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Helsinki, 10 February 2022

Addressees
Registrant(s) of JS_104-74-5_[redacted] as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
05/02/2019

Registered substance subject to this decision ("the Substance")
Substance name: 1-dodecylpyridinium chloride
EC number: 203-232-2
CAS number: 104-74-5

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 ***15 November 2022***.

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

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

1. Surface tension (Annex VII, Section 7.6.; test method: EU A.5./OECD TG 115)

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

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

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

Reasons for the request(s) are explained in the following appendix:

- Appendix entitled "Reasons to request information required under Annexes VII of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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.

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

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 A: Reasons to request information required under Annex VII of REACH

1. Surface tension

Surface tension is a standard information requirement under Annex VII to REACH (Section 7.6).

You have provided the following information:

i. an adaptation under Annex VII, Section 7.6., Column 2 with the following justification: *"the study does not need to be conducted because surface activity is not a desired property of the material".*

We have assessed this information and identified the following issue:

According to Annex VII, Section 7.6, Column 2, the study need only be conducted if:

a) based on structure, surface activity is expected or can be predicted, or
b) surface activity is a desired property of the material.

The Substance contains hydrophilic (pyridine ring with charged nitrogen) and lipophilic (alkyl chain) moieties.

Your adaptation addresses point b) only, but the study need to be conducted if either criteria a or b is met.

Based on the structure of the Substance, surface activity can be expected.

Therefore, the adaptation is rejected.

In your comments to the initial draft decision you agree to perform the study with the Substance according to the OECD TG 115.

2. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have adapted the standard information requirement mentioned above according to Annex XI, Section 1.2. of REACH (weight of evidence).

In support of your adaptation, you have provided the following sources of information:

i. 2018, in vitro gene mutation study in bacteria with the following strains TA 98 and TA 100, with the analogue substance Methyltrioctyl ammonium chloride (CAS no 5137 - 55 -3);
ii. 1980, in vitro gene mutation study in bacteria with the following strains TA 98 and TA 100, with the analogue substance 1-Hexadecanaminium, N,N,N-trimethyl-, chloride (EC 203-928-6);
iii. 1980, in vitro gene mutation study in bacteria with the following strains TA 98 and TA 100, with the analogue substance Benzylcetyldimethylammonium Chloride Hydrate (EC 204-526-3);

Based on the presented sources of information, you argue that the available data gives sufficient information to conclude on the gene mutation in bacteria because: no positive result was found.

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or

has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

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 that the Substance has or has not the (dangerous) property investigated by the required study.

Annex XI, Section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

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 that the Substance has or has not the dangerous property investigated by the required study.

Irrespective of the above mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

A. Relevance of the provided information

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).

The pieces of information (i, ii and iii) are *in vitro* gene mutation studies in bacteria. However, they contain information only on two of the five required strains.

In conclusion, the sources of information (i-iii) provide partly relevant information on gene mutation in bacteria.

In addition, all sources of information have the following deficiency affecting their reliability.

B. Reliability of the provided sources

Information from source substances can contribute to weight of evidence adaptation only if the read-across is acceptable.

Absence of justification for use of information on analogue substances

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 a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).

You have provided studies conducted with substances other than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is reliable for your Substance to be used as part of weight-of-evidence.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s). Therefore, the information from the analogue substances submitted under your weight-of-evidence adaptation is not considered reliable.

Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 (read-across approach).

A read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[2]. It should explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the structural similarity between the source substance(s) and your Substance is a sufficient basis for predicting the properties of your Substance.

Structural similarity is a prerequisite for applying the grouping and read-across approach. You have not established the structural similarity between the substance and the source substances. Therefore, a reliable prediction for toxicological propoerties, based on recognition of the structural similarities and differences between the source substances and your Substance is not possible.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and the information provided is not reliable.

C. Conclusion for the property

As a conclusion, sources of information as indicated above, provide only partly relevant information and they are not reliable.

Accordingly, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 471 study.

Therefore your adaptation is rejected and information requirement is not fulfilled.

In your comments to the initial draft decision you agree to perform the study with the Substance according to the OECD TG 471.

[2] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471).

3. Short-term toxicity testing on aquatic invertebrates

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

- *Studies submitted to fulfil this information requirement*

You have provided the following information:

i. OECD TG 202 key study (2017)
ii. supporting study: scientific publication (1965), no guideline specified, method: Cationic surfactant effect observed in development of fertilized eggs of *M. Mercenaria*.
iii. supporting study: scientific publication (1965), no guideline specified, method: Cationic surfactant effect observed in development of fertilized eggs of *C. Virginica*.
iv. supporting study: scientific publication (2003), guideline Polish Standards (PN-90/C- 04610/04), equivalent to OECD TG 202.

ECHA understands that the last three studies are provided under Annex XI, Section 1.1.2.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 202 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH), or to comply with Annex XI, Section 1.1.2, that study myst have adequate and reliable coverage of the key parameters of OECD 202. Therefore, the following specifications must be met:

Key parameter to be measured:

- the key parameter to be measured is the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test is estimated.

