~~Confidential~~

Helsinki, 20 February 2024

Addressees
Registrants of JS_EC_429-280-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
09 January 2023

Registered substance subject to this decision ("the Substance")
Substance name: 1,6-bis((dibenzylthiocarbamoyl)disulfanyl)hexane
EC/List number: 429-280-6

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 ***25 February 2028***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.)

    a) *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and

    b) only if the *in vitro/in chemico* test methods specified under point a) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429).

2. Growth inhibition study on aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3/OECD TG 201).

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

3. *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490).

4. Long-term toxicity testing on fish, also requested below (triggered by Annex VIII, Section 9.1.3., Column 2).

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

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

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

8. Bioaccumulation in aquatic species, also requested below (triggered by Annex VIII, Section 9.3., Column 2.).

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

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

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

11. 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.

12. 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.

13. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.23/OECD TG 307 and EU C.24/OECD TG 308).

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

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

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

Appendix 1: Reasons for the request(s)

Contents

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

1 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

2 You have provided:

(i) a Guinea Pig Maximisation Test (1999, report number [redacted]) with the Substance;

(ii) a Bühler Test (1992) with the Substance.

1.2. Assessment of the information provided

1.2.1. Assessment whether the Substance causes skin sensitisation

1.2.1.1. The provided studies do not meet the specifications of the test guideline(s)

3 To fulfil the information requirement and to enable concluding whether the Substance causes skin sensitisation, a study must comply with the EU Method B.6/OECD TG 406 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) a dose level selection rationale is provided. However, in the studies (i) and (ii) no dose level selection rationale was provided;

b) the induction concentration is the highest causing mild-to-moderate irritation to the skin. However, in study (i) and (ii), the concentration used for induction did not cause mild-to-moderate irritation;

c) positive control is included to establish the sensitivity and reliability of the experimental technique. However, in study (ii), no information on positive control group(s) was provided.

4 The information provided does not cover the specifications required by the EU Method B.6/OECD TG 406, as mentioned above.

5 On this basis, it cannot be concluded whether the Substance causes skin sensitisation.

6 In your comments to the draft decision, you acknowledge the limitations of study (ii). For study (i), you provided additional information which address the study deficiencies identified above. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set in the decision.

1.2.2. No assessment of potency

7 To be considered compliant and enable a conclusion in cases where the substance is considered to cause skin sensitisation, the information provided must also allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

8 As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section 1.2.1. above), this condition cannot be assessed.

9 Therefore, the information requirement is not fulfilled.

1.3. Study design

10 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

11 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated in vitro/in chemico data, *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

2. Growth inhibition study aquatic plants

12 Growth inhibition study on aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

2.1. Information provided

13 You have provided a Growth inhibition study on algae (1992), performed according to the EU Method C.3, with the Substance.

2.2. Assessment of the information provided

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

14 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). The Substance is poorly water soluble (WS <0.05 mg/L), highly adsorptive (Log K_{ow} of 10.4) and thus difficult to test. Therefore, the following specifications must be met:

Reporting of the methodology and results

a) the test design is reported (*e.g.*, number of replicates, number of test concentrations and geometric progression used);

b) the test conditions are reported (*e.g.*, composition of the test medium, biomass density at the beginning of the test);

c) the method for determination of biomass and evidence of correlation between the measured parameter and dry weight are reported. Algal biomass is normally determined based on dry weight per volume, or alternatively as cell counts or biovolume using microscopy or an electric particle counter. If an alternative method is used (e.g. flow cytometry, *in vitro* or *in vivo* fluorescence, or optical density), a satisfactory correlation with biomass must be demonstrated over the range of biomass occurring in the test;

d) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

e) microscopic observation performed to verify a normal and healthy appearance of the inoculum culture are reported. Any abnormal appearance of the algae at the end of the test is reported;

f) adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations is provided;

g) as explained above the Substance is difficult to test. Therefore, the following additional information must be provided:

- the results of a preliminary solubility and stability study,
- a description of the methods used to prepare stock and test solutions,
- if the test material is tested at the saturation concentration, evidence that all reasonable efforts have been taken to achieve a saturation concentration.

