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Helsinki, 31 October 2022

Addressees
Registrant(s) of RM CuSO4 DETA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/10/2021

Registered substance subject to this decision ("the Substance")
Substance name: reaction mass of copper sulfate and deta to Reaction products of 2,2'-iminodi(ethylamine) and copper sulphate (1:1)
EC/List number: 701-411-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***7 November 2023***.

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

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

1. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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.

Appeal

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

Failure to comply

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

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

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

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

Appendix 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

1 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

1.1. Information provided

2 You have adapted this information requirement by using a Grouping of substances and read-across approach based on experimental data from the following substances:

(i) an in vitro gene mutation study in bacteria (2017) with the source substance CuTEPA, EC 701-400-4

3 You have also adapted this information requirement by applying weight of evidence (WoE) adaptation in accordance with Annex XI, section 1.2. You have submitted the following information:

(ii) QSAR Ames with the source substance DETA EC 203-865-4 (2018)
(iii) A "voluntary risk assessment report" of copper and copper compounds (2008)

4 To support your adaptation, you have also provided the following statement:"*Both constituents of Copper diethylenetriamine sulfate were evaluated for their mutagenic potential. Diethylenetriamine (DETA) was predicted to be mutagenic based on the CAESAR QSAR for mutagenicity (Ames test). Similarly, a positive Ames test was found for the category member "reaction product of copper sulfate and tetraetylene pentamine". Further tests were required to decide on the mutagenicity of DETA and these were performed for the registration dossier of DETA. A large number of tests, both in vitro and in vivo were performed and the evidence if these in vitro and three in vivo shows that DETA is not mutagenic. DETA is therefore also not classified as a mutagenic. CuSO4 has been extensively studied, both in vitro and in vivo. Although certain in vitro tests have shown signs of mutagenecity at very high copper sulfate concentrations, the weight of evidence of all available studies - with a large weight being given to in vivo tests where mutagenecity was not observed - leads to the conclusion that copper sulfate is not mutagenic. Because both constituents of Copper diethylenetriamine sulfate were found to be non-mutagenic, the substance itself is also considered non-mutagenic*".

1.2. Assessment of the information provided

1.2.1. The proposed category read-across adaptation is rejected

1.2.1.1. Scope of the grouping of substances (category)

5 You provide a read-across justification document in IUCLID Section Linked categories.

6 For the purpose of this decision, the following abbreviations are used for the category members:

- CuTETA, Reaction product of copper sulfate ($CuSO_4$) and N'-[2-(2-aminoethylamino)ethyl]ethane-1,2-diamine (TETA), EC No. 701-399-0
- CuTEPA, Reaction product of copper sulfate ($CuSO_4$) and N'-[2-[2-(2-aminoethylamino)ethylamino]ethyl]ethane-1,2-diamine (TEPA), EC No. 701-400-4
- CuDETA, Reaction product of copper sulfate ($CuSO_4$) and N-(2-aminoethyl)ethane-

1,2-diamine (DETA), EC No. 701-411-4

7 You justify the grouping of the substances as: "[redacted]".

8 You define the applicability domain as follow: "*Any copper chelate with polyamines where the chelating agents has stability constants similar or higher than CuDETA can thus be a category member for the ecotoxicity.* […] *Any metal chelate with DETA, TETA or TEPA can be considered a member of the category if the toxicity of the metal ion is lower or similar to copper*".

9 ECHA understands that this is the applicability domain of the grouping and your predictions are assessed on this basis.

1.2.1.2. Predictions for toxicological properties

10 You predict the properties of the Substance from information obtained from the following source substance:

11 CuTEPA, Reaction product of copper sulfate ($CuSO_4$) and N'-[2-[2-(2-aminoethylamino)ethylamino]ethyl]ethane-1,2-diamine (TEPA), EC No. 701-400-4

