic amines are tested for biodegradability at test concentrations at environmentally realistic concentrations (i.e.,mg/L) which are typically below the toxicity threshold, that biodegradation does occur*". You also refer to other publications which you consider supportive of "*the biodegradability of branched aliphatic hydrocarbons*". You refer to the QSAR predictions provided under section 5.2 of your IUCLID dossier for a single putative isomer of the substance. You consider that the results of Biowin 2, 3 and 6 support that the whole substance is expected to biodegrade fast. You consider that taken together this information support that the substance is not persistent.

ii. You also state that "*all PEC/PNEC ratios are <1"*. In relation to this statement, ECHA understands that you intend to adapt this information requirement under Annex XI, Section 3 ('by using substance-tailored exposure-driven testing') using the provisions specified under Section 3.2(a).

iii. You have adapted this information requirement by using Column 2 of Annex IX, Section 9.2.1.4. To support the adaptation, you have provided following statement: "*Sediment simulation testing does not need to be conducted as direct and indirect exposure of the sediment is unlikely*".

9.2. Assessment of information provided

9.2.1. Annex IX, Section 9.1., Column 2 (see point i. above) is not a valid basis to omit the study

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

information on simulation testing on ultimate degradation in surface water required under Annex IX, Section 9.2.1.4, Column 1.

88 Therefore, your adaption is rejected.

9.2.2. The Substance screens as PBT/vPvB and therefore the conditions of Annex XI, Section 3.2(a) cannot be demonstrated with sufficient reliability (point ii. above)

89 For the reasons already explained under Request 6, you have not demonstrated that the ratio between the reported PECs and the currently available PNEC provide a reliable mean to demonstrate the absence of significant exposure of the environment. Therefore, the conditions set out to justify substance-tailored exposure-driven testing under Annex XI, Section 3.2(a) (i) to (iii) are not met. Therefore, your adaption is rejected.

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

9.2.1. The information from your dossier in reference to point iii. above indicate likely exposure to the sediment compartment

91 Under Annex IX, Section 9.2.1.4., column 2, second indent, the study may be omitted if direct and indirect exposure of sediment is unlikely.

92 In section 10 of tour CSR, you report significant release to water (2.05E3 kg/year). As explained above, the Substance has high adsorption potential to sediment.

93 Therefore, the information from your dossier does not indicate unlikely direct and indirect exposure to the sediment compartment and your adaptation is rejected.

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

95 In your comments to the draft decision, you provided the same considerations as those described under Request 8. ECHA's reply equally applied to this information requirement.

9.3. Study design and test specifications

96 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.

97 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.

98 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.

99 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.

100 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.).

10. Identification of degradation products

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

102 You have provided no information nor an adaptation on the identity of transformation/degradation products for the Substance.

103 Therefore, this information requirement is not met.

104 This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

10.1. Study design and test specifications

105 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You must obtain this information from one of the degradation studies requested in Requests 7, 8 or 9.

106 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Request 7) 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).

107 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308/307 (Requests 8 and 9) 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).

11. Bioaccumulation in aquatic species

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

11.1. Information provided

109 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.3.2. To support the adaptation, you have provided following justification: "the substance has a low potential for bioaccumulation since its log Kow <=3".

11.2. Assessment of information provided

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

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

112 Your registration dossier provides an adaptation stating that the log Kow is < 3 without further explanation.

113 The Substance is ionisable under relevant environmental pH and is surface active (surface tension < 60 mN/m based on EU method A.5).

114 Therefore, log Kow is not a valid descriptor of the bioaccumulation potential of the Substance and your adaptation is rejected.

115 In your comments on the draft decision, you "*agree with the general statement made by the Agency that log Kow is not a valid descriptor for assessing the bioaccumulation potential of ionizable substances*".

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

117 In your comments on the draft decision, you state that "*log Dow may be used as an indicator of bioaccumulation potential as it accounts for different states of ionization of the ionizable substances*". You propose propose to conduct further literature work and modeling to develop an estimate of BCF using a weight of evidence approach. You intend to conduct a bioaccumulation test in fish only "*if further refinement is deemed necessary for the purposes of B assessment, chemical safety assessment, or classification & labeling*".

