~~Confidential~~

Helsinki, 22 June 2022

**Addressees**
Registrant(s) of Joint subm. NDBC as listed in Appendix 3 of this decision

**Date of submission of the dossier subject to this decision**
02 July 2019

**Registered substance subject to this decision ("the Substance")**
Substance name: Nickel bis(dibutyldithiocarbamate)
EC number: 237-696-2

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

## DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***27 June 2025***.

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.) test method:
   i) *In vitro/in chemico* skin sensitisation 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 EU B.71/OECD TG 442E); and

   ii) Only in case no conclusion on the skin sensitisation potency can be made for the Substance based on the 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. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211).

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

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

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

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

6. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: using an appropriate test method);

7. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: EU C.13./OECD TG 305, aqueous exposure).

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

**Information required depends on your tonnage band**

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

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

**How to comply with your information requirements**

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

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

**Appeal**

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

**Failure to comply**

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

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

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

## Appendix 1: Reasons for the decision

### Contents

**Reasons related to the information under Annex VII of REACH**

## 1. Skin sensitisation

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

### *1.1. Information provided*

2 You have provided a delayed contact hypersensitivity in the guinea-pig study (1986) with the Substance.

### *1.2. Assessment of the information provided*

3 We have assessed this information and identified the following issue(s):

#### *1.2.1. Non-compliant study*

4 To be considered compliant and enable concluding whether the Substance causes skin sensitisation, a study has to meet the requirements of the EU Method B.6/OECD TG 406. The key parameter(s) of this test guideline include

a. The induction concentration should be the highest causing mild irritation (Buhler test) to the skin and the challenge dose should be the highest non-irritation concentration (OECD TG 406, paragraph 27).
b. Appropriate number of animals: 20 in test and 10 in control group
c. Positive controls to establish the sensitivity and reliability of the experimental technique (OECD TG 406, paragraph 11)

5 In the provided study:

a. Only one concentration is used in both the induction and the challenging phase. No information is available to evaluate if the concentration used caused mild irritation in the induction phase.
b. Only 10 animals were used in the test group.
c. Positive controls were not included in the study and there are no other information available to confirm the sensitivity and reliability of the experimental technique.

6 Therefore, the study does not fulfil the key parameter(s) set in the EU method B.6/OECD TG 406 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

7 In the comments to the draft decision, you agree with ECHA's reasoning, related to the delayed contact hypersensitivity in the guinea-pig study. You indicate your intention to classify the Substance for Skin Sensitisation Cat. 1 based on the structurally similar sodium bis(dibutyldithiocarbamate) (SDBC, CAS 136-30-1) and Zinc bis(dibutyldithiocarbamate) (ZDBC, CAS 136-23-2). Therefore, ECHA understands that you intent to adapt this information requirement by means of grouping and read-across approach according to Annex XI, section 1.5 of the REACH Regulation.

8 ECHA acknowledges your intentions to adapt this information using a read-across approach. As this strategy relies on a read-across approach that has not yet been fully described and

justified, as well as on data which is yet to be provided, no conclusion on the compliance of the proposed adaptation can be made.

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

*1.3. Specification of the 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 EU B.71/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 in vitro/in chemico 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. Long-term toxicity testing on aquatic invertebrates

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

*2.1. Information provided*

13 You have provided an OECD TG 202 study. You have also indicated in your dossier that a long-term study toxicity on aquatic invertebrate is ongoing. However, no information in the dossier is currently available on long-term toxicity on aquatic invertebrates for the Substance.

*2.2. Assessment of the information provided*

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

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

16 In the provided OECD TG 105 study (1995), the saturation concentration of the Substance in water was determined to be 8.93 µg/L.

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

18 In your comment to the draft decision, you state that information on Long-term toxicity testing on aqiatic Invertebrate (i.e. OECD TG 211) is available and that you will provide this information in an updated of your registration dossier. However, the information in your comments is not sufficient for ECHA to make an assessment, because you have not provided any new scientific information that could address the information requirement. Please note that this decision does not take into account updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation")."

19 On this basis the information requirement is not fulfilled.

*2.3. Study design and test specifications*

20 The Substance is difficult to test due to the low water solubility (0.00893 mg/L) and adsorptive properties: log kow=5.44 ). The OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in the OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e., measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in the OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

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

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

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

**Reasons related to the information under Annex VIII of REACH**

## 3. Long-term toxicity testing on fish

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

### *3.1. Information provided*

24 You have provided an OECD TG 203 study. You have also provided an OECD TG 212 study as an information on long-term toxicity on fish for the Substance.

