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Helsinki,08 November 2023

Addressees
Registrants of 85711-46-2_701-043-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/12/2019

Registered substance subject to this decision ("the Substance")
Substance name: Addition reaction products of conjugated sunflower-oil fatty acids and tall-oil fatty acids with maleic anhydride
EC number: 701-043-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***13 August 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.)

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.

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, Section 9.2.3.; test method: EU C.23/OECD TG 307, EU C.24/OECD TG 308 and 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.

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the request(s)

Contents

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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 301F), and
- 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;

3 Your registration dossier provides the following:

- the Substance is not readily biodegradable (30-40% degradation after 28 days in OECD TG 301F);
- the Substance is surface active (based on surface tension of 45.7 mN/m; OECD TG 117, 2013) therefore high potential for bioaccumulation cannot be excluded based on available information;

4 Furthermore, the Substance is claimed to be hydrolytically unstable. No information is provided on the identity of the potential transformation products and their bioaccumulation potential.

5 Under section 2.3 of your IUCLID dossier and section 8 of your CSR ('PBT assessment') you conclude that "No conclusion can be reached based on available information" regarding P/vP and that the Substance is not B/vB, since it "has a very low octanol/water partition coefficient (<< log Pow 4.5)".

6 However, your adaptation based on log Kow value below 4.5 is not acceptable since, as explained above, the Substance is surface active hence, mechanisms other than lipid partitioning need to be considered in the assessment of bioaccumulation potential. Therefore the data in the dossier is not conclusive for B/vB.

7 In your comments to the draft decision, you disagree with this request. You claim that "*the UVCB is mostly comprised of natural fatty acids and constituents that are readily biodegradable*" and you consider that the available screening data, indicated above, shows that the Substance is inherently biodegradable hence, it can be concluded not P and "*It logically follows that more than half of the substance fully degrades within 40 days*".

Therefore, you propose to adapt this information requirement by means of weight of evidence.

8 You further consider to strengthen this adaptation by performing additional screening studies, i.e. an enhanced biodegradation test according to OECD TG 301 B.

9 First, as explained above, the Substance is composed of constituents of variable structural composition, including structures of higher complexity than fatty acids. The PBT assessment must take into account these constituents (see Annex XIII, introductory paragraph).

10 Second, the available screening data, OECD TG 301F, provide data on ready biodegradability, in this case absence of ready biodegradability, but it is not designed to provide information on inherent biodegradation.

11 In any case, ECHA notes that the Substance is complex, composed of constituents of variable structure (i.e. linear, cyclic and bicyclic, saturated and unsaturated carbon chains and combinations thereof) potentially leading to differences in biodegradation rates. Hence, the results of a ready biodegradability study on the whole substance may be sufficient to conclude on absence of ready biodegradability but it cannot inform on the degradation potential of each relevant constituent (OECD Guidelines For Testing Of Chemicals, Section 3 Part I). Therefore, you have not yet demonstrated that all constituents of the Substance are not persistent.

12 Third, ECHA acknowledges your intention to further strengthen the proposed argument however, as this proposal relies on data yet to be generated, no conclusion on the compliance can currently be made. Therefore, you remain responsible for complying with this decision by the set deadline.

13 Therefore, the additional information from your PBT assessment and in your comments is not adequate to conclude that the Substance is not a potential PBT/vPvB substance.

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

15 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Request 5.

16 You have provided additional comments to the draft decision regarding this information requirement, in particular with regards to technical feasibility of the test. This additional comments are addressed under Request 5 below.

2. Soil simulation testing

17 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

18 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.).

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

20 Further, the Substance is surface active (surface tension of 45.7 mN/m), indicating high potential to adsorb to sediment.

21 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.

22 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Request 6.

23 In your comments to the draft decision you refer to consideration similar to the ones provided for the water simulation study requested in this decision. Such comments are already addressed in Request 1 and 5 of this decision.

3. Sediment simulation testing

24 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

25 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.).

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

27 Further, the Substance is surface active (surface tension of 45.7 mN/m), indicating high potential to adsorb to sediment.

28 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.

29 The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed respectively in Request 7.

30 In your comments to the draft decision you refer to consideration similar to the ones provided for the water simulation study requested in this decision. Such comments are already addressed in Request 1 and 5 of this decision.

4. Identification of degradation products

31 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).

32 In your comments to the draft decision you refer to the impact of concluding that the Substance is not P/vP, i.e. based on weigh of evidence adaptation possibility, and technical considerations. This arguments are common to other requests in the decision and are addressed under Requests 1 and 5 of this decision.

4.1. Triggering of the information requirement

33 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.).

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

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

36 The examination of the available information or adaptations, as well as further information on the selection of the approach to generate this information are addressed in Request 8.

Reasons related to the information under Annex IX of REACH

5. Simulation testing on ultimate degradation in surface water

37 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

38 You have adapted this information requirement and provided the following justifications:

(i) "the study does not need to be conducted because direct and indirect exposure of sediment is unlikely"

39 In addition, ECHA understands that you also seek to adapt this information requirement by using Annex XI, Section 2. (testing not technically possible) and provided the following justifications:

(ii) "The substance is a UVCB substance based on raw materials of biological origin. A specific analytical method is not available. It is not possible to prepare radiolabeled substance. Thus, it is not possible to quantify biodegradation in water systems."