15 However, for the provided study, you have not provided any of the information listed under points a) to g) above

16 Based on the above, it is not possible to conduct an independent assessment as to whether the provided study was conducted under conditions that are consistent with the specifications of the OECD TG 201, whether the validity criteria of the test guideline were met and whether the interpretation of the results is adequate.

17 On this basis, the specifications of OECD TG 201 are not met.

18 Therefore, the information requirement is not fulfilled.

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

2.3. Study design

20 The Substance is difficult to test due to the low water solubility (<0.05 mg/L) and adsorptive properties (Log K_{ow} of 10.4). OECD TG 201 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 the 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 201. 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.

Reasons related to the information under Annex VIII of REACH

3. In vitro gene mutation study in mammalian cells

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

3.1. Triggering of the information requirement

22 Your dossier contains negative results for both an *in vivo* micronucleus study, and an *in vitro* gene mutation study in bacteria.

23 Therefore, the information requirement is triggered.

3.2. Information provided

24 You have adapted this information requirement by using Annex VIII, Section 8.4., Column 2. To support the adaptation, you have provided the following information:

(i) *in vivo* mammalian comet assay (2005, report number: [redacted]) with the Substance.

3.3. Assessment of the information provided

3.3.1. The provided adaptation does not meet the criteria of Annex VIII, Section 8.4., Column 2

25 Under Annex VIII, Section 8.4., Column 2, the study may be omitted if adequate data from a reliable in vivo mammalian gene mutation test are available. The Guidance on IRs and CSA, Section R.7.7.6.3. clarifies that the in vivo study must be a Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay (TGR), performed according to the OECD TG 488. This test investigates gene mutations using reporter genes.

26 Alternatively, an in vivo mammalian comet assay is a suitable test to investigate primary DNA damage that may lead to gene mutations and/or structural chromosomal aberrations. However, in such case, the in vivo mammalian comet assay must be conducted in accordance with the OECD TG 489 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the study includes a minimum of three dose level groups of treated animals, as well as a negative control group and a positive control group;
b) at least 150 cells are analysed for each sample, per tissue, and per animal.

27 However, in study (i):

a) Only one dose level group of treated animals (i.e., less than three doses/groups) was included;
b) 100 cells (i.e., less than 150 cells) have been analysed for each sample, per tissue, and per animal.

28 In your comments to the draft decision, you consider that the comet assay conducted prior to the test OECD guideline is valid and reliable. You refer to the fact that the test is performed at the limit dose, but you do not provide specific information addressing the issues identified above. Therefore, the information provided in your comments does not change the assessment's outcome.

29 The information provided does not cover the specifications required by the OECD TG 489.

30 Therefore, your adaptation under Annex VIII, Section 8.4., Column 2 is rejected and the information requirement is not fulfilled.

3.4. Study design

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

4. Long-term toxicity testing on fish

32 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, Section 9.1.3. However, long-term toxicity testing on fish may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

33 In the provided EU Method A.6 using the Column elution method (1999), the saturation concentration of the Substance in water was determined to be <0.05 mg/l.

34 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information requirement not fulfilled

35 The information provided, its assessment and the specifications of the study design are addressed under request 10.

5. Soil simulation testing

36 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

5.1. Triggering of the information requirement

37 This information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (i.e., <60/70% degradation in an OECD 301/310, and
  - it shows <70% degradation within 14 days in an inherent biodegradation test OECD 302C and/or lag phase > 3 days;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as it has a high potential to partition to lipid storage (e.g. Log Kow > 4.5);

- 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.

38 Your registration dossier provides the following:

- the Substance is not readily biodegradable (14 % degradation after 28 days based on EU Method C.5) and not inherently biodegradable (0 % degradation after 56 days based on OECD TG 302C).
- the Substance has a high potential to partition to lipid storage (Log K_{ow} of 10.4 based on EU Method A.8).

39 Furthermore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 14of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see the Requests 2, 3, 4, 9 and 10 of this decision).

40 Under section 2.3 of your IUCLID dossier and section 8 of your CSR ('PBT assessment'), you conclude that the Substance is not B/vB nor T.

