~~Confidential~~

Helsinki, 08 September 2021

Addressees
Registrant of C11unsat.MEA,N2 sulfosuccinate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
06/05/2020

Registered substance subject to this decision ("the Substance")
Substance name: Disodium 4-[2-[(1-oxoundec-10-enyl)amino]ethyl] 2-sulphonatosuccinate
EC number: 247-873-6
CAS number: 26650-05-5

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 September 2023***.

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)

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

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. Short-term repeated dose toxicity (28 days; Annex VIII, Section 8.6.1.) to be combined with the Screening for reproductive/developmental toxicity below

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

5. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

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 VIII 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 and VIII to REACH, for registration at 10-100 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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations 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 Christel Schilliger-Musset, 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 your read-across approach under Annex XI, Section 1.5.**

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach 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.)*
- *Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)*
- *Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)*
- *Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)*
- *Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)*

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach 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 (addressed under 'Scope of the grouping'). 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.

A. Scope of the grouping

In your registration dossier you have formed a group (category) of Sulfosuccinates. You have provided two justification documents as separate attachments in IUCLID, section 13: a read-across justification document for the group of sulfosuccinates named "[redacted]", hereafter "category justification document" and a justification document for the N2-subgroup "[redacted]", hereafter "justification document".

In the category justification document you provide the general structures of the sulfosuccinates and make a general characterization of their (eco)toxicity. You conclude that "[…] *in total there are 5 subgroups considered for the detailed read across argumentation. Within the subgroups, the substances may be ordered according to their C-Chain-Lengt*".

In the justification document you have specifically addressed the N2-subgroup, providing the reasoning for grouping and read-across between the members. You have also provided a data matrix on physico-chemical and (eco)toxicological properties of the substances.

In the justification document you list the substances below as members of the N2-subgroup:

- C11'-MEA: Disodium 4-[2-[(1-oxoundec-10-enyl)amino]ethyl] 2-sulphonatosuccinate (EC: 247-873-6; CAS: 26650-05-5), hereafter "the Substance"

- C12-C18/C18'-MEA: Butanedioic acid, 2(or 3)-sulfo-, 4-[2-[(1-oxo(C12-C18(even numbered) and C18 unsaturated)alkyl))amino]ethyl]esters, disodium salts (EC: 939-637-2), hereafter the "source substance"

- C12-MEA: Butanedioic acid, 2(or 3)-sulfo-, 4-[2-[(1-oxododecyl)amino]ethyl] ester,disodium salt (EC: 939-648-2)

- C18'-MiPA: Butanedioic acid, 2-sulfo-, 4-[1-methyl-2-[(1-oxo-9-octadecen-1-yl)amino]ethyl] ester, sodium salt (EC: 267-199-6; CAS: 67815-88-7)

- C18'-OH-MEA: Reaction products of ricinoleic acid with 2-aminoethanol and maleic acid and sodium hydrogensulfite (EC: 939-654-5)

- C18'- DEA: Butanedioic acid, sulfo-, 4-[2-[(2-hydroxyethyl)amino]ethyl] ester, N-C18-unsatd. acyl derivs., disodium salts (EC: 308-072-8; CAS: 97862-28-7)

You have provided the following reasoning for the sub-grouping: *"All members of the N2-sulfosuccinate subgroup, are monoesters of sulfosuccinic acid. Beside the sulfosuccinate group they do not contain other bonds than C-C , C-N, C-O and C-H. The alkyl rests may be linear, saturated or unsaturated".* Further, you list the following characteristics of the subgroup:

- *"similarities in the chemical process*
- *functional groups*
- *general composition"*

You defined the applicability domain of the subgroup as follows: "*The subgroup can only be applied to those substances that share all the same functional groups and for which the alkyl group comprises a C-chain length from C10 to C22 (even-numbered, C18: saturated or unsaturated or double unsaturated, C20 and C22 unsaturated or C18-OH unsaturated). The main C-chain distribution is C12 and C18 of all members of this subgroup"*.