### *3.2. Assessment of the information provided*

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

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

27 As already explained under request 2 the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

28 As specified under the Guidance on IRs and CSA, Section R.7.8.4.1, the OECD TG 212 is considerably shorter and less sensitive than the Fish, Early-Life Stage (FELS) Toxicity Test (OECD TG 210) and offers an alternative to the FELS toxicity test for substances with log Kow less than 4.

29 In your dossier you have indicated a log kow of 5.44 (above 4), therefore the OECD TG 212 is not an appropriate alternative to test the Substance.

30 Furthermore, besides the important consideration of the length and sensitivity of the tests, ECHA points out that in the Fish Toxicity Testing Framework (OECD Series on Testing and Assessment, No. 171) the use of the OECD TG 212 is not advised due to animal welfare issues and the guideline is proposed to be deleted (section 11.2 of the framework).

31 In your comments to the draft decision, you agree that the study provided in your dossier i.e., OECD TG 212 is not an appropriate alternative to test the Substance. However, you propose to adapt the long-term testing on fish based on the fact that the fish is the least sensitive species, you state: *"the available aquatic toxicity studies on three trophic levels (fish, invertebrate and algae) show that fish is the least sensitive species".* Further you add that based on the EC50 values determined in algae study and short-term studies of fish and aquatic invertebrate, the fish is over 1000 times more tolerant to acute exposure to the Substance compared to the other two species.

32 On this basis, you consider that there is sufficient information available to conclude on the absence of risks, you claim: "with the available aquatic toxicity information, the chemical safety assessment indicates that the risks of the Substance to the aquatic organisms are controlled".

33 ECHA understands that you intend to adapt this information requirement according to Annex XI, Section 3.2 (a) of the REACH Regulation.

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

35 Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet the following criteria:

(1) It can be demonstrated that all the following conditions are met:

i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and

ii. a PNEC can be derived from available data, which:

- must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in Guidance on IRs and CSA, Section R.10.3.
- the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

36 For the reasons explained under this request and request 2, your dossier does not include reliable information on the hazardous properties of the substance on at least three trophic levels, since the short data on invertebrate and fish are not considered as reliable for poorly water soluble substance.

37 Therefore, you have not demonstrated that an appropriate PNEC can be derived and your adaptation is rejected.

*3.3. Study design and test specifications*

38 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.).

39 The Substance is difficult to test due to the low water solubility (0.00893 mg/L) and adsorptive properties: log kow=5.44 ). The OECD TG 210 specifies that, for difficult to test substances, you must consider the approach described in the OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in the OECD TG 210. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

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

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

- use loading rates that are sufficiently low to be in the solubility range of most

constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (Guidance on IRs and CSA, Appendix R.7.8.1-1, Table R.7.8-3);provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique); prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

## 4. Soil simulation testing

42 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).

43 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 301B), and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log $K_{ow}$ > 4.5);
- 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.

### *4.1. Information provided*

44 Your registration dossier provides the following:

- The Substance is not readily biodegradable (0% degradation after 28 days in the OECD TG 301B);
- The Substance has a high potential to partition to lipid storage (Log $K_{ow}$ of 5.44 based on QSAR prediction);

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

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Request 9. of this decision), and
- it is not possible to conclude on the toxicity of the Substance (see Requests 3 and 5 of this decision).

46 Under section 2.3 of your IUCLID dossier ('PBT assessment'), you conclude that further information for the PBT assessment is necessary. You have also provided a QSAR prediction using a BCFBAF (v3.02) model indicating a BCF value of 75.96 L/kg and you conclude that the Substance should not be classified as B/vB.

47 However, the QSAR prediction you provide to support the conclusion for not B or vB is not reliable because as you have indicated in your dossier the Substance is outside the applicability domain of the model.

48 Under ECHA Guidance R.6.1.5.3., a prediction is within the applicability domain of the model, when, among others, the substance and the structures selected for the prediction fall within descriptor, structural, mechanistic and metabolic domain.

49 The selected structures (i.e. training set) used as an input for the prediction are outside of the applicability domain because there are no analogues in the training set, or any substance, containing the Nickel function.

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

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

52 Further, the Substance has low water solubility (0.00893 mg/L), high partition coefficient (log Kow=5.44 and high adsorption coefficient (log $K_{oc,soil}$ of 6.25), indicating high potential to adsorb to sediment.