41 You base your conclusion on the following:

a) "*With a very high log Kow of 10.4 and a molecular weight near to 700 (693.1) it is unlikely that the substance is B or vB*";
b) "*A biomagnification test was performed where the substance was applied to fish by feed. Because no Vulcuren was detectable in fish after the feeding phase of 11 days with both concentrations (100 and 1000 µg/g fish food) used, it can be concluded that the Substance does not have a significant bioaccumulation potential*".
c) The substance is not classified for any relevant hazard class.

42 In your comments to the draft decision, you state that you agree that the Substance is not readily biodegradable nor inherently biodegradable, and hence it is potentially P or vP based on the available screening criteria. However, you state that although the Substance is highly insoluble in water, it can be hydrolysable. Furthermore, you reinstate that the Substance is unlikely to be B nor vB based on the high logK_{ow} and molecular weight, as well as, the bioaccumulation study (2007). In addition, you provide calculated molecular size D_{max} /MML (21.6 Å) from QSAR Toolbox. Finally, you state that you agree to perform the long-term fish study, as requested in requests 4 and 10, to strengthen the absence of chronic toxicity.

43 However, ECHA considers that:

- On point a) above, available information on the Substance do not support that the Substance is unlikely to cross biological membranes because your justification does not include reliable indications from physico-chemical indicators (e.g. molecular size D_{max} > 17.4 Å and MW > 1100 or MML > 4.3 nm) combined with experimental evidence to support hindered uptake (no chronic toxicity for mammals and birds, no chronic ecotoxicity, no uptake in mammalian toxicokinetic studies, very low uptake after chronic exposure).

  In your comment to the draft decision, you provide D_{max} (21.6 Å) but you also agree that the experimental evidence to support hindered uptake is still incomplete.
- On point b), as explained in the Request 14 below, the study is not adequate to conclude on the bioaccumulation potential.
- On point c), as already explained above, the information you provided does not allow concluding on the toxicity of the Substance.

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

45 The information provided in your comments does not change the assessment.

46 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.

47 Further, the Substance high partition coefficient (Log K_{ow} 10.4) and high adsorption coefficient (Log $K_{oc,soil}$ of 4.98-8.45), indicating high potential to adsorb to soil.

48 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.

5.2. Information requirement not fulfilled

49 The information provided, its assessment and the specifications of the study design are addressed under request 11.

6. Sediment simulation testing

50 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

51 This information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

52 As already explained in request 5, the Substance is a potential PBT/vPvB substance.

53 Further, the Substance has high partition coefficient (Log K_{ow} 10.4) and high adsorption coefficient (Log $K_{oc,soil}$ of 4.98-8.45) , indicating high potential to adsorb to sediment.

54 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.

6.1. Information requirement not fulfilled

55 The information provided, its assessment and the specifications of the study design are addressed under request 12.

7. Identification of degradation products

56 Under Annex VIII, Section 9.2., Column 2, further information on degradation or further testing as described in Annex IX must be generated if the chemical safety assessment (CSA) in accordance with Annex I indicates the need to investigate further the degradation of the substance.

7.1. Triggering of the information requirement

57 Therefore, this information requirement is triggered in case if for example additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

58 As already explained in request 5, the Substance is a potential PBT/vPvB substance.

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

60 In your comments to the draft decision, you state that you are of the opinion that "*the trigger according to Annex VIII, column 2 refers to the testing of the substance and that is an Annex IX requirement to also test the degradation products, as specified in section 9.2, column 2 of Annex IX, respectively*". In addition, although you acknowledge that "*the Guidelines for simulation studies include the identification of all degradation products from 10%*", you claim that "*it is not required at an Annex VIII requirement*". Consequently, you state your intention to fill the requirement according to Annex VIII with relevant simulation studies as requested in the decision, but "*without identification of the degradation products from 10% nor further evaluation of degradation products from 0.1 %*".

61 Annex XIII to reach lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance. This Annex specifies that the identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products. Therefore, ECHA maintains that the identification of relevant degradation products is required for the purpose of the PBT/vPvB assessment of the Substance. As a results, your comment does not change the assessment's outcome.