5.1. Assessment of information provided

5.1.1. Your justification (i) to omit the study has no legal basis

40 A registrant may only adapt this information requirement based on the specific rules set out in Annex IX, Section 9.2.1.2., Column 2 or the general rules set out in Annex XI.

41 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH or Annex IX, Section 9.2.1.2., Column 2.

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

43 In your comments to the draft decision, you indicate your intention to waive this information requirement under Annex IX, Section 9.2.1.2. Column 2 based on the Substance being highly insoluble.

5.1.2. The provided adaptation does not meet the criteria of Annex IX, Section 9.2.1.2., Column 2

44 Under Annex IX, Section 9.2.1.2., Column 2, first indent, the study can be omitted in case the Substance is highly insoluble.

45 There is no cut off value in the REACH Regulation. Since any substance may be persistent, what is most important is what can be assessed in a study, i.e., it is necessary to demonstrate that it is not reasonably possible to develop an analytical method with sufficient sensitivity to meet the test guideline requirements taking into account the specific technical limitations of the OECD TG 309 which include, in particular:

- for the determination of biodegradation kinetics, the concentrations of the test substance must be below its water solubility, and
- the limit of quantification (LOQ) should be equal to or less than 10% of the applied concentration.

46 Consequently, a substance has an insolubility too high for conducting a simulation testing on ultimate degradation in surface water in accordance with OECD TG 309 if the LOQ of a sensitive analytical method is not at least ten times lower to the water solubility of the substance.

47 You did not provide any information in support of your claim.

48 You did not provide any argument in relation to the specific technical limitations of the OECD TG 309.

49 In the provided OECD TG 105 (2013), the saturation concentration of the Substance in water was determined to be <= 8.3 mg/L. From experimental studies on aquatic toxicity, e.g. long-term toxicity study in aquatic invertebrates (2018) it can be understood that an analytical method is available to detect the Substance with an LOQ of 5.01 ug/L.

50 Therefore, you have not demonstrated that the solubility of the Substance is too low to perform the study.

51 On this basis, the adaptation is rejected.

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

52 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 309, more specifically on the technical limitations of a specific method, shall always be respected.

53 Any technical difficulties to perform the test and the considered solutions must be clearly documented.

54 You claim that there are no available analytical methods suitable for the Substance and that a radiolabeled test material cannot be prepared.

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

56 The OECD TG 309 provides no particular restriction regarding the testing of UVCB substances nor does it require mandatory use of radiolabelled test materials.

57 Furthermore, you do not provide any considerations with regards to the (un)feasibility of the study using non-radiolabelled test material.

58 The information provided in your comments refers to the same issues already addressed above hence, does not change the assessment.

59 Therefore, your adaptation is rejected.

60 In your comments to the draft decision, you indicated a weight of evidence adaptation under Annex XI, Section 1.2 and an intention to develop this adaptation further relying on generic considerations on fatty acids, the existing screening data and a future study. To the extent that this proposal relies on data yet to be generated, no conclusion on the compliance can currently be made. Therefore, you remain responsible for complying with this decision by the set deadline. For the remainder, ECHA refers to the corresponding considerations set under Request 1.

61 Based on the above, the information requirement is not fulfilled.

5.2. Study design and test specifications

62 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.

63 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.).

64 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.

65 As specified in Guidance on IRs and CSA, Section R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test material concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Paragraph 52 of the OECD TG 309 provides that the "*total recovery (mass balance) at the end of the experiment should be between 90% and 110% for radiolabelled substances, whereas the initial recovery at the beginning of the experiment should be between 70% and 110% for non-labelled substances*". NERs contribute towards the total recovery. Therefore, the quantity of the (total) NERs must be accounted for the total recovery (mass balance), when relevant, to achieve the objectives of the OECD TG 309 to derive degradation rate and half-life. The reporting of results must include a scientific justification of the used extraction procedures and solvents.

66 For the persistence assessment by default, total NERs is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NERs may be differentiated and quantified as irreversibly bound or as degraded to biogenic NERs, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website (NER – summary 2019 (europa.eu)).

67 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.).

68 ECHA acknowledges your considerations with regards to the sequence of simulation test and choice of most relevant compartment, and notes that they refer to the considerations provided in Appendix 4, Section 2, of this decision.

6. Soil simulation testing

69 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.

70 The Substance is surface active (surface tension 45.7 mN/m) and therefore has high potential for adsorption to soil.

6.1. Information provided

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

(ii) ECHA understands that you also seek to adapt this information requirement by using Annex XI, Section 2. (testing not technically possible). To support the adaptation, you have provided following information: *"The substance is a UVCB substance based on raw materials of biological origin. A specific analytical method is not available. It is not possible to prepare radiolabeled substance. Thus, it is not possible to quantify biodegradation in sediment systems."*

6.2. Assessment of information provided

6.2.1. The provided adaptation (i) does not meet the criteria of Annex IX, Section 9.2.1.3., Column 2

71 Under Section 9.2.1.3., Column 2, second indent of Annex IX to REACH, the study may be omitted if direct and indirect exposure of the aquatic compartment is unlikely.