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

B. Predictions for toxicological properties

You have provided the following reasoning for the prediction of toxicological properties:

"*The subgroup […] is built on the following characteristics:*
- similarities in the chemical process
- similar functional groups
- similar general composition […]
The assumption that the properties of the subgroup members are similar can be shown by a comparison of the physical-chemical and toxicological data […]"

You have provided the following hypothesis for the prediction of toxicological properties: "*no trend with the subgroup could be observed, which is primarily explainable by the general low toxicity in the whole subgroup*". In order to support your hypothesis, you further referred to similarities in the acute toxicity, skin irritation, eye irritation, skin sensitisation properties of the category members.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. Thus, the toxicological properties of the Substance are predicted to be quantitatively equal to those of the source substances.

ECHA has analysed the provided information and has identified the following issues:

(i) *Missing relevant supporting information*

According to the ECHA Guidance[2] "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that the substances included in the sub-group have similar properties for the endpoints under consideration in the read-across approach, you refer to the acute toxicity, skin irritation, eye irritation, skin sensitisation properties of the sub-group members.

Whilst all the supporting information you have provided suggests that the substances may have similar properties for acute toxicity, skin and eye irritation, and skin sensitisation, none of it informs on mutagenicity or repeated-dose, developmental and reproductive toxicity of the category members. Accordingly, this information is not considered as relevant to support prediction of all the endpoints under consideration.

In the absence of relevant supporting information, you have not established that the Substance and source substance [1] are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

In your comments to the draft decision you agree that there is limited supporting information specifically for the mutagenicity, repeated-dose, developmental and reproductive toxicity for the members of the N-2 subgroup, including your Substance.

You express your intention to generate more data with the members of the category, including your Substance, which you intend to use as bridging information to strengthen the read-across approach.

As this strategy relies essentially on data which is yet to be generated, no conclusion on the compliance can currently be made.

As a consequence, there is currently no sufficient information that could be used to support your read-across. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to the present decision making process under Article 42(1) of the REACH Regulation.

C. Predictions for ecotoxicological properties

You have provided the following reasoning for the prediction of ecotoxicological properties:

- Functional groups – *"the substances of this subgroup share the same functional groups"*
- Similar physico-chemical properties

[2] ECHA Guidance R.6: Section R.6.2.2.1.f

- Similar ecotoxicological properties*:* you state that "*the toxicity on aquatic organisms is relatively minor*." You further indicate that "*Within the N2 subgroup, the toxicity does not show a clear C-chain dependency, i.e. the EC50/LC50 data for all members of this subgroup are similar*".

Furthermore, you consider that the predictions using the source substance are justified based on the following:

- For C11'-MEA because both substances differ only in the C-chain length.
- For C12-MEA because both substances have the same main C-chain length of C12 constituent ([redacted] for the source substance) and there is a small difference in C14 constituent [redacted] in the source).

You indicate that "*since no specific mode of action is likely, there is no evidence that the read-across from the source substance C12-18/C18' would not reflect the worst-case.*"

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted based on a worst-case approach.

ECHA has analysed the provided information and has identified the following issue(s):

(i) 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*"[3]. 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 for example bridging studies of comparable design and duration for the Substance and the source substance(s), information to confirm your claimed worst-case prediction.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effect(s) and that the source substance constitutes a worst case for the prediction of the aquatic toxicity property. In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that both substances cause the same type of effects.

In the technical dossier, you have provided algae growth inhibition studies for the Substance C11'-MEA and for the source substance. In addition, for the source substance you have provided studies on short-term toxicity to aquatic invertebrates and to fish studies, as listed under the relevant information requirement of Appendix A, Section 2 and Appendix B Section 5 below. Furthermore, the data matrix included in the justification document reports data on algae growth inhibition, short-term toxicity to aquatic invertebrates and short-term toxicity to fish for category members C18'-MiPA, C18'-OH-MEA and C18'-DEA.

However, the information you provided cannot be used to support your hypothesis, for the following reason(s):

[3] ECHA Guidance R.6, Section R.6.2.2.1.f

ECHA notes that there are no aquatic toxicity studies conducted with C12-MEA. Therefore, no comparison of toxicity can be made between the source substance and C12-MEA.

For C11'-MEA there is only an algae growth inhibition study available to compare toxicity. However, you have not provided any evidence that information on algae toxicity is relevant for the prediction of toxicity to fish and aquatic invertebrates for the Substance (e.g. considering differences in uptake and toxicity among different trophic levels). Accordingly, this information is not considered as relevant to support prediction of short-term toxicity testing on aquatic invertebrates and short-term toxicity testing on fish.