7.2. Information requirement not fulfilled

62 The information provided, its assessment and the specifications of the study design are addressed under request 13.

8. Bioaccumulation in aquatic species

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

64 This information requirement is triggered in case if for example additional information on bioaccumulation as set out in Annex XIII, point 3.2.2, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex.

65 As already explained in request 6, the Substance is a potential PBT/vPvB substance.

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

8.1. Information requirement not fulfilled

67 The information provided, its assessment and the specifications of the study design are addressed under request 14.

Reasons related to the information under Annex IX of REACH

9. Sub-chronic toxicity study (90 days)

68 A sub-chronic toxicity study (90 days) is an information requirement under Annex IX, Section 8.6.2.

9.1. Information provided

69 We understand that you have adapted this information requirement by using Annex IX, Section 8.6.2., Column 2. To support the adaptation, you have provided the following information: "According to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex IX column 2, the sub-chronic toxicity study (90 days) does not need to be conducted if: the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure".

9.2. Assessment of the information provided

9.2.1. Column 2 criteria not met

70 Under Annex IX, Section 8.6.2., Column 2, Indent 4, the study may be omitted if the following cumulative conditions are met:

(1) the substance is unreactive, insoluble and not inhalable;

(2) there is no evidence of absorption; and

(3) no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure.

71 You claim that the Substance is (1) unreactive, insoluble and not inhalable, that (2) there is no evidence of absorption, and (3) no evidence of toxicity in a 28-day 'limit test'.

72 However, on point (1):

- you have provided no justification as to why the Substance should be regarded as unreactive,
- you reported an unbounded water solubility estimate (<0.05 mg/l) and no further justification as to why the Substance should be regarded as insoluble, and
- you report in Section 4.5. of IUCLID a study according to OECD TG 110 which indicate that the Substance includes a fraction corresponding to fine particles having a DT50 of 9.3 µm. Therefore, it cannot be regarded as not inhalable.

73 Furthermore, on point (2), you provided no evidence that the Substance is not absorbed.

74 Finally on point (3), some statistically significant haematological findings were seen in sub-acute study according to OECD TG 407. In addition, based on the information in your CSR, potential exposure for workers cannot be excluded. There is an exposure scenario (ES 2) with use of 100% solid substance with high dustiness and no technical risk management measures are applied. The highest exposure estimate in the ES2 is 20 mg/m^3 for PROC 9 in the contributing scenario 4. Therefore, it can be concluded that human exposure is <u>not</u> limited.

75 Your assumption on the Substance being unreactive, insoluble, not inhalable and not absorbed and having limited human exposure are unsubstantiated and therefore cannot be accepted.

76 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

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

9.3. Study design

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

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

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

10. Long-term toxicity testing on fish

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

10.1. Information provided

82 You have provided following statement:

83 "It is demonstrated by the results of the exposure assessment that no significant exposure of the water compartment occurs in all scenarios of the manufacture and of all identified uses."

10.2. Assessment of the information provided

10.2.1. Your justification to omit the study has no legal basis

84 A registrant may only adapt this information requirement based on the general rules set out in Annex XI.

85 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

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

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

10.3. Study design

88 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

89 OECD TG 210 specifies that, for difficult to test substances, OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 2.

11. Soil simulation testing

90 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.

91 The Substance has a low water solubility (<0.05 mg/L), high partition coefficient (log K_{ow} 10.4) and high adsorption coefficient (log $K_{oc,soil}$ 4.98 - 8.45) and therefore has high potential for adsorption to soil.

11.1. Information provided

92 ECHA understands that 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 statement: "the study does not need to be conducted because direct and indirect exposure of soil is unlikely".

11.2. Assessment of the information provided

11.2.1. No conclusion on PBT/vPvB is yet reached

93 Information required under Annex IX, Section 9.2.1.3., and 9.2.1.4 is essential in assessment of PBT/vPvB properties of substances (Annex XIII, Section 3.2). Therefore, to adapt simulation degradation studies by using arguments of unlikely direct and indirect exposure, the Substance must be demonstrated to not be a PBT/vPvB candidate (Guidance on IRs and CSA, Section R.7.9.2.3. and R.7.10.4.5).

