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Helsinki, 23 March 2022

Addressees
Registrant(s) of JS_Manganese_2Ethylhexanoate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
09/02/2021

Registered substance subject to this decision ("the Substance")
Substance name: 2-ethylhexanoic acid, manganese salt
EC number: 240-085-3
CAS number: 15956-58-8

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 ***28 August 2024***.

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

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

1. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

2. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

3. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

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

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

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX 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 Annexes VII to REACH, for registration at 1-10 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.

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 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 on Reasons common to several requests

1. **Assessment of the Grouping of substances and read-across approach under Annex XI, Section 1.5.**

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

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 R.6. and related documents[2,3].

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances, Manganese (II) sulfate **monohydrate**, EC No. 600-072-9, (CAS No. 10034-96-5), manganese sulphate **dihydrate**, (CAS No. 15244-36-7), manganese **dichloride** EC No. 231-869-6, (CAS No. 7773-01-5), and manganese **sulphate**, EC No. 232-089-9, (CAS No. 7785-87-7), and 2-ethylhexanoic acid, EC No. 205-743-6 (CAS number: 149-57-5), as source substances and the Substance as target substance.

You have provided the following reasoning for the prediction of toxicological properties (in IUCLID sections 7.5, 7.6 and 7.8, summaries): *"Selected endpoints for the human health hazard assessment are addressed by read-across, using a combination of data on the organic acid counterion and the metal (or one of its readily soluble salts). This way forward is acceptable, since metal carboxylates dissociate to the organic anion and the metal cation upon dissolution in aqueous media. (No indications of complexation or masking of the metal ion through the organic acid were apparent during the water solubility tests.) 2-ethylhexanoic, manganese salt is the manganese metal salt of 2-ethylhexanoic acid, which*

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

readily dissociates to the corresponding divalent manganese cation and 2-ethylhexanoic acid anions. The manganese cation and the 2-ethylhexanoic acid anion are considered to represent the overall toxicity of 2-ethylhexanoic, manganese salt in a manner proportionate to the free acid and the metal (represented by one of its readily soluble salts).”

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/dissociation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following shortcoming(s) with regards to prediction(s) of toxicological properties.

1. *Missing supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that “*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*”. For this purpose “*it is important to provide supporting information to strengthen the rationale for the read-across*”[4]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include toxicokinetic information on the formation of the common compound and bridging studies to compare properties of the Substance and source substances.

1.a Information on the formation of common compounds

As indicated above, your read-across hypothesis is based on the transformation/dissociation of the Substance. In this context, information characterising the rate and extent of the dissociation of the Substance and of the source substances is necessary to confirm the formation of the proposed known dissociation products and to assess the impact of the exposure to the parent compounds as well as the impact of dissociation products.

In your dossier you claim that “*2-ethylhexanoic, manganese salt is the manganese metal salt of 2-ethylhexanoic acid, which readily dissociates to the corresponding divalent manganese cation and 2-ethylhexanoic acid anions.”*

In the comments to the draft decision you reiterate your adaptation of the information requirement according to Annex XI, Section 1.5. You present a strategy relying on the generation of additional supporting information on the Substance and on the analogue substance without including supporting information. You indicate your intention to provide this in a future update of your registration dossier.

However, you have not provided, neither in the dossier nor with your comments, experimental data on the dissociation rate of the Substance to the organic acid counterion and the metal. Furthermore, you have not provided evidence to demonstrate an absence of effects of the counterion (2-ethylhexanoate) on the uptake, bioavailability and toxicity of manganese cation.

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

ECHA acknowledges your intentions to improve the (eco)toxicological profile of the Substance and your plans to refine your read-across approach. As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. The information in your comments is not sufficient for ECHA to make an assessment, because (i) you propose to follow a conservative approach taking manganese sulfate as a source substance without further explanation while the dissociation constant would indicate that manganese dichlore would be more conservative; and (ii) you do not indicate reliable data for all products of the proposed (bio)transformation to manganese (II) cation *and* 2-ethyl-hexanoate for all endpoints and therefore it is not possible to assess whether the prediction is reliable for the Substance as a whole. Please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation).

In the absence of this information, you have not provided supporting evidence establishing that the proposed common dissociation products are formed in a rate, that eliminates any significant exposure to the parent substance, as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

1.b Missing supporting information to compare toxic properties of the substances

As indicated above, your read-across hypothesis is based on the assumption that the target and source substances dissociate to common compounds, which cause same type of effect(s). Due to the deficiencies identified in the previous sub-section, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substances cause the same type of effects. Such information can be obtained, for example, from **bridging studies** of comparable design and duration for the Substance and of the source substance(s).

You have provided an in vitro gene mutation studies in bacteria, in vitro cytogenicity studies, in vitro gene mutation study in mammalian cells, sub-chronic and chronic toxicity studies, and non-guideline reproductive toxicity studies, as specified below on the source substances, while you did not provide studies on these toxic effects of the Substance.

The data set reported in the technical dossier does not include relevant, reliable and adequate toxicological information on the relevant toxicological endpoints for the Substance and of the source substance(s) to support your read-across hypothesis.

