~~Confidential~~

Helsinki, 03 May 2023

Addressees
Registrant(s) of barium chloride ec 233-788-1 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
10/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: Barium chloride
EC/List number: 233-788-1

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 ***9 February 2026***.

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

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

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

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

2. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit)

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.

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

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Reasons related to the information under Annex IX of REACH

1. Long-term toxicity testing on aquatic invertebrates

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

1.1. Information provided

2 You have provided:

3 in the registration dossier before the commenting period:

(i) a study on long-term toxicity to aquatic invertebrates (1972) with the Substance
(ii) a study on long-term toxicity to aquatic invertebrates (1988) with the Substance

4 with your comments on the initial draft decision and in the registration dossier updated during the commenting period:

(iii) a study on long-term toxicity to aquatic invertebrates (2010) with the analogue substance barium carbonate, together with a justification for the grouping and read-across approach.

1.2. Assessment of the information provided

1.2.1. Studies not conducted according to GLP

5 (Eco)toxicological studies must comply with GLP or another recognised international standard; Art. 13(4) of REACH.

6 You have indicated that studies (i), (ii) and (iii) are "not GLP-compliant", without further explanation.

7 The tests do not comply with GLP or another recognised international standard and are therefore rejected.

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

8 To fulfil the information requirement, a study must comply with the OECD TG 211 or another international test method recognised by the Commission or ECHA (Article 13(3) of REACH). For tests on *Ceriodaphnia dubia* not conducted according to OECD TG, US EPA TGs (Method 1002.0) are deemed acceptable by ECHA (Guidance on IRs & CSA, Chapter R.7b). Therefore, the following specifications must be met:

9 Key parameters to be measured

a) the concentrations of the test material leading to no observed effect (NOECs) on the following parameters are estimated:

(i) the reproductive output of Daphnia sp. expressed as the total number of living offspring produced at the end of the test, and
(ii) the survival of the parent animals during the test, and
(iii) the time to production of the first brood.

10 Validity criteria

b) the percentage of mortality of the parent animals (female *Daphnia*) in the control

is ≤ 20% at the end of the test;

c) the mean number of living offspring produced per surviving parent animal in the control is ≥ 60 at the end of the test with *Daphnia magna* (≥ 15 for *Ceriodaphnia dubia*).

11 Technical specifications impacting the sensitivity/reliability of the test

d) young female *Daphnia*, aged less than 24 hours at the start of the test, are used;
e) parental animals are not first brood progeny;
f) the test duration is 21 days or sufficient to produce at least three broods (7 days for *Ceriodaphnia dubia*);
g) the test is conducted on *Daphnia magna* Straus as test species or any other clearly identified daphnids if the selected species meets the validity criteria and appropriate justification is provided;
h) the test is conducted with a fully defined test medium. Any deviation (e.g. use of undefined additives) must be specified and clearly described (including its impact on the test medium composition);
i) the test medium fulfils the following condition(s): total organic carbon (TOC) ≤ 2 mg/L, dissolved oxygen concentration ≥ 3 mg/L, hardness ≥ 140 mg/L (as $CaCO_3$), pH between 6 and 9;
j) when testing metals, the test medium does not contain chelating agents;
k) the pH variation is < 1.5 units in one test;
l) if a solvent is used, its concentration is ≤ 100 mg/L (or 0.1 mL/L);
m) number of animals used are:
    - for semi-static tests, ≥ 10 animals at each test concentration and in the control series. Test animals are individually held;
n) for semi-static tests, the frequency of medium renewal is at least three times per week;
o) the feed ration level is between 0.1 and 0.2 mg C/*Daphnia*/day;
p) the test temperature is within 18°C and 22°C (25 °C for *Ceriodaphnia dubia*) and not varying by over ±1°C;
q) test vessels are not aerated during the test;
r) at least five test concentrations are used;
s) test concentrations follow a geometric series with a spacing factor ≤ 3.2;
t) the test concentrations are below the limit of solubility of the test material in the dilution water;
u) oxygen concentration, temperature, hardness and pH values are measured at least once a week, in fresh and old media, in the control(s) and in the highest test substance concentration.

12 Characterisation of exposure

v) 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;
w) if the concentration of the test material:
    - in semi-static tests,
        (i) is expected to remain within ± 20 % of the nominal concentration, then the test material concentration must be determined (in one replicate) in the highest and lowest test concentrations when freshly prepared and at the time of renewal on one occasion during each week of the test,
        (ii) is not expected to remain within ± 20 % of the nominal concentration, then all test concentrations must be determined when freshly prepared and at the time of renewal on one occasion during each week of the test.