94 For the reasons already explained under Section 5.1, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Therefore, this information requirement cannot be omitted based unlikely direct and indirect exposure to soil.

11.2.2. The provided adaptation does not meet the criteria of Annex IX, Section 9.2.1.3., Column 2

95 Under Section 9.2.1.3., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure to the soil is unlikely. The requirements for absence of direct and indirect exposure to the soil must be met for all uses throughout the life-cycle including the waste stage (ECHA Guidance R.5).

96 In the section 3.5 of your registration dossier you report industrial uses (ERC 3 - Formulation into solid matrix, ERC 6D - Use of reactive process regulators in polymerisation processes at industrial site). You report that the Substance is used in production of rubber goods and tyres but you have provided no information on article service life.

97 The industrial uses reported in your technical dossier are expected to lead to some release to the environment as ERC3 and ERC 6D have default emission factors to soil (before STP) of 0.1% and 0.025%. Therefore, exposure to the soil compartment may occur. Furthermore, indirect exposure through spreading of sewage sludge on land cannot be excluded. Finally, you have not included any information on articles service life for the Substance.

98 In your comments to the draft decision, you provided the following information:

- You acknowledge that the information on article service life is missing, but as the substance is not incorporated into an article, no information on article life is needed;
- Waste is only produced during the two reported uses (ERC 3 and 6d) and addressed appropriately;
- Only exposure path of the Substance by waste is emission to air, with its maximum emission amount to 1.5 kg/year, which you consider as negligibly low;

- You consider the default emission factors to soil (i.e. 0.1 % and 0.025%) as negligible release and they represent worst case, as the actual release is even lower;
- Release to water and air (based on ETRMA SpERC3/6d.3v.1 and ETRMA SpERC 3.6d2 specific for the rubber and tyre industry) are also very low and indirect exposure to soils is unlikely;
- You acknowledge that the indirect exposure through spreading of sewage sludge on land cannot be excluded;
- However, you argue that it is rather unlikely as:
  (i) no sewage sludge is applied to agricultural soil for "formulation into solid matrix" (ERC 3); and
  (ii) Most industrial sewage treatment plants send the sewage to specific treatment facilities or utilise it on-site (e.g. in thermal combustion);
  (iii) The amount of the Substance reaching a sewage treatment plant via the water compartment is 0.008%, which you consider as negligibly low.
- Based on above, you conclude that direct and indirect exposure to the soil is unlikely.

99 Regarding the information on article service life, ECHA reiterates that you do not provide any actual evidence (e.g. laboratory report), other than theoretical considerations to support your claim that all the Substance is consumed during the vulcanization reaction and that the Substance is not released during the life-cycle. In addition, ECHA notes that for substances that are not included in articles, it must be demonstrated for all relevant scenarios that strictly controlled conditions (SCC) as set out in Article 18(4)(a) to (f) apply throughout the life cycle. To demonstrate that the different requirements listed in Article 18(4)(a) to (f) are met, the registrant must provide "*a thorough and rigorous exposure assessment in accordance with section 5 of Annex I*" with a detailed description of all activities for each processing step throughout the whole life cycle of the substance. You have not provided any information to assess these conditions. Thus, without this information you have not demonstrated that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply throughout the life cycle of the Substance.

100 Regarding direct and indirect exposure, ECHA disagrees that release is negligible. You state that the assessment is based on ETRMA SpERC3/6d.3v.1 and ETRMA SpERC 3.6d2, for which some releases are assumed in water and air. As such, the presence of releases disqualifies SCC.

101 Finally, you claim that the actual release is lower than the default emission factors to soil according to the ECHA guidance R.16 for the specified use. ECHA points out that for the purpose of an exposure-based adaptation, a high level of confidence is needed to demonstrate that every RCR is low enough to ensure that the risks are always controlled, under every plausible condition of uses of the Substance. The possible sources of variability and uncertainty must be considered in the assessment of exposure. Uncertainty must be taken into account, either by carrying out the environmental exposure assessment using conservative assumptions and default values, which are provided in ECHA guidance R.16. Alternatively, an uncertainty analysis must be conducted to demonstrate that the risks are adequately controlled. You have not demonstrated that your assessments are conservative enough and RCR always low enough to cover the possible sources of variability and uncertainty.