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

2. Adequacy and reliability of source study

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

- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

Related deficiencies are addressed under the corresponding Appendices below.

In the comments to the draft decision you state that "The key studies on relevant endpoints [….] meet all quality, relevancy and completeness requirements and are all considered valid."

We acknowledge the distinction between key and supporting studies and that, if your read-across adaptation is valid, only the studies with the relevant source substances need to meet the requirements of article 13(3). However, you did not address the issues identified in the corresponding Appendices below.

B. Conclusions on the read-across approach

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 your grouping and read-across approach is rejected.

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

1. *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 provided an adaptation according to Annex XI, Section 1.5. in your dossier. In support of your adaptation you have provided the following information:

i) Bacterial Reverse Mutation Assay, OECD Guideline 471, with the analogue substance, manganese sulphate monohydrate, EC No. 600-072-9, (CAS No. 10034-96-5), reliability 2, GLP not specified, performed in 1985

ii) Bacterial Reverse Mutation Assay, OECD Guideline 471, with the analogue substance, manganese sulphate, EC No. 232-089-9, (CAS No. 7785-87-7), reliability 2, GLP not specified, performed in 1986

iii) Bacterial Reverse Mutation Assay, OECD Guideline 471, with the analogue substance, 2-ethylhexanoic acid, EC No. 205-743-6 (CAS No. 149-57-5), reliability 2, no GLP, performed in 1988

iv) Bacterial Reverse Mutation Assay, OECD Guideline 471, with the analogue substance, 2-ethylhexanoic acid, EC No. 205-743-6 (CAS No. 149-57-5), reliability 1, according to GLP, performed in 1998

v) Bacterial Reverse Mutation Assay, OECD Guideline 471, with the analogue substance, manganese dichloride, EC No. 231-869-6 (CAS No. 7773-01-5), reliability 2, according to GLP, performed in 2009.

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

The read-across that you propose is not acceptable as explained above in **Appendix on Reasons common to several requests.**

In addition, we have identified the following shortcomings:

As provided in the Appendix on reasons common to several requests, a study must have adequate and reliable coverage of the key parameters of the corresponding test guidelines, in this case OECD TG 471[5] (1997). Two of the key parameters of this test guideline include:

a) Two separate test conditions must be assessed: in absence of metabolic activation and in presence of metabolic activation.
b) The test must be performed with 5 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 reported data for the studies i) and ii) you have provided did not include:
a) two separate test conditions, but only in absence of metabolic activation,

The reported data for the studies i), ii) and iii) you have provided did not include:
b) results for the appropriate 5 strains.

[5] ECHA Guidance R.7a, Table R.7.7–2, p.557

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Based on the above, the information you provided does not fulfil the information requirement.

Study design

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

Appendix B: Reasons to request information required under Annex VIII of REACH

1. *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier. In support of your adaptation you have provided the following information:

1. *In vitro* Mammalian Chromosome Aberration Test, OECD Guideline 473, with the analogue substance manganese sulphate monohydrate EC No. 918-733-8, reliability 2, GLP not specified, performed in 1987

2. *In vitro* Mammalian Chromosome Aberration Test, OECD Guideline 473, with the analogue substance 2-ethylhexanoic acid, EC No. 205-743-6 (CAS No. 149-57-5), reliability 1, accroding to GLP, performed in 1998

3. *In vitro* Mammalian Chromosome Aberration Test, OECD Guideline 473, with the analogue substance manganese dichloride, EC No. 231-869-6, (CAS No. 7773-01-5), reliability 2, according to GLP, performed in 2009.

ECHA also understands that you have provided the following *in vivo* tests using a read-across adaptation under Column 2 of Section 8.4.2:

4. Non-guideline study, erythrocytes micronucleus study, with the analogue substance 2-ethylhexanoic acid, EC No. 205-743-6 (CAS No. 149-57-5), reliability 1, according to GLP, performed in 1994

5. Non-guideline study, chromosome aberrations, with the analogue substance manganese sulphate EC No. 232-089-9 (CAS No. 7785-87), reliability 2, no GLP, performed in 1990

6. Non-guideline study, erythrocytes micronucleus study, with the analogue substance manganese dichloride, EC No. 231-869-6 (CAS No. 7773-01-5), reliability 2, no GLP, performed in 2009.

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

Your read-across adaptation is not considered acceptable, as explained above in **Appendix on Reasons common to several requests.**

Therefore, the requirements of Section 8.4.2., Column 1 as well as Column 2, first indent, Annex VIII to REACH are not met.

To fulfil the information requirement for the Substance, either *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

2. *In vitro* gene mutation study in mammalian cells

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

i. Triggering of the study

Your dossier contains an adaptation for an *in vitro* gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or *in vitro* micronucleus study. Both are rejected for the reasons provided above.