12 You provide the following reasoning for the prediction of in vitro gene mutation study in bacteria:

- "[…] *tests were again performed for the worst-case copper chelate. For this, the toxicity of the different constituents is first compared. In the ECHA dissemination database, no information is available on the toxicity of copper polyamines with DETA, TETA or TEPA. Therefore, the classification of copper sulphate and DETA, TETA and TEPA is considered. For human toxicology, the chelating agents have comparable toxicity compared to the copper sulphate*";
- "*All possible toxicokinetic and toxicodynamic interactions among the source substance's constituents are inherently reflected in the test results*";
- "*The category approach is justified based on a range of physicochemical and (eco)toxicological endpoints. Many physicochemical endpoints were experimentally tested to prove that the substances are indeed very similar*";
- "*Based on the mutagenicity of the individual constituents and QSARs, a weight-of-evidence approach has demonstrated that CuDETA is not mutagenic. For CuTEPA and CuTETA, a positive Ames test was available and further in vivo tests are planned to clarify the mutagenicity. Based on the absence of genotoxicity in the individual substances, these two metals chelates are at the moment not classified as mutagenic*".

13 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance based on a worst-case approach.

14 We have identified the following issue with the prediction of in vitro gene mutation study in bacteria:

1.2.1.2.1. Missing supporting information

15 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.).

16 Supporting information must include bridging studies to compare properties of the category members, supporting information to confirm the formation of common (bio)transformation products and information to confirm your claimed worst-case prediction.

17 As indicated above, your read-across hypothesis is based on the assumption that the source substance (CuTEPA) constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm a conservative prediction of the properties of the Substance from the data on other category members. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

18 For the source substance (CuTEPA), you provide the study, an in vitro gene mutation study in bacteria, used in the prediction in the registration dossier. Apart from that study, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of bridging studies, studies on (bio)transformation of category members to common compound(s) or other supportive data for the source substance that would confirm a conservative prediction of the properties of the Substance.

19 In the absence of such information, you have not established that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

1.2.1.3. Conclusion on the read-across approach

20 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. is rejected.

1.2.2. Your weight of evidence adaptation is rejected

21 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

22 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

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

24 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

25 You have not included a justification for your weight of evidence adaptation, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

26 In spite of this critical deficiency, ECHA has nevertheless assessed the validity of your adaptation. Your weight of evidence approach has deficiencies that are common to all information requirements under consideration and also deficiencies that are specific for these information requirements individually.

27 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.1 at Annex VII include:

- Detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies; and
- Data provided on 5 bacterial strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

28 The sources of information (ii) and (iii) may provide relevant information on detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies and on data provided on 5 bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

29 However, the reliability of these sources of information is significantly affected by the following deficiency:

1.2.2.1. The constituent-based read-across is not reliable

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 (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2].

30 You provide a read-across justification document in IUCLID Section Linked categories.

31 You predict the properties of the Substance from information obtained from the following constituents of the Substance :

DETA	diethylenetriamine , EC No. 203-865-4.
CuSO4	copper sulfate, EC No. 231-847-6

32 You provide the following reasoning for the prediction of toxicological properties:

[2] ECHA Guidance R.6

- "*The copper polyamines considered in this category consist of two main functional groups:* [redacted].
- "*Based on the mutagenicity of the individual constituents and QSARs, a weight-of-evidence approach has demonstrated that CuDETA is not mutagenic*".

33 ECHA understands that your read-across hypothesis is based on the formation of common (bio)transformation products. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

34 We have identified the following issues with the prediction of in vitro gene mutation study in bacteria:

1.2.2.1.1. Missing supporting information

35 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.).

36 Supporting information must include bridging studies to compare properties of the category members and information to confirm dissociation of the complex formed between the copper ion and the poly-amine chelating agent.

37 As indicated above, your read-across hypothesis is based on the assumption that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance. In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm a conservative prediction of the properties of the Substance from the data on other category members. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

38 For the source substances, you provide a reference voluntary risk assessment report on copper and its compounds and a QSAR prediction for DETA. Apart from this information, your read-across justification or the registration dossier does not include any robust study summaries or descriptions of data for the Substance that would support the prediction.

39 In the absence of such information, you have not established that the provided information provide a reliable basis to support the hypothesis of the read-across.

1.2.2.1.2. Missing robust study summaries for the source substance copper sulfate

40 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 include robust study summary for each source study used in the adaptation.

41 Robust study summary must provide a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study (Article 3(28)).

42 For the source of information (iii), you have only provided a reference to a voluntary risk assessment report on copper and copper compounds.