102 Therefore, you have not demonstrated that exposure to soil is unlikely.

103 On this basis, your adaption is rejected and the information requirement is not fulfilled.

11.3. Study design

104 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(2) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(3) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

105 In accordance with the specifications of OECD TG 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).

106 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.

107 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.

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

12. Sediment simulation testing

109 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.

110 The Substance has a low water solubility (<0.05 mg/L), high partition coefficient (log K_{ow} 10.4) and high adsorption coefficient (log $K_{oc,soil}$ 4.98 - 8.45) and therefore has high potential for adsorption to sediment.

12.1. Information provided

111 ECHA Understands that 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 information: "the study does not need to be conducted because direct and indirect exposure of sediment is unlikely".

12.1. Assessment of the information provided

12.1.1. No conclusion on PBT/vPvB is yet reached

112 Information required under Annex IX, Section 9.2.1.3., and 9.2.1.4 is essential in assessment of PBT/vPvB properties of substances (Annex XIII, Section 3.2). Therefore, to adapt simulation degradation studies by using arguments of unlikely direct and indirect exposure, the Substance must be demonstrated to not be a PBT/vPvB candidate (Guidance on IRs and CSA, Section R.7.9.2.3. and R.7.10.4.5).

113 For the reasons already explained under Section 7.1, the available information on the Substance indicates that it is a potential PBT/vPvB substance. Therefore, this information requirement cannot be omitted based unlikely direct and indirect exposure to sediment.

12.1.2. The provided adaptation does not meet the criteria of Annex IX, Section 9.2.1.4., Column 2

114 Under Section 9.2.1.4., Column 2 of Annex IX to REACH, the study may be omitted if direct and indirect exposure to the sediment is unlikely. The requirements for absence of direct and indirect exposure to the sediment must be met for all uses throughout the life-cycle including the waste stage (ECHA Guidance R.5).

115 In the section 3.5 of your registration dossier you report industrial uses (ERC 3 - Formulation into solid matrix, ERC 6D - Use of reactive process regulators in polymerisation processes at industrial site). You report that the Substance is used in production of rubber goods and tyres but you have provided no information on article service life.

116 The industrial uses reported in your technical dossier are expected to lead to moderate release to the environment as ERC3 and ERC 6D have default emission factors to water (before STP) of 0.2% and 0.005%. Furthermore, considering the properties of the Substance (i.e. low solubility, high adsorption potential and low biodegradation potential), exposure to the sediment compartment cannot be excluded. Finally, you have not included any information on articles service life for the Substance. Therefore, you have not demonstrated that exposure to sediment is unlikely.

117 In your comments to the draft decision, you submit the same comments which you provide for the request 11 above. These comments are addressed under request 11 above.

118 On this basis, your adaption is rejected and the information requirement is not fulfilled.

12.2. Study design

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 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.

121 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.

122 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.

123 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.).

13. Identification of degradation products

124 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

125 You have not submitted any information for this requirement.

126 In your comments to the draft decision, you agree to perform the requested study, if the Substance still screens for PBT after performing the requested (eco)toxicity studies. However, ECHA notes that the identification of degradation products is not conditional but is a standard information requirement at Annex IX. Therefore, you are required to provide this information, regardless of the outcome of the (eco)toxicity studies and PBT assessment.

127 Therefore, the information requirement is not fulfilled.

13.1. Study design

128 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.

129 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.

130 You must obtain this information from the degradation studies requested in requests 11 and 12.

131 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 14 and 15) 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).

