~~Confidential~~

Helsinki, 08 September 2021

Addressees
Registrants of C18'-MiPA-sulfosuccinate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
27/04/2018

Registered substance subject to this decision ("the Substance")
Substance name: C18 unsaturated fatty acids, reaction products with 1-aminopropan-2-ol, maleic anhydride and sodium bisulfite
List number: 947-655-7
CAS number: NS

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 ***14 December 2023***.

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

A. 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 test 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

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 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.)*

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. ECHA notes that your Substance is not among those substances:

- C11'-MEA: Disodium 4-[2-[(1-oxoundec-10-enyl)amino]ethyl] 2-sulphonatosuccinate

(EC: 247-873-6; CAS: 26650-05-5)

- 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)

- 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 within the subgroup:

- Functional groups – *"the substances of this subgroup share the same functional groups"*
- Similar physico-chemical properties
- Similar toxicological properties*:* you state that due to the general low toxicity in the whole subgroup "*for the toxicological endpoints no clear trend within the subgroup could be observed* […]"

You intend to predict the properties for the Substance from information obtained from 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).

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 to be quantitatively equal to those of the source substance.

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

a. *Absence of adequate read-across documentation*

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).[2]

You have provided read-across justification document, which does not cover your Substance i.e. your Substance is not among the listed category members. There is no other read-across documentation provided covering your Substance.

Therefore, you did not provide justification why you consider that the properties of the Substance under consideration can be predicted from information on the source substance. In the absence of adequate documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

The lead registrants, on behalf of the respective joint submissions, have provided joint comments to the draft decisions sent by ECHA for the Substance (EC: 947-655-7) and for the following substances, members of the N2-subgroup: C11'-MEA (EC: 247-873-6); C12-MEA (EC: 939-648-2) and C18-DEA (EC: 308-072-8).

In your comments to the draft decision you did not address the specific issue, identified by ECHA, specifically that your Substance is not among the listed category members.

Further, ECHA notes that you have submitted a dossier update on 25 February 2021. In the justification document, attached in Section 13 of IUCLID, you have added the identifier of your Substance (EC:947-655-7) next to the CAS number (CAS: 67815-88-7) without any further explanation. However, ECHA points out that the CAS: 67815-88-7 corresponds to EC number 267-199-6 (Butanedioic acid, 2-sulfo-, 4-[1-methyl-2-[(1-oxo-9-octadecen-1-yl)amino]ethyl] ester, sodium salt) which is one constituent of your Substance. Therefore, CAS: 67815-88-7 is not the correct identifier for your Substance, as it does not cover the entire composition.

You have not provided any new documentation, justifying why you consider that the properties under consideration (i.e. mutagenicity, systemic and developmental/reproductive toxicity) of the Substance, which is not listed among the N2-category members, can be predicted from information on the source substances, members of the N2-category. In the absence of adequate information allowing to compare the properties of the Substance and of the source substances it cannot be confirmed that the listed category members and the Substance cause the same type of effects. In any event, as explained in the notification letter of the initial draft decision, ECHA does not take into account updates of the registration dossiers after the date on which you were notified the initial draft decision according to Article 50(1) of REACH.

In addition, in your consolidated comments to the draft decision you agree that there is limited supporting information specifically for the mutagenicity or repeated-dose, developmental and

[2] ECHA Guidance, Chapter R.6: Section R.6.2.6.2

reproductive toxicity for the substances: C11'-MEA (EC 247-873-6); C12-MEA (EC 939-648-2), C18-DEA (EC 308-072-8) and your Substance. In order to address the data gaps as well as to strengthen the read-across approach, you propose a tier-based strategy. In the first tier you propose to perform the OECD TG 422 study for all above-mentioned substances for the purposes of submitting bridging information for systemic and reproductive toxicity. You also propose to conduct genotoxicity studies with "*borderline*" substances or substances with "*worst-case molecular properties*." You claim that "*Based on this information and comparison, the decision will be taken to further test or apply 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. You remain responsible for complying with this decision by the set deadline.

Last, ECHA understands that the comments submitted on other issues related to read-across approach and which ECHA has identified for the members of the N2-subgroup, but not for the Substance, are not considered relevant for the present decision making and thereby ECHA has not addressed them herein.

Conclusions on the read-across approach

Based on the above considerations we conclude that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoints in consideration. 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 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 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 your comments to the draft decision you refer to the tier-based testing strategy relying on the generation of additional supporting information. For this information requirement you propose first to perform *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (OECD TG 473 / OECD TG 487) with two analogue substances, namely the substances with EC: 247-873-6 and EC: 308-072-8. Based on the results from these studies you indicate that you will decide on further testing on the Substance or apply a read-across approach.

As indicated in the Appendix on Reasons common to several requests no conclusion on the compliance of the intended tier-based testing strategy can currently be made. 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. You remain responsible for complying with this decision by the set deadline.

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 negative data for *in vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.) with the Substance and inadequate data for *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.), performed with the source substance which is rejected for the reasons provided above (Appendix A, Section 1).

The results of the requests for information in Appendix A. 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 the source substance (EC: 939-637-2):

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

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 your comments to the draft decision you refer to the tier-based testing strategy relying on the generation of additional supporting information. For this information requirement you propose first to perform *in vitro* gene mutation study in mammalian cells OECD TG 476 or OECD TG 490) with two analogue substances, namely the substances with EC: 247-873-6 and EC: 308-072-8. Based on the results from these studies you indicated that you will decide on further testing on the Substance or apply a read-across approach.

As indicated in the Appendix on Reasons common to several requests no conclusion on the compliance of the intended tier-based testing strategy can currently be made. 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. You remain responsible for complying with this decision by the set deadline.

Stydy 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.

Information on the design of the study to be performed

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.[3]

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.

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.

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

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[4].

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:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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

a) 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.
b) The reported composition must include The reported composition must identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex).
c) Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

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

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 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 the deadline. ECHA considers that a deadline of 24 months from the adoption of the decision is sufficient to enable performing and submitting the studies.

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 D: List of references - ECHA Guidance[6] 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)[7]

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

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] 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 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]
[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.