72 Therefore, it must be demonstrated that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

73 In your chemical safety assessment, you claim that, regarding manufacture and formulation uses, "Liquid and solid wastes are collected as described above. The regular waste management is performed by a specialised and accredited disposal company".

74 However, you report additional uses in you dossier, including widespread uses (both indoor and outdoor uses) by professional workers, for example in the following process categories (PROC: Application by rolling and brushing (PROC 10), spray application (PROC 11), and by dipping and pouring (PROC 13).

75 Your CSA does not contain an exposure assessment and you have not provided documentation regarding the release to the environmental compartment during the life cycle of the Substance.

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

77 Therefore your adaptation is rejected.

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

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

79 You claim that there are no available analytical methods suitable for the Substance and that a radiollabeled test material cannot be prepared.

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

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

82 Furthermore, you do not provide any considerations with regards to the (un)feasibility of the study using non-radiolabelled test material.

83 As already explained in Requests 1 and 5 of this decision, the information provided in your comments does not change the assessment.

84 Therefore, your adaptation is rejected.

85 Based on the above, the information requirement is not fulfilled.

6.3. Study design and test specifications

86 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.

87 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).

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

89 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.

90 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.

91 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.).

7. Sediment simulation testing

92 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.

93 The Substance is surface active (surface tension 45.7 mN/m) and therefore has high potential for adsorption to sediment.

7.1. Information provided

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

(ii) ECHA understands that you also seek to adapt this information requirement by using Annex XI, Section 2. (testing not technically possible). To support the adaptation, you have provided following information: *"The substance is a UVCB substance based on raw materials of biological origin. A specific analytical method is not available. It is not possible to prepare radiolabeled substance. Thus, it is not possible to quantify biodegradation in sediment systems."*

7.2. Assessment of information provided

7.2.1. The provided adaptation (i) does not meet the criteria of Annex IX, Section 9.2.1.3., Column 2

94 Under Section 9.2.1.3., Column 2, second indent of Annex IX to REACH, the study may be omitted if direct and indirect exposure of the aquatic compartment is unlikely. Therefore, it must be demonstrated that there is no release to the environment at any stage in the life cycle of the substance (Guidance on IRs and CSA, Section R.7.10.4.5.).

95 In your chemical safety assessment, you claim that, regarding manufacture and formulation uses, "Liquid and solid wastes are collected as described above. The regular waste management is performed by a specialised and accredited disposal company".

96 However, you report additional uses in you dossier, including widespread uses (both indoor and outdoor uses) by professional workers, for example in the following process categories (PROC: Application by rolling and brushing (PROC 10), spray application (PROC 11), and by dipping and pouring (PROC 13).

97 Your CSA does not contain an exposure assessment and you have not provided documentation regarding the release to the environmental compartment during the life cycle of the Substance.

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

99 Therefore your adaptation is rejected.

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

100 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 308, more specifically on the technical limitations of a specific method, shall always be respected.

101 Any technical difficulties to perform the test and the considered solutions must be clearly documented.

102 You claim that there are no available analytical methods suitable for the Substance and that a radiollabeled test material cannot be prepared.

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

104 The OECD TG 308 provides no particular restriction regarding the testing of UVCB substances nor does it require mandatory use of radiolabelled test materials.

105 Furthermore, you do not provide any considerations with regards to the (un)feasibility of the study using non-radiolabelled test material.

106 As already explained in Requests 1 and 5 of this decision, the information provided in your comments does not change the assessment.

107 Therefore, your adaptation is rejected.

108 Based on the above, the information requirement is not fulfilled.

7.3. Study design and test specifications

109 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.

110 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.

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

112 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.

113 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.

114 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.).

8. Identification of degradation products

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

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

117 Therefore, this information requirement is not met.

118 In your comments to the draft decision you refer to the impact of concluding that the Substance is not P/vP, i.e. based on weight of evidence adaptation possibility, and technical considerations. These arguments are common to other requests in the decision and are addressed under Requests 1 and 5 of this decision.

8.1. Study design and test specifications

119 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.

120 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

121 You must obtain this information from the degradation studies requested in requests 5, 6 and 7.

122 To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (request 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).

123 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 6 and 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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

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

The compliance check was initiated on 08 December 2021.

The information requirement for bioaccumulation testing is not addressed in this decision. This may be addressed in a separate decision once the information from the simulation studies (OECD 307, 308, 309) requested in the present decision is provided.

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

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

In your comments, you mention the difficulty to synthesize a stable radiolabelled UVCB based on fatty acid chemistry and the impredictability of CRO’s lag times without any substantiation. As mentioned above, the deadline already include a 12-month extension.

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 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
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as

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

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

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.

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