13 Reporting of the methodology and results

x) parental mortality may only be excluded from the data analysis of the test result if it can be demonstrated that mortality does not follow concentration-response pattern;
y) the test design is reported (*e.g.* semi-static or flow-through, number of replicates, number of parents per replicate);
z) the test procedure is reported (*e.g.* loading in number of *Daphnia* per litre, test medium composition);
aa) if an undefined organic material is included in the test medium, its composition, source, method of preparation, TOC/DOC of stock preparations, estimation of resulting TOC/DOC in the final test medium are provided;
bb) detailed information on feeding, including amount (in mgC/daphnia/day) and schedule is reported;
cc) results from any preliminary studies on the stability of the test substance is reported;
dd) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are reported;
ee) water quality monitoring within the test vessels (*i.e.* pH, temperature and dissolved oxygen concentration, and TOC and/or COD and hardness where applicable) is reported;
ff) the full record of the daily production of living offspring during the test by each parent animal is provided;
gg) the number of deaths among the parent animals (if any) and the day on which they occurred is reported;
hh) the coefficient of variation for control reproductive output is reported;
ii) 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.

14 <u>In study (i) described as a long-term toxicity study on daphnids</u>:

15 Key parameters measured

a) The concentrations of the test material leading to no observed effect (NOECs) were not estimated on the following parameter(s):

- the reproductive output of Daphnia sp. expressed as the total number of living offspring produced at the end of the test, and
- the survival of the parent animals during the test, and
- the time to production of the first brood.

16 Validity criteria

b) the percentage of mortality of the parent animals in the control at the end of the test was unknown;
c) the mean number of living offspring produced per parent animal surviving in the control at the end of the test was unknown.

17 Technical specifications impacting the sensitivity/reliability of the test

e) parental animals were first brood progeny
f) the test duration is 21 days and you have not demonstrated that this duration was sufficient to produce at least three broods;
g) the test was conducted on *Daphnia magna*;
h) the test was conducted using an undefined medium (lake water), including barium and other metals, and you have not clearly described the test medium composition (for instance, TOC and/or COD chelating capacity);
i) the test was conducted with a test medium having the following characteristics: unknown particulate matter, unknown total organic carbon, hardness of 45.3 mg/L

(as $CaCO_3$), pH of 7.74;

k) the pH variation was unknown;
l) no information if a solvent was used is present;
m) the test was conducted under semi-static conditions and the number of test animals was 20 animals/tested level (4 replicates with 5 animals each);
n) the test was conducted under semi-static conditions and the frequency of medium renewal was weekly;
o) the feeding rate was in terms of mgC/daphnia/day is unknown;
p) the test temperature was 18 °C, varying by 1 °C
q) test vessels were not aerated during the test;
r) 5-12 concentrations were tested (not specified);
s) the spacing factor between test concentrations is unknown;
u) no information on measurements of oxygen concentration, temperature, hardness and pH values was reported.

18 Characterisation of exposure

v) no analytical monitoring of exposure was conducted;
w) the test was conducted under semi-static conditions and the concentration of the test material was not determined.

19 Reporting of the methodology and results

x) no detailed information on parental mortality is reported;
aa) the test medium contains lake water and you have not provided adequate information on the final test medium composition (for instance, TOC/DOC content, salinity, conductivity) of the final test medium;
bb) adequate information on feeding rate is not provided;
cc) results from preliminary studies on the stability of the test substance is not reported;
dd) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are not reported;
ee) water quality monitoring within the test vessels (pH, temperature, dissolved oxygen concentration, TOC and/or COD and hardness) are not reported;
ff) the full record of the daily production of living offspring during the test by each parent animal is not provided;
gg) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;
hh) the coefficient of variation for control reproductive output is not reported;
ii) no analytical method adequate information is reported.

20 Based on the above,

- the information provided does not cover the key parameter(s) required by the OECD TG 211;
- the validity criteria of OECD TG 211 are not met;
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no information on a adequate analytical method and analytical measurement is available. Available information on the test medium does not allow an assessment of its suitability for the test. The lack of information on the spacing factor between the tested concentrations does not allow to verify the correct study design;
- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. The lack of analytical measurements does not allow to assess the exposure of the tested organisms during the test. The lack of numerical results does not allow to verify the statistical analysis.