Characterisation of exposure:

- the concentrations of the test material are measured at least at the highest and lowest test concentration, at the beginning and end of the test;
- the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20% of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1).

However, in the studies you have provided the following pieces of information are missing:

- the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test was not estimated (study ii. and iii.)
- no analytical monitoring of exposure was conducted (studies i.-iv.).

The Substance may be difficult to test due to potential surface active properties (surface activity is expected based on the structure) of the Substance

Based on the above:

- the key parameter of OECD TG 202 is not covered for studies ii. and iii.;
- there are critical methodological deficiencies resulting in the rejection of the study

results (studies i.-iv.). Specifically, information on analytical monitoring and analytical method is missing. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material and thus the study is not reliable.

You have not provided specific information addressing the issues identified above.

- *Weight of evidence adaptation*

In your comments you provided an adaptation which ECHA understands is based on Annex XI, Section 1.2 (weight of evidence).

To justify your adaptation you indicate*: "(…) we have assessed the acute toxicity data of aquatic invertebrates of the target chemical (…) and have further adapted the weight of evidence approach in the technical dossier by updating the new studies conducted as per the OECD TG/ of the structurally & functionally similar read across analogue i.e. 1-dodecylpyridinium bromide (CAS no. 104-73-4; EC no. 203-231-7)."*

ECHA understands that you propose to fulfil the information requirement by applying a weight of evidence approach according to Annex XI, Section 1.2. of REACH. In support of your adaptation, you refer to the following sources of information:

A. the existing key study (i.) and supporting studies (ii. – iv.) performed with the Substance

and you provide in your comments to the draft decision the following data:

B. outline of the study performed with an analogue substance – 1-dodecylpyridinium bromide (CAS 104-73-4; EC 203-231-7) according to [redacted] Standard Operating Procedure and the [redacted] procedure; [redacted] report, 1984 (published literature/secondary source).

Based on the above sources of information you argue that the available data gives sufficient information to conclude on short-term toxicity to aquatic invertebrates.

We have assessed this information and identified the following issues:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular hazardous property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

To fulfil the information requirement, normally a study according to OECD 202 must be provided. One of the key investigations of this test is:

- the concentration of the test material leading to the immobilisation of 50% of daphnids (EC50) at the end of the test

For studies withing the source A. the key study (i) and supporting study (iv.) provide EC50 (immobilisation). The supporting studies (ii. – iii.) provide either LC50 (mortality) or EC50 with reduction in number of fertilised eggs as a basis for the effect (test species other than Daphnia have been used). The study within the source B provides EC50 value without specifying the basis for effect.

Therefore, source A. (i) and (iv) contribute to the key investigation, (ii) and (iii) partly contribute to the key investigation. The source B partly contribute to the key investigation.

The reliability of these sources of information is also significantly affected by the following deficiencies:

A. Reliability of the existing key study and supporting studies

For the same reasons as explained above, the reliability of the key study and supporting studies is significantly affected.

B. Reliability of the read-across approach

To fulfil the information requirement, a study must comply with OECD TG 202. The conditions of OECD 202 TG include (among others):

Technical specifications impacting the sensitivity/reliability of the test:
- at least 20 animals are used at each test concentration and for the controls;

Characterisation of exposure:
- the effect values can only be based on nominal or measured initial concentration if the concentration of the test material has been satisfactorily maintained within 20% of the nominal or measured initial concentration throughout the test (see also ECHA Guidance R.7b, Section R.7.8.4.1).
- 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;
- adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided;

However, in the study provided in your comments the following pieces of information are missing:
- only 10 daphnids per vessel have been used,
- you have not indicated if analytical monitoring of exposure concentrations throughout the test duration was performed.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study. Specifically, information on analytical monitoring and analytical method is missing. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material and thus the study is not reliable. In addition, it is not possible for ECHA to verify whether all the validity criteria were fulfilled for study. Therefore, the reliability of this source of information is significantly affected.

C. Conclusion on the weight of evidence approach

Taken together, sources of information A. (i) and (iv) provide information, while A. (ii), (iii) and source B provide partial information on the concentration of the test material leading to the immobilisation of 50% of daphnids at the end of the test. However, the reliability of these sources is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, it is not possible to conclude, based on any source of information alone or considered together, whether your Substance has or has not the particular hazardous property foreseen to be investigated by OECD TG 202 study.

Therefore, the requirements of OECD TG 202 are not met and you have not demonstrated adequate and reliable coverage of its key parameters.

On this basis, the information requirement is not fulfilled.

Study design

The Substance may be difficult to test. OECD TG 202 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 202. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

4. Growth inhibition study aquatic plants

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

- *Studies submitted to fulfil this information requirement*

You have provided the following information:

i. OECD TG 201 key study (2017), no GLP applied,
ii. supporting study: scientific publication (1990),
iii. supporting study: OECD TG 201 study (2003).

