~~Confidential~~

Helsinki, 29 August 2022

Addressees
Registrant(s) of JS_4196-89-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
11/06/2018

Registered substance subject to this decision ("the Substance")
Substance name: 2,2-dimethylpropane-1,3