53 In the comments to the draft decision, you indicate that you plan to explore ways to address this information requirement. You mention that before deciding if a simulation test on ultimate degradation in soil is necessary for the Substance you will first investigate further the results of read-across proposed on simulation test on ultimate degradation in sediment i.e. request 5. However, in your comments you have not provided any new scientific information that could address the information requirement.

54 On this basis the information requirement is not fulfilled.

### *4.2. Study design and test specifications*

55 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.

56 In accordance with the specifications of the 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).

57 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.

## 5. Sediment simulation testing

58 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).

59 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.).

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

61 Further, the Substance has low water solubility (0.00893 mg/L), high partition coefficient (log Kow=5.44 and high adsorption coefficient (log $K_{oc,soil}$ of 6.25), indicating high potential to adsorb to sediment.

62 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.

63 In the comments to the draft decision, you indicate your intention to adapt this information requirement by using a Grouping of substances and read-across approach and provided the following information: a preliminary Read-across justification that you have attached to your comments in which you propose to predict the properties of the Substance for Simulation testing on ultimate degradation from source studies on the analogue substance Copper bis(dibutyldithiocarbamate) (i.e. CDBC, CAS No. 13927-71-4).

64 You provide the following reasoning for the prediction of this information requirement: You claim that the two substances are similar and the only difference between these two substances is that two identical esters are connected to a Nickel for the Substance and to a Copper for the source substance. You also add that based on the physico-chemicals properties both substances have the same bioavailability.

65 Further, you have provided a data matrix that includes the OECD TG 308 results of the source substance indicating a DT50 of 22.1 days (at 12°C).

66 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

*5.1. Assessment of the information provided*

67 We have assessed this information and identified the following issue(s):

*Read-across adaptation rejected*

68 Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

69 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

70 We have identified the following issue(s) with the prediction of the fate properties:

*5.1.1.1. Missing supporting information*

71 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide

supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

72 Supporting information must include supporting information to compare properties of the Substance and source substances.

73 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

74 For the source substance you have provided a data matrix that includes the OECD TG 308 results of the source substance indicating a DT50 of 22.1 days (at 12 degrees C). Apart from that information, your read-across justification does not include any robust study summaries or descriptions of data for the source substance that would confirm that both substances cause the same type of environmental fate.

75 In the absence of such information, you have not established that the Substance and the source substance(s) are likely to have similar properties. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

76 As explained above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

*5.2. Study design and test specifications*

77 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.

78 In accordance with the specifications of the 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.

79 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.

80 In accordance with the specifications of the 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.

81 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.).

## 6. Identification of degradation products

82 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.).

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

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

85 In the comments to the draft decision, you indicate that you plan to explore ways to address this information requirement. You mention that it will depend on the necessity to perform simulation testing on ultimate degradation in sediment or soil. However, in your comments you have not provided any new scientific information that could address the information requirement.

86 On this basis the information requirement is not fulfilled.

### *6.1. Study design and test specifications*

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

88 To determine the degradation rate of the Substance, the requested studies according to the OECD TG 308/307 (Requests 4 and 5) must be conducted at 12°C and at a test material application rate 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).

## 7. Bioaccumulation in aquatic species

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

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

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

92 In your comment to the draft decision, you mention that the bioaccumulation in aquatic species is not a standard information requirement at Annex VIII and therefore the performance of an experimental study will depend on the persistence property of the Substance. In this context you propose to conclude first on P/vP properties of the Substance before deciding to investigate the bioaccumulation potential of the Substance.

93 As mentioned under Appendix 4, ECHA advises to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. On this basis, ECHA acknowledges your strategy. However, as already indicated above and explained in Request 4, the Substance is a potential PBT/vPvB substance. Currently, you have not provided specific information allowing to conclude on the P/vP properties of the Substance. Therefore, the information provided in your comments does not change the assessment outcome.

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

*7.1. Study design and test specification*

95 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.

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

97 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 the OECD Guidance Document on Aspects of the 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).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

***Read-across assessment framework (RAAF)***

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

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

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

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

**Appendix 2: Procedure**

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

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

The compliance check was initiated on 16 June 2021.

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

ECHA took into account your comments and did not amend the request(s).

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.

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

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

## Appendix 4: Conducting and reporting new tests for REACH purposes

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

### 1.1. Test methods, GLP requirements and reporting

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

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

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

### 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.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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

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

References to Guidance on REACH and other supporting documents can be found in Appendix 1.