43 You have not provided detailed information on the methods, results and conclusions, allowing for an independent assessment as to whether the information from the underlying study(ies) provide adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for this information requirement. Therefore, you have failed to provide a robust study summary for each source study used in the adaptation as required by Annex XI, Section 1.5.

1.2.2.1.3. The Modelled endpoint not well defined

44 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must, among other conditions, have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement.

45 Under the Guidance on IRs and CSA, Section R.6.1.3., a (Q)SAR model must fulfil the principles described in the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) to be considered scientifically valid. The first OECD principle requires the endpoint of a (Q)SAR model to be well defined. Guidance on IRs and CSA, Section R.6.5.1.2 specifies that for a well-defined endpoint the effect modelled being predicted by the (Q)SAR must be the same as the effect measured by a defined test protocol relevant to the information requirement, which in this case includes data provided on 5 bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101).

46 You specify that the effect that is modelled is in vitro gene mutation study in bacteria.

47 You have used a (Q)SAR model (CAESAR 2.1.13) which is based on data generated using the following methodology: Mutagenicity (Ames test) model. You only refer to Salmonella typhimurium as the corresponding test species and do not indicate specifically which strains are represented in the training set

48 Therefore, the endpoint of the model is not well defined. As a result, it cannot be assessed whether the prediction from the selected (Q)SAR provide an adequate and reliable coverage of the key parameters foreseen to be investigated as required by Annex XI, Section 1.5.

1.2.2.1.4. Conclusion on the read-across approach

49 For the reasons 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. cannot be considered a reliable source of information that could contribute to the conclusion on this key parameter investigated by the required study.

1.2.2.2. Conclusion on the weight of evidence adaptation

50 In summary, the sources of information (ii) to (iii) provide limited relevant information on detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies and data provided on 5 bacterial strains: four strains of S. typhimurium (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli

WP2 uvrA (pKM101). However, these sources of information have significant reliability issues as described above and cannot contribute to the conclusion on the information requirement for in vitro gene mutation in bacteria.

51 It is not possible to conclude, based on any source of information alone or considered together, on the information requirement for in vitro gene mutation in bacteria. Therefore, your adaptation is rejected.

52 On the basis of the above, the information requirement is not fulfilled.

1.3. Specification of the study design

53 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) is considered suitable.

2. Short-term toxicity testing on aquatic invertebrates

54 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

2.1. Information provided

55 You have provided a study on short-term toxicity to Daphnia (2017) with the Substance.

2.2. Assessment of the information provided

2.2.1. The provided study does not meet the information requirement

56 To fulfil the information requirement, a study must comply with OECD TG 202 (Article 13(3) of REACH). Therefore, the following specifications must be met:

57 Characterisation of exposure

a) analytical monitoring must be conducted. A reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range must be available;

58 Reporting of the methodology and results

b) the test procedure is reported (e.g. composition of the test medium, age of daphnids);
c) the dissolved oxygen and pH measured at least at the beginning and end of the test is reported.

59 Your registration dossier provides an OECD TG 202 study showing the following

60 Characterisation of exposure

a) the concentration of the test material was determined in the medium with a method that measures only Cu concentration. However, the concentration of the whole Substance (CuDETA) or its organic part, i.e. DETA, are not measured and it is not shown that the Cu concentration could be used as a surrogate measurement of the Substance or DETA concentration in the test medium.

61 Reporting of the methodology and results

b) on the test procedure, you have not specified age of daphnids. Also, the test

medium characteristics, particularly hardness is not reported;

c) the dissolved oxygen and pH measured at least at the beginning and end of the test is not reported. You have reported only the range (pH 7.7-8.0 and dissolved oxygen 8.7-8.9 mg/L) in both cases without specifying the time points of the measurements.

62 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the applied analytical method measures only concentration of the Cu part of the substance in the test medium and the concentration of the Substance (CuDETA) or its organic part (DETA) is not measured. Therefore, the concentration of the Substance or DETA in the test medium during the test is not known.