21 Therefore, the requirements of OECD TG 211 are not met.

22 In your comments on the draft decision you challenge ECHA's assessment of the publicly available literature study Biesinger and Christensen (1972 – namely study (i) above) provided to fulfil the requirement among others on information long-term toxicity to aquatic invertebrates. More specifically, you contested ECHA's evaluation on GLP compliance and the use of OECD TG on toxicity to aquatic invertebrates to assess the acceptability and reliability of the study. It must be noted that all these specific points have been used together to assess the validity of the study first of all. We further point out that according to Article 13(3) REACH, where tests are to generate information for registration purposes, they need to comply with the standards set out in the EU Test Methods Regulation or other recgnised international standards. REACH Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b (Endpoint specific guidance, version 4.0; June 2017) similarly states "*The information requirements of REACH are, in principle, met by studies carried out according to the currently adopted OECD test guidelines*".

23 As far as you refer to an adaptation under Annex XI, Section 1.1.2 in this context, it is in the first place pointed out that you did not refer to any such legal basis in the information provided in your registration dossier. This is why the information was assessed against the standard set out in Article 13(3) REACH. Secondly, such an adaptation would demand among others adequate and reliable coverage of key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3) REACH as well as adequate and reliable documentation of the study. For the same reasons as set out above you have not demonstrated that these conditions for an adaptation under Annex XI, Section 1.1.2 would be met.

24 <u>In study (ii) described as a long-term toxicity study on aquatic invertebrates:</u>

- The tested species is not a daphnids (*Cancer anthonyi*), it is a marine species tested in filtered seawater medium. The preferred species for the OECD TG 211 is the freshwater daphnids. Effects on 24h-acclimated embryo's stripped from the pleopods of ovigerous females were observed for an exposure period of 7 days, therefore the study describes the effects on embryo development and not on reproduction for adult organisms. Information on number of animals in the test, number of tested levels, spacing factor is not reported. No analytical verification has been performed. No detailed numerical results are available, therefore it is not possible to verify the statistical analysis.

25 Therefore, the requirements of OECD TG 211 are not met.

26 <u>In study (iii) described as a long-term toxicity study on daphnids:</u>

27 Key parameters measured

a) The concentrations of the test material leading to no observed effect (NOECs) were not estimated on the following parameter(s):

- the reproductive output of daphnids expressed as the total number of living offspring produced at the end of the test, and
- the survival of the parent animals during the test, and
- the time to production of the first brood.

28 Validity criteria

b) the percentage of mortality of the parent animals in the control at the end of the test was unknown;

29 Technical specifications impacting the sensitivity/reliability of the test

f) the test duration is 7 days and you have not demonstrated that this duration was sufficient to produce at least three broods;

h) the test was conducted using an undefined medium (tap water diluted with demineralised water), including barium and other metals, and you have not clearly described the test medium composition (for instance, TOC and/or COD chelating capacity);

i) the test was conducted with a test medium having the following characteristics: unknown particulate matter, unknown total organic carbon, hardness of 40 mg/L (as $CaCO_3$), pH of ranging between 7.5 and 8;

j) no information about the presence of chelating agent in the test medium was reported;

l) no information if a solvent was used during the test was reported;

p) the test temperature was 26 °C, varying by 1 °C;

q) no information on aeration was reported;

u) no information on timing of measurement on oxygen concentration, temperature, hardness and pH values was reported;

30 Characterisation of exposure

v) no information on specificity, recovery efficiency, precision, limits of determination (i.e. detection and quantification) and working range of analytical monitoring was available;

31 Reporting of the methodology and results

x) no detailed information on parental mortality is reported;
z) test medium composition was not reported;
bb) adequate information on feeding rate is not provided;
cc) results from preliminary studies on the stability of the test substance is not reported;
dd) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are not reported;
ee) water quality monitoring within the test vessels (pH, temperature, dissolved oxygen concentration, TOC and/or COD and hardness) are not reported;
ff) the full record of the daily production of living offspring during the test by each parent animal is not provided;
gg) the number of deaths among the parent animals (if any) and the day on which they occurred is not reported;
hh) the coefficient of variation for control reproductive output is not reported;
ii) no analytical method adequate information is reported.

32 Based on the above,

- the information provided does not cover the key parameter(s) required by the Method 1002.0;
- the validity criteria of Method 1002.0 are not met;
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no information on a adequate analytical method and analytical measurement is available. Available information on the test medium does not allow an assessment of its suitability for the test.;

33 the reporting of the study is not sufficient to conduct an independent assessment of its reliability. The lack of numerical results does not allow to verify the statistical analysis.

