~~Confidential~~

Helsinki, 15 June 2021

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

Date of submission of the dossier subject to this decision
23/01/2017

Registered substance subject to this decision ("the Substance")
Substance name: 2-decyltetradecanoic acid
EC number: 298-190-5
CAS number: 93778-52-0

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 ***22 June 2022***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

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

4. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210)

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.

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 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.)
- 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[2,3].

A. Scope of the grouping

i. Description of the grouping

In your registration dossier you have formed a category of *'the substances ISOCARB 11, 12, [redacted], 24 and Docosanoic acid*'. You have provided a read-across justification document in IUCLID Section 13.

For the purpose of this decision, the following abbreviations are used for the group members:

[1] ISOCARB 11 (Reaction mass of 2-methyldecanoic acid and 2-ethylnonanoic acid and 2-propyloctanoic acid and 2-butylheptanoic acid, EC No. 941-570-9);
[2] ISOCARB 12 (2-butyloctanoic acid, CAS No. 27610-92-0, EC No. 248-570-1);
[3] ISOCARB 24 (2-decyltetradecanoic acid, CAS No. 93778-52-0, EC No. 298-190-5);
[4] [redacted] and
[5] Docosanoic acid, CAS No. 112-85-6, EC No. 204-010-8.

You provide the following reasoning for the grouping the substances. *"In this particular case the similarity of the ISOCARB category members is justified,* […] *on basis of scope of*

[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

variability and overlapping of composition, representative molecular structure, physico-chemical properties, toxicological, ecotoxicological profiles and supported by various QSAR methods. […]*".*

You define the applicability domain of the category as follows: *"ISOCARB are aliphatic branched carboxylic acids and include substances with carbon chain lengths of C11 to C24. Their only functional group is the carboxyl group, which they share in common. As can be seen from the graphical representation a single branching exists at the C2 position, where the branches differ in chain length from methyl to decyl".*

ii. Assessment of the grouping

ECHA notes the following shortcomings with regards to your grouping approach.

Applicability domain of the category

According to the ECHA Guidance, a category (grouping) hypothesis should address "*the set of inclusion and/or exclusion rules that identify the ranges of values within which reliable estimations can be made for category members for the given endpoint".*[4] Particularly, "*the applicability domain of a (sub)category would identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members*".[5] Therefore, to reliably predict properties within a category the applicability domain should be described including the borders of the category, for which chemicals the category does not hold and a justification for the inclusion and/or exclusion rules.

You describe the applicability domain of the substances covered by the grouping as: "*ISOCARB are aliphatic branched carboxylic acids and include substances with carbon chain lengths of C11 to C24. Their only functional group is the carboxyl group, which they share in common. As can be seen from the graphical representation a single branching exists at the C2 position, where the branches differ in chain length from methyl to decyl".*

First, this applicability domain defines branched substances with one functional group and a chain length of C11 to C24. However, category member [5] is linear and does not fullfill the criterion of branched C2 position, which is used to define the applicability domain of the ISOCARB category.

Second, the applicability domain of your category does not identify the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the category members.

Therefore, the applicability domain does not describe the borders of the category covering all category members nor unambiguously identifies the structural requirements and ranges of physico-chemical, environmental fate, toxicological or ecotoxicological properties within which reliable estimations can be made for the (sub)category members.

B. Predictions for properties

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

[4] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.4.1
[5] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.1.2

available experimental data indicate that the target and source substances are not acutely toxic and do not have sensitizing properties. Repeated dose toxicity was shown to be low for all substances. None of the substances showed mutagenic effects or toxicity to reproduction. Only the Category Member 1 has skin and eye irritating properties whereas all other Category Member are not skin or eye irritating".

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.

You intend to predict the properties for the category members from information obtained from the following source substances:

In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)

- Substance [1], ISOCARB 11 / Reaction mass of 2-butylheptanoic acid and 2-ethylnonanoic acid and 2-methyldecanoic acid and 2-propyloctanoic acid (EC No. 941-570-9), OECD TG 473 (2015)
- Substance [5], docosanoic acid (EC No. 204-010-8), OECD TG 473 (2002)

Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.)

- Substance [5], docosanoic acid (EC No. 204-010-8), OECD TG 422 (2002)

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

- Substance [5], docosanoic acid (EC No. 204-010-8) OECD TG 422 (2002)

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

1. *Read-across hypothesis contradicted by existing data*

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. The ECHA Guidance[6] indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*". 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 category members. The observation of differences in the toxicological properties among some members of a category is a warning sign. An explanation for such a difference resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties needs to be provided and supported by scientific evidence.

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).

In the "mammalian toxicity" data matrix (table 4) of your justification document, the results obtained with substance [2] in an OECD TG 414 study from 1998 are inconsistent with the results obtained with substance [1] in an OECD TG 407 study from 2015 and with substance [5] in an OECD TG 422 study from 2002. Specifically, the NOAELs identified in these studies

[6] Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.6, Section R.6.2.2.1.f

were 25 mg/kg bw/d for substance [2] for maternal systemic toxicity, and 1000 mg/kg bw/d for both substance [1] and substance [5] for systemic toxicity.

You have not provided any explanation for this difference.

In your comments to the draft decision, you indicate your intention to use an analogue approach instead of the ISOCARB category approach addressed above and that you will provide this information in an update of the registration dossier. To support your new read-across hypothesis, you also intend to perform additional testing to demonstrate that the presence of carbon-chain branching in the Substance has no significant impact on toxicity compared to that of the linear source substance docosanoic acid.

The information in your comments is not sufficient for ECHA to make an assessment, because you have not provided new supporting (experimental) data to support a read-across adaptation. Furthermore, ECHA cannot conclude on the reliability of the read-across approach proposed in the comments because acceptability will depend on the outcome of the proposed studies and the relevance of the supporting information.