  In your comments to the draft decision, you state that "[d]*ue to the high water solubility of the test item itself (more than 1000 g/L) and the high water solubility of the parent components (copper sulfate and 2,2'-iminodi(ethylamine)) the measurement of copper is believed to be representative for the availability and presence of the substance in the test medium*". You provided a method validation report for the analytical method (*i.e.*, ICP/OES) used in study (i). You state that "[s]*ince no deviations were reported (i.e. precipitations or other phenomena which should indicate that the test substance as such would not be available in the test medium) the analysis of the copper content was considered to be representative for the test Substance*".
  However, stability of measured copper concentrations over the study period does not demonstrate that the organometallic complex remained stable. Also, in case the organic moiety (DETA) and the copper ion dissociates, stable concentrations stability of measured copper concentrations does not demonstrate stable exposure to the organic moiety. Therefore, while this report provides supporting information that the method to measure copper was adequate, it does not address the issue identified above.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. You have not reported that the age of the test animals. As a result, it is not possible to conclude that the age of the test animals followed the requirements of the test guideline, i.e. the animals were aged less than 24 h at the start of the test. Also, you have not reported the test medium characteristics in full detail, and the characteristics of the test water cannot be confirmed to be in line with the test guideline requirements, particularly water hardness is not reported to be within the required range between 140 and 250 mg/L (as CaCO3). In addition, the measurement of dissolved oxygen and pH were not reported to have taken place at the beginning and at the end of the test and it is not possible assess if the dissolved oxygen concentration and pH remained within acceptable range throughout the experiment.
  In your comments to the draft decision, you have attached the full study report for the study. The report includes the missing information listed above. This information supports that the study was conducted under test conditions that are mostly consistent with the OECD TG 202 (with the exception of water hardness which was 270 mg/L (as CaCO3) hence above the maximum value specified in the test guideline). However, as the information is currently not available in your registration dossier, you should submit this information in an updated registration dossier by the deadline set in the decision.

63 Therefore, as you have not provided adequate information to demonstrate tha exposure was satisfactorily maintained in this test, the requirements of OECD TG 202 are not met.

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

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

3. Growth inhibition study aquatic plants

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

3.1. Information provided

67 You have provided a growth inhibition test on freshwater algae (2018) with the Substance.

3.2. Assessment of the information provided

3.2.1. The provided study does not meet the information requirement

68 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

69 Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

70 Reporting of the methodology and results

b) the test conditions are reported (e.g., composition of the test medium);
c) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form.

71 Your registration dossier provides an OECD TG 201 study showing the following:

72 Characterisation of exposure

a) analytical monitoring of the Substance was not conducted and only Cu concentration was measured in the medium. However, the concentration of the whole Substance (CuDETA) or its organic part, i.e. DETA, are not measured and it is not shown that the Cu concentration could be used as a surrogate measurement of the Substance or DETA concentration in the test medium;

73 Reporting of the methodology and results

b) on the test conditions, you have not specified composition of the test medium;
c) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

74 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the applied analytical method measures only concentration of the Cu part of the substance in the test medium and the concentration of the Substance (CuDETA) or its organic part (DETA) is not measured. Therefore, the concentration of the Substance or DETA in the test medium during the test is not known.

  In your comments to the draft decision, you provided similar comments as those detailed under Request 2. You also provided a method validation report for the

analytical method (*i.e.*, ICP/OES) used in study (i). ECHA's reply to your comment provided under Request 2 equally applies to this endpoint.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, the composition of the test medium is not provided and it is not possible to assess the suitability of the applied test medium for the test. In addition, tabulated data on the algal biomass determined daily for each treatment group and control are not reported and therefore, it is not possible to conduct an independent assessment of whether the validity criteria of the test guideline were met and of the interpretation of the study results.

  In your comments to the draft decision, you have attached the full study report for the study. The report includes the missing information listed above. This information supports that the study was conducted under test conditions that are consistent with the OECD TG 201. However, as the information is currently not available in your registration dossier, you should submit this information in an updated registration dossier by the deadline set in the decision.

75 Therefore, as you have not provided adequate information to demonstrate tha exposure was satisfactorily maintained in this test, the requirements of OECD TG 201 are not met.

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

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

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 December 2021.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 6 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

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

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.

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

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

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

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

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

Appendix 4: Conducting and reporting new tests for REACH purposes

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

1.1. Test methods, GLP requirements and reporting

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

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

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

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

1.2. Test material

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

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must 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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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