34 Therefore, the requirements of the relevant US EPA TG (Method 1002.0) are not met.

1.2.3. Read-across rejected

35 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on the following experimental data from a source substance in study (iii.) above.

36 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.

37 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).

38 You provide the following reasoning for the prediction of this information requirement: "*In sum, transport, fate, and toxicity of barium in the environment are largely controlled by the solubility of barium minerals. The barium cation is the moiety of toxicological concern, and thus the hazard assessment is based on Ba_2^+. Since the dissolved concentration of Ba_2^+ was determined in the current study, a full read-across is considered justified.".*

39 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

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

1.2.3.1. Read-across hypothesis contradicted by existing data

41 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 must 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 (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

42 The observation of differences in the toxicological properties between the source substance(s) and the Substance would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substance(s). An explanation why such differences do not affect the read-across hypothesis must to be provided and supported by scientific evidence.

43 Your read-across hypothesis is based on the assumption that the structurally similar Substance and source substance(s) cause the same type of effect(s). The moiety of toxicological concern is the potentially bioavailable metal ion (i.e., Ba_2^+). In your justification for read-across from an analogue substance you claim that: "*The dissolution of barium substances in the environment and corresponding dissolved Ba levels are controlled by the solubility of barite ($BaSO_4$) and witherite ($BaCO_3$), two naturally occurring barium minerals (Ball and Nordstrom 1991; Menzie et al, 2008), and the concentration of dissolved Ba cations in freshwater is rather low. However, in the dissolved state, the divalent barium cation, is the predominant form in soil, sediments and water.*"

44 The data available in your dossier indicates that the solubility of the Substance (Barium chloride) is significantly higher (360 g/L at 20°C, pH unreported) than the solubility of the source substance (Barium carbonate; 0.014-0.024 g/L at 20°C, pH 6).

45 This difference in solubility implies a a much higher concentration of Ba^{2+} ions when tested with the Substance than with the source substance. However, you have not supported and scientifically justified why such differences in the concentration and therefore bioavailability to the test organism would not affect your read-across hypothesis. 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.

1.2.3.2. Inadequate or unreliable source study

46 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;
(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information requirement;
(3) cover an exposure duration comparable to or longer than the one specified in the test guideline for the corresponding study that shall normally be performed for a particular information requirement, in this case OECD TG 211, and meet the requirements of OECD GD 23.

47 Specific reasons why study (iii) does not meet these requirements are explained in sections 1.2.1 and 1.2.2 above.

48 The study submitted in your adaptation does not provide an adequate and reliable coverage of the key parameter(s) and no reliable prediction can be made for this information requirement.

49 Therefore, the information requirement is not fulfilled.

1.3. Study design and test specifications

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

Reasons related to the information under Annex X of REACH

2. Pre-natal developmental toxicity study in a second species

51 Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X, Section 8.7.2.

2.1. Information provided

52 You have adapted this information requirement by using Annex IX, Section 8.7.3, Column 2. To support the adaptation, you have provided a justification:

53 "According to Regulation (EC) 1907/2006 Annex IX-X, section 8.7.3, column 2, the need for testing developmental toxicity in a second species is to be decided based on the outcome of developmental toxicity in the first species (rat) and all other relevant available data […]".

2.2. Assessment of the information provided

54 Pre-natal developmental toxicity (PNDT) studies in two species is a standard information requirement at Annex X and is thus not conditional on the basis of available data. The column 2 text you refer to in your adaptation applies for Annex IX information requirements only.

55 Therefore, your adaptation is rejected.

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

2.3. Specification of the study design

57 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species. The study in the first species was carried out by using a rodent species (rat).

58 Therefore, a PNDT study in a second species must be performed in the rabbit as preferred non-rodent species.

59 The study must be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

60 Based on the above, the study must be conducted in rabbits with oral administration of the Substance.

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 17 November 2021.

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

ECHA took into account your comments and amended the requests.

You have provided data with your comments during the decision-making phase which were found to be compliant with the information required in the draft decision. The same information is also included in your updated registration dossier. Therefore the original request 1. Short-term toxicity testing on aquatic invertebrates was removed.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

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

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

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

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- 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]
[redacted]	[redacted]	[redacted]
[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[2].

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

1.2. Test material

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

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

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