As explained above, the data set reported in the technical dossier does not include relevant, reliable and adequate information to support your read-across hypothesis for C12-MEA nor C-11'-MEA.

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

Conclusions on the grouping of substances and 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 a standard information requirement in Annex VII to REACH.

You have provided the following study record with the source substance (EC: 939-637-2):

(i) *In vitro* gene mutation in bacterial cells (key study, according to OECD TG 471, GLP) giving negative results

ECHA has assessed this information and has identified the following issues:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

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

2. 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.).

You have provided an OECD TG 202 study with the source substance (EC: 939-637-2).

ECHA has assessed this information and has identified the following issues:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

The Substance is difficult to test due to the surface active properties (surface tension 31.7 mN/m). 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.

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 a standard information requirement in Annex VIII to REACH.

You have provided the following study record with the source substance (EC: 939-637-2):

(i) *In vitro* micronucleus assay (according to OECD TG 487, GLP) giving negative results.

ECHA has assessed this information and has identified the following issues:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *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 a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Triggering

Your dossier contains inadequate data for *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.) and for *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.), performed with the source substance (EC: 939-637-2) which is rejected for the reasons provided in Appendix A, Section 1 and Appendix B, Section 1.

The results of the requests for information in Appendix A, Section 1 and Appendix B. section 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.

You have provided the following study record with source substance (EC: 939-637-2):

(i) *In vitro* gene mutation in mammalian cells (according to OECD TG 476) giving negative results.

ECHA has assessed this information and identified the following issue(s):

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

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

3. Short-term repeated dose toxicity (28 days)

A Short-term repeated dose toxicity study (28 days) is a standard information requirement in Annex VIII to REACH.

You have provided the following information:

(i) Screening for reproductive/developmental toxicity study (key study; according to OECD TG 422, GLP) performed with the source substance (EC: 939-637-2):

ECHA has assessed this information and has identified the following issue:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix of Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407), nor for the screening study for reproductive/ developmental toxicity (OECD TG 421 or TG 422), the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided. Such an approach offers the possibility to avoid carrying out a 28-day study according to OECD TG 407, because the OECD TG 422 can at the same time fulfil the information requirement of REACH Annex VIII, 8.6.1 and that of REACH Annex VIII, 8.7.1.[4]

ECHA has evaluated the most appropriate route of administration for the study. Referring to the criteria in Annex VIII, Section 8.6.1, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a solid and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

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

According to test method OECD TG 422, the test is designed for use with rats. On the basis of this default assumption ECHA considers that testing should be performed with rats.

4. Screening for reproductive/developmental toxicity

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. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided the following information:

(i) Screening for reproductive/developmental toxicity study (key study; according to OECD TG 422, GLP) performed with the source substance (EC: 939-637-2):

ECHA has assessed this information and has identified the following issue:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix of Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

For the reasons explained above under request 3., the conduct of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) is preferred to ensure that unnecessary animal testing is avoided.

Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats with oral administration of the Substance.

5. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

You have provided an OECD TG 203 study with the source substance (EC: 939-637-2).

ECHA has assessed this information and has identified the following issue:

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

Therefore, the information requirement is not fulfilled.

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

Study design

OECD TG 203 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. section 2.

Appendix C: 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[5].

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 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[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix D: 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 08 April 2020.

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

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

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 12 months from the date of the adoption of the decision. In your comments on the draft decision you requested ECHA to extend the deadline to a total of 24 months to ensure adequate time to cover the testing programme phases 1 and 2, including the preparation of the test materials, decision process between phase 1 and 2 and the IUCLID dossier generation. You provided a statement from a CRO, indicating that based on the current capacity of the laboratory, 24 months is more relevant timeline.

ECHA took into account the reasoning of your request for an extension of deadline. ECHA considers that a deadline of 24 months from the adoption of the decision is sufficient to enable performing and submitting the study under the current circumstances.

Therefore, ECHA has granted the requested extension and set the deadline to 24 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 E: List of references - ECHA Guidance[7] 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)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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 F: 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.