118 ECHA notes that log Dow provides an estimate of the pH dependency of the partitioning of ionisable substances between octanol and water and therefore only informs on bioaccumulation mechanisms driven by lipophilicity. As it does not inform on bioaccumulation mechanisms other than partitioning to lipid storage (e.g., ionic binding, interaction with cell membranes), a justification that such mechanisms are not relevant for the Substance will need to be provided.

119 ECHA also acknowledges your intention to adapt this information based on a weight of evidence approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

11.3. Study design and test specifications

120 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.

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

122 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).

12. Long-term toxicity on terrestrial invertebrates

123 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

12.1. Triggering of Long-term toxicity to terrestrial invertebrates

124 The has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to soil. Furthermore, the Substance is not readily biodegradable. Therefore, in the absence of soil specific data, the Substance is considered potentially highly persistent in soil.

125 On this basis, information on long-term toxicity on terrestrial invertebrates must be provided.

12.2. Information provided

126 You have provided:

i. an adaptation under Annex IX, Section 9.4., column 2, first paragraph with the following justification: "The supported uses for this test substance are for industrial applications with no direct application to the terrestrial compartment. Indirect exposure to the terrestrial compartment via volatilization and redeposition would be negligible based on physical/chemical parameters and fugacity modeling. Fugacity modeling in STP suggests that the fraction of the emission directed to water, sludge, and air is 28.5%, 67.2% and 4.3%, respectively. In addition, this substance has been shown to undergo some degradation under test conditions that are less than optimal for biodegradation. Thus, based on the assumption of no direct application to soil and the physical/chemical characteristics of this substance it is anticipated that exposure to the terrestrial compartment would be negligible".

ii. an adaptation under Annex IX, Section 9.4., column 2, second paragraph with the following justification: "using a PNECsoil calculated via the equilibrium partitioning method [EPM], the PEC/PNECsoil ratio for this substance is substantially <1".

12.3. Assessment of the information provided

12.3.1. The information from your dossier in reference to point i. above indicate likely exposure to the sediment compartment

127 Under Annex IX, Section 9.4., column 2, first paragraph, the study may be omitted if direct and indirect exposure of soil is unlikely.

128 In section 10 of tour CSR, you report release to soil (2.27E3 kg/year).

129 Therefore, the information from your dossier does not indicate unlikely direct and indirect exposure to the soil compartment and your adaptation is rejected.

12.3.2. The information from your dossier in reference to point ii. indicate that the EPM does is not applicable for the Substance

130 Under Annex IX, Section 9.4., column 2, second paragraph, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. In this context, the Guidance on IRs and CSA, Section R.7.11.16. describes an integrated testing strategy (ITS) for Effects on Terrestrial Organisms. For the soil compartment there are currently no criteria for classification and PBT assessment, therefore the ITS for soil is especially focussed on generating data for the chemical safety assessment. This approach relies on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

131 The following information indicates that Substance falls into the soil hazard category 4 (HC4):

- the Substance is considered very toxic to aquatic organisms as the lowest short-term EC/LC50 for the Substance is < 1 mg/L ;
- the Substance is considered to be highly persistent in soil as it is considered not readily biodegradable based on available ready biodegradability studies;
- the Substance is considered to have high adsorption potential to soil as you report a Log Koc value of > 4 based on OECD TG 121.

132 As specified in the Guidance on IRs and CSA, Table R.7.11-2, for such substance, the screening assessment based on EPM is not recommended as the intrinsic properties of the Substance indicate a high hazard potential to soil organisms. Therefore, for concluding on the chemical safety assessment, long-term toxicity tests as set out under Annex X, Section 9.4. (invertebrates and plants) need to be provided. Therefore, your adaptation is rejected.