14. Bioaccumulation in aquatic species

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

14.1. Information provided

133 You have provided a bioaccumulation in fish study (2007), performed according to the OECD TG 305 with the Substance.

14.2. Assessment of the Information provided

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

134 To fulfil the information requirement, a study must comply with the OECD TG 305 (Article 13(3) of REACH). Therefore, the following specifications must be met:

Technical specifications impacting the sensitivity/reliability of the test

a) the study can be stopped if no significant uptake is shown after 28 days;

Reporting of the methodology and results

b) the dilution water fulfils the following condition(s): particulate matter ≤ 5 mg/L, total organic carbon (TOC) ≤ 2 mg/L, pH between 6.0 and 8.5;

c) the lipid content of the fish measured at least before the beginning and at the end of the uptake phase and end of depuration phase, the method used for its determination and the lipid normalisation factor (Ln), if applicable, are reported.

135 In the provided study:

Technical specifications impacting the sensitivity/reliability of the test

a) the uptake phase was 11 days and you state that "[a]*s no test item was found in fish after the uptake phase of 11 days, the test was ended without depuration phase*".

In your comment to the draft decision, you disagree that the short uptake phase of 11 days impacts the sensitivity of the test. You state that the requirement of 28-day uptake phase is relevant for aquatic exposure only. You explain that the study was conducted with dietary exposure as agreed previously with the German competent authority, following the Flow-through Fish Test (June 1996) and "fish dietary bioaccumulation study -basic protocol". You claim that according to the protocol, an uptake phase of 10 day is recommended. Furthermore, you state that according to the OECD TG 305-III, an uptake phase of 7-14 days is generally sufficient. Hence, you conclude that the uptake phase of 11 days is in compliance with the test guideline.

ECHA acknowledges that OECD TG 305-III states that the uptake phase of 7-14 days is usually sufficient. However, ECHA points out that OECD TG 305-III also states:

- "[i]*t is important to ensure that a sufficiently high (non-toxic) body burden of the test substance is achieved with respect to the analytical method, so that at least an order of magnitude decline can be measured during the depuration phase. In special cases, an extended uptake (up to 28 days) may be used with additional sampling to gain insight into uptake kinetics*";

- "[i]*n some cases it may be known that uptake of chemical in the fish over 7-14 days will be insufficient for the food concentration used to reach high enough concentration to analyse at least an order of magnitude decline during the depuration,* […] *In such cases it may be advantageous to extend the initial feeding phase to longer than 14 days*".

Therefore, ECHA reiterates that the study is not adequate because the uptake duration was too short to conclude on the bioaccumulation of the Substance.

Reporting of the methodology and results

b) the TOC/particulate matter of the dilution water is not reported.

In your comment to the draft decision, you provided additional information on the dilution water. However information on TOC/particulate matter is still missing.

c) the lipid content measured at before the beginning and at the end of the uptake phase was not determined.

In your comment to the draft decision, you state that this information is not provided in the study report. However, you consider that since the Substance was not taken up by the test organisms during the uptake phase, it is not essential and does not influence the reliability of the study.

ECHA acknowledges that this information would not be essential in case it can reliably be demonstrated that no uptake of the Substance occurs. However, for the reasons explained above, the uptake phase in this study was too short to allow such demonstration. Therefore, your comments do not change the assessment's outcome.

136 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the study duration of the uptake phase was shorter than specified by the test guideline requirements. As the Substance has high logK_{ow}, it is expected to require long time to achieve steady state. Therefore, the uptake phase should have been extended beyond 11 days.
- the reporting of the study is still not sufficient to conduct an independent assessment of its reliability.

137 The information provided in your comments does not change the assessment's outcome.

138 On this basis, the specifications of OECD TG 305 are not met.

139 Therefore, the information requirement is not fulfilled.

14.3. Study design

140 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.

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

142 You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

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

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

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

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

Appendix 2: Procedure

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

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

The compliance check was initiated on 14 June 2022.

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.

You have provided comments during the decision-making phase which were found to address the incompliance identified in the draft decision and you included this information in an update of your registration dossier (submission date: 26 May 2023). Therefore the original requests

- *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471),
- Long-term toxicity testing on aquatic invertebrates, also requested at Annex IX (triggered by Annex VII, Section 9.1.1., Column 2) and
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

were removed.

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

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

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

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[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 (https://echa.europa.eu/practical-guides).

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

1.2 Test material

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

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested (e.g. purity).

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 (https://echa.europa.eu/manuals).

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.