ECHA understands that the last two studies are provided under Annex XI, Section 1.1.2.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH) or to comply with Annex XI, Section 1.1.2, that study myst have adequate and reliable coverage of the key parameters of OECD 201. Therefore, the following specifications must be met:

Validity criteria:

- exponential growth in the control cultures is observed over the entire duration of the test;
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%;

Characterisation of exposure:

- 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. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

However, the information on those specifications is missing:

- no analytical monitoring of exposure was conducted (studies i.-iii.);
- no information on exponential growth in the control cultures over the entire duration of the tests (studies i.-ii.);
- no information on the increase in biomass in the control cultures by the end of the tests (studies i.-ii.);
- no information on the mean coefficient of variation for section-by-section specific growth rates in the control cultures (studies i.-iii.);
- no information on the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures (studies i.-ii.).

The Substance is difficult to test.

Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. Specifically, information on analytical monitoring and analytical method is missing for the three studies. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material and thus the study is not reliable.

Furthemore, under Article 13(4) of REACH, the tests and analyses carried out after 1 June 2008 must comply with the principles of good laboratory practice (GLP).

The key study, performed in 2017, was not performed under GLP. Therefore, the key study does not comply with the requirements of Article 13(4) of REACH.

You have not provided specific information addressing the issues identified above.

- *Weight of evidence adaptation*

In your comments you provided an adaptation which ECHA understands is based on Annex XI, Section 1.2 (weight of evidence). To justify your adaptation you indicate*: "(…) we have assessed the acute toxicity data of algae of the target chemical (…) and have further adapted the weight of evidence approach in the technical dossier by updating the new studies conducted as per OECD TG of it."*

ECHA understands that you propose to fulfil the information requirement by applying a weight of evidence approach according to Annex XI, Section 1.2. of REACH. In support of your adaptation, you refer to the following sources of information:

A. the existing key study performed with the Substance (i.) and supporting studies (ii. – iii.)

and you provide in your comments to the draft decision the following data:

B. outline of a new OECD 201 TG study performed with the Substance.

Based on the above sources of information you argue that the available data gives sufficient information to conclude on toxicity to aquatic algae.

ECHA has assessed the validity of your adaptation and identified the following issues:

Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular hazardous property, while information from a single source alone is insufficient to support this notion.

According to ECHA Guidance R.4.4, a weight of evidence adaptation involves an assessment of the relative values/weights of 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 of the information for the given regulatory information requirement. Subsequently, relevance, reliability, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the dangerous property investigated by the required study.

Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence adaptation.

To fulfil the information requirement, normally a study according to OECD 201 must be provided. The key investigation of this test is:

- the concentrations of the test material leading to a 50% and 0% (or 10%) inhibition of growth at the end of the test.

The key study (i.) and supporting study (iii.) with the source A., provide 72h EC50 (growth rate). The supporting study (ii.) provide only EC value without specifying the percentage of inhibition of growth (only marine test species have been used). The study within the source B provides EC50 value without specifying the basis for effect. Therefore, source A.(i.) and (iii) contribute to the key investigation, while A.(ii) and source B. partly contribute to the key investigation.

The reliability of these sources of information is also significantly affected by the following deficiencies:

A. Reliability of the existing key study and supporting studies

For the same reasons as explained above, the reliability of these studies is significantly affected.

B. Reliability of the new study

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

Validity criteria:

- exponential growth in the control cultures is observed over the entire duration of the test,
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test,
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%,
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with *Desmodesmus subspicatus*. For other less frequently tested species, the value is ≤ 10%.

Characterisation of exposure:

- 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. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided,
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20% of the nominal or measured initial concentration throughout the test.

However, in the study outline provided in your comments the following pieces of information are missing:

- no information on exponential growth in the control cultures over the entire duration of the test,
- no information on the increase in biomass in the control cultures by the end of the tests,
- no information on the mean coefficient of variation for section-by-section specific growth rates in the control cultures,
- no information on the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures.
- you have not indicated if analytical monitoring of exposure was performed.

Based on the above, you have not demonstrated that the validity criteria are met and there are critical methodological deficiencies resulting in the rejection of the study. Specifically, information on analytical monitoring and analytical method is missing. Without analytical monitoring, it is not possible to determine whether and to what extent the tested organisms were exposed to the test material and thus the study is not reliable.

Therefore, the reliability of this source of information is significantly affected.

C. Conclusion on the weight of evidence approach

Taken together, sources of information A(i) and (iii) provide information, while A(ii) and source B. partly provide information on the concentration of the test material leading to a 50% and 0% (or 10%) inhibition of growth at the end of the test. However, the reliability of these sources is affected so significantly that they cannot be taken into consideration in a weight of evidence approach.

Therefore, it is not possible to conclude, based on any source of information alone or

considered together, whether your Substance has or has not the particular hazardous property foreseen to be investigated by OECD TG 201 study.

Therefore, the requirements of OECD TG 201 are not met and you have not demonstrated adequate and reliable coverage of its key parameters.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.3.

Appendix B: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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].

B. 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 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

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Appendix C: 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 1 October 2020.

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 D: List of references - ECHA Guidance[5] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[8]

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[8] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

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

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.