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

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

12.4. Study design and test specifications

135 Guidance on IRs and CSA, Section R.7.11.3.1. specifies that the earthworm reproduction test (OECD TG 222), the Enchytraeid reproduction test (OECD TG 220), and the Collembolan reproduction test (OECD TG 232) are appropriate to cover the information requirement for long-term toxicity testing on terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol since this decision is dependent upon species sensitivity and substance properties. However, when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

13. Effects on soil micro-organisms

136 Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

13.1. Information provided

137 You have provided:

i. an adaptation under Annex IX, Section 9.4., column 2, first paragraph with the following justification: "The supported uses for this test substance are for industrial applications with no direct application to the terrestrial compartment. Indirect exposure to the terrestrial compartment via volatilization and redeposition would be negligible based on physical/chemical parameters and fugacity modeling. Fugacity modeling in STP suggests that the fraction of the emission directed to water, sludge, and air is 28.5%, 67.2% and 4.3%, respectively. In addition, this substance has been shown to undergo some degradation under test conditions that are less than optimal for biodegradation. Thus, based on the assumption of no direct application to soil and the physical/chemical characteristics of this substance it is anticipated that exposure to the terrestrial compartment would be negligible".

ii. an adaptation under Annex IX, Section 9.4., column 2, second paragraph with the following justification: "using a PNECsoil calculated via the equilibrium partitioning method [EPM], the PEC/PNECsoil ratio for this substance is substantially <1".

13.2. Assessment of the information provided

138 For the reasons already explained under Request 12, your adaptation under Annex IX, Section 9.4., column 2, first and second paragraphs are rejected.

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

140 In your comments on the draft decision, you refer to "*a step-wise approach to address the terrestrial toxicity concerns*". You propose to "*conduct an earthworm reproduction test (OECD TG 222) to verify toxicity to soil microorganisms. The results of this test will be used to guide species and test guideline selection of any additional tests, if needed*".

141 ECHA understands that you may intend to adapt this information requirement. However, your comments on the draft decision does not provide an unambiguous description of the legal basis you intend to invoque for such adaptation. Furthermore, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

13.3. Test selection and study specifications

142 Guidance on IRs and CSA, Section R.7.11.3.1. specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

14. Long-term toxicity on terrestrial plants

143 Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

14.1. Triggering for Long-term toxicity to terrestrial plants

144 The has high adsorption coefficient (log $K_{oc,sewage}$ of 4.01 and log $K_{oc,soil}$ of 4.33 based on OECD TG 121) and is ionisable, indicating high potential to adsorb to soil. Furthermore, the Substance is not readily biodegradable. Therefore, in the absence of soil specific data, the Substance is considered potentially highly persistent in soil.

145 Therefore, the Substance has a high potential to adsorb to soil. On this basis information on long-term toxicity on terrestrial plants must be provided.

14.2. Information provided

146 You have provided:

iii. an adaptation under Annex IX, Section 9.4., column 2, first paragraph with the following justification: "The supported uses for this test substance are for industrial applications with no direct application to the terrestrial compartment. Indirect exposure to the terrestrial compartment via volatilization and redeposition would be negligible based on physical/chemical parameters and fugacity modeling. Fugacity modeling in STP suggests that the fraction of the emission directed to water, sludge, and air is 28.5%, 67.2% and 4.3%, respectively. In addition, this substance has been shown to undergo some degradation under test conditions that are less than optimal for biodegradation. Thus, based on the assumption of no direct application to soil and the physical/chemical characteristics of this substance it is anticipated that exposure to the terrestrial compartment would be negligible".

iv. an adaptation under Annex IX, Section 9.4., column 2, second paragraph with the following justification: "using a PNECsoil calculated via the equilibrium partitioning method [EPM], the PEC/PNECsoil ratio for this substance is substantially <1".

14.3. Assessment of the information provided

147 For the reasons already explained under Request 12, your adaptation under Annex IX, Section 9.4., column 2, first and second paragraphs are rejected.

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

149 In your comments to the draft decision, you provided the same considerations as those described under Request 13. ECHA's reply equally applied to this information requirement.

14.4. Study design and test specifications

150 The Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

151 The OECD TG 208 considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

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 06 July 2021.

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

In your comments to the draft decision, you request to extend the deadline with 12 months. You argue that this is necessary because of capacity constraints at contract research organisations, which are linked to the COVID-19 pandemic. 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;

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

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)
The Test Material used to generate the new data must be selected taking into account the following:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- 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,
- The reported composition must also include other parameters relevant for the property to be tested, in this case the distribution of C-chain length, information on branching of alkyl chain length (degree of branching and relative abundance of relevant isomers).

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

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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.

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