Please note that this decision does not take into account 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").

The available set of data on the category members indicates differences in the toxicological properties of the substances. This contradicts your read-across hypothesis whereby the structurally similar category members cause the same type of effect(s). Therefore, you have not demonstrated and justified that the properties of the category members are likely to be similar despite the observation of these differences.

2. *Supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects 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*"[7]. 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 other category members.

Supporting information must include bridging studies to compare properties of the category members.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effects. In this context, relevant, reliable and adequate information allowing to compare the properties of the category members is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the category members.

In the read across justification document you claim that: *"All available experimental data indicate that the target and source substances are not acutely toxic and do not have sensitizing properties. Repeated dose toxicity was shown to be low for all substances. None of the substances showed mutagenic effects or toxicity to reproduction. Only the Category Member 1 has skin and eye irritating properties whereas all other Category Member are not*

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

skin or eye irritating. All of the studies presented in the dossier were reliable, means assessed as Klimisch 1 or 2."

In your comments to the draft decision, you indicate your intention to "*strengthen the approach in order to show that for saturated carboxylic acids with such a long C-chain (22 and 24) there is no difference in the toxicological behavior and the toxicokinetics even if one is linear and one is branched at one position."*

Your dossier contains information generated with source substances [1] and [5] for the endpoints which you intend to adapt. It does not contain information with the Substance for these endpoints except for gene mutation in bacteria.

The data set reported in the technical dossier does not include relevant, reliable and adequate information on repeated dose toxicity and chromosomal aberration for the target substance, the Substance, to support your read-across hypothesis.

ECHA observes that your intention to "*strengthen the approach*" does not include the generation of information on repeated dose toxicity and reproductive and developmental toxicity with the target substance, and that the deficiency identified in this subsection is likely to remain. Furthermore, you have not provided evidence that would demonstrate your claim that "*there is no difference in toxicological behaviour*" between linear and branched organic acids.

Furthermore, and as discussed in section A.ii above, substance [5] does not fullfill the criteria you defined for the category and you have not demonstrated that data on that substance can be used for prediction. Therefore, the OECD TG 422 study and the OECD TG 473 study with substance [5] you indicated cannot be used to provide information on repeated dose toxicity and chromosomal aberration, respectively, for the category. With only information on chromosomal aberration from source substance [1], it is not possible to compare properties with the Substance.

In the absence of the above information, you have not established that all the category members are likely to have similar properties. Therefore, you have not provided reliable and adequate bridging studies to strengthen the rationale for the read-across.

C. 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. Long-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.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 202 study but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

You have provided information which indicates that the Substance includes constituents that are poorly water soluble In section 4.8 of your IUCLID dossier, you provided an estimation of the water solubility (below 0.5 mg/l at pH 4) based on a OECD 105 study and an estimated value of 0.0122 µg/l (based on QSAR).

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

In your comments you have agreed to perform the requested test.

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

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

In vitro cytogenicity study in mammalian cells is a standard information requirement in Annex VIII to REACH (Section 8.4.2.).

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

i. OECD TG 473 study (2002) with the analogue substance docosanoic acid (EC No. 204-010-8).

As explained in the *Appendix on Reasons common to several requests* your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

Study design

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.

In your comments to the draft decision, you agree to perform the study with the Substance, according to the OECD TG 473.

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

Short-term repeated dose toxicity (28 day) is a standard information requirement in Annex VIII to REACH (Section 8.6.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

i. OECD TG 422 study (2002) with the analogue substance docosanoic acid (EC No. 204-010-8).

As explained in the *Appendix on Reasons common to several requests* your adaptation is rejected.

In your comments to the draft decision, you indicate your intention to submit a read-across justification for the repeated dose toxicity endpoints. Please refer to ECHA's reply in the Appendix on *reasons common to several requests.*

Please note that, as indicated in the *Appendix on Reasons common to several requests*, this decision does not take into account 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").

Therefore, the information requirement is not fulfilled.

Information on the design of the study to be performed (route/ species/ strain)

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 with limited potential for generation of particles of inhalable size and for exposure of humans through inhalation.

Further information on the study design is provided under Section B.3 below.

3. Screening for reproductive/developmental toxicity

Screening for reproductive/developmental toxicity is a standard information requirement in Annex VIII to REACH (Section 8.7.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

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

i. OECD TG 422 study (2002) with the analogue substance docosanoic acid (EC No. 204-010-8).

As explained in the *Appendix on Reasons common to several requests* your adaptation is rejected.

In your comments to the draft decision, you indicate your intention to submit a read-across justification for the reproductive/developmental toxicity endpoints. Please refer to ECHA's reply in the Appendix on *reasons common to several requests.*

Please note that, as indicated in the *Appendix on Reasons common to several requests*, this decision does not take into account 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").

Therefore, the information requirement is not fulfilled.

Study design

When there is no information available neither for the 28-day repeated dose toxicity endpoint (EU B.7, OECD TG 407) (as explained above under section B.2), 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.[8]

Therefore, a study according to the test method EU B.64/OECD TG 422 must be performed in rats with oral[9] administration of the Substance.

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2., pages 484 to 485 of version 6.0 – July 2017. (https://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf)
[9] ECHA Guidance R.7a, Section R.7.6.2.3.2.

4. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided an OECD TG 203 study but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issues:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

As already explained under Section A.1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

In your comments you have agreed to perform the requested test.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 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.1.

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[10].

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[11].

[10] https://echa.europa.eu/practical-guides
[11] 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 8 June 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 requests and the deadline.

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[12] 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)[13]

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

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[14]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[12] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[13] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[14] 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.