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier. In support of your adaptation you have provided in vitro studies listed in A.1 and B.1 and in addition, the following in vitro studies:

1. *In vitro* Mammalian Cell Gene Mutation Test, OECD Guideline 476 with the analogue substance manganese dichloride, EC No. 231-869-6 (CAS No. 7773-01-5), reliability 1, according to GLP, performed in 2009

2. *In vitro* Mammalian Cell Gene Mutation Test, OECD Guideline 476 with the analogue substance 2-ethylhexanoic acid EC No. 205-743-6 (CAS No. 149-57-5), reliability 1, according to GLP, performed in 1998

3. *In vitro* Mammalian Cell Gene Mutation Test, OECD Guideline 476 with the analogue substance 2-ethylhexanoic acid EC No. 205-743-6 (CAS No. 149-57-5), reliability 1, according to GLP, performed in 2007.

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

The read-across that you propose is not acceptable as explained above in **Appendix on Reasons common to several requests.**

The results of the request for information in sections A.1 and B.1 will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

Study design

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

3. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant.

You have provided an adaptation according to Annex XI, Section 1.5. in your dossier. In support of your adaptation you have provided the following information:

1. a non-guideline study, with the analogue substance manganese sulphate dihydrate (CAS No. 15244-36-7), in rats, reliability 2, GLP not specified, performed in 1998

2. a non-guideline study, with the analogue substance manganese sulphate, EC No. 232-089-9 (CAS No. 7785-87-7), in rats, reliability 4, , GLP not specified, performed in 2007

3. a non-guideline study with the analogue substance 2-ethylhexanoic acid, EC No. 205-743-6 (CAS No. 149-57-5), reliability 2, GLP not specified, performed in 1993

4. two generation reproductive toxicity study TG 416, with the analogue substance manganese chloride, EC No. 231-869-6 (CAS No. 7773-01-5), in rats, via inhalation, reliability 2, according to GLP, performed in 2013

5. two generation reproductive toxicity study TG 416, with the analogue substance manganese chloride, EC No. 231-869-6 (CAS No. 7773-01-5), in rats, via inhalation, reliability 1, GLP not specified, performed in 2016.

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

The read-across that you propose is not acceptable as explained above in **Appendix on Reasons common to several requests.** In addition, the following shortcomings have been identified:

As provided in the Appendix on reasons common to several requests, a study must have adequate and reliable coverage of the key parameters of the corresponding test guidelines, in this case EU B.63/OECD TG 421 or EU B.64/OECD TG 422. The key parameters of these test guidelines include for example:

- Testing of at least three dose levels and a concurrent control
- Dosing of the Substance for a minimum of four weeks for males and approx. 63 days for females to cover premating, conception, pregnancy and at least 13 days of lactation
- Monitoring of oestrus cycles
- Haematological examinations
- Clinical biochemistry
- Weights and histopathology of organs and tissues

The studies i) and ii) you have provided were conducted with one dose level and the the estrous cyclicity was not covered. In study i) females were not exposed to the test substance, and in study ii) the females were only exposed for 2 days. In study ii) the organ weights were not examined. In the studies i), ii) and iii) hematology and clinical chemistry were not addressed.

Therefore the studies do not fulfil the criteria set in EU B.63/OECD TG 421 or EU B.64/OECD TG 422.

Based on the above, the information you provided does not fulfil the information requirement.

Information on study design

A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats with oral[6] administration of the Substance.

[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix C: Reasons to request information required under Annex IX of REACH

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

A Sub-chronic toxicity study (90 day) is a standard information requirement under Annex IX to REACH.

ECHA understands that you have provided a read-across adaptation using the following studies:

i.) A study that follows the US test guidelines, according to TSCA (1992) Health Effects Testing Guidelines for Subchronic Oral Toxicity Studies, with the analogue substance 2-ethylhexanoic acid EC No. 205-743-6 (CAS No. 149-57-5), reliability 2, GLP not specified, performed in 1989

ii.) A study equivalent or similar to OECD Guideline 453 with the analogue substance Manganese (II) sulfate monohydrate, EC No. 600-072-9 (CAS No. 10034-96-5,) reliability 2, no GLP, performed in 1993

iii.) A study equivalent or similar to OECD Guideline 408 with the analogue substance Manganese (II) sulfate monohydrate EC No. 600-072-9 (CAS No. 10034-96-5), reliability 2, no GLP, performed in 1993.

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

Your read-across adaptation is not considered acceptable, as explained above in **Appendix on Reasons common to several requests.**

Based on the above, the information you provided do not fulfil the information requirement.

Information on the design of the study to be performed

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is solid and according to the granulometry information it is without a significant proportion (>1% on weight basis) of particles of inhalable size.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance

Appendix D: 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[7].

B. 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 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[8].

[7] https://echa.europa.eu/practical-guides
[8] https://echa.europa.eu/manuals

Appendix E: 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 03 November 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) but amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 26 months from the date of adoption of the decision. You provided a justification from a testing laboratory, confirming the time needed to conduct the studies.

On this basis, ECHA has granted the request and extended the deadline to 26 months.

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 F: List of references - ECHA Guidance[9] 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)[10]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[11]

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[12]

[9] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[10] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[11] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[12] 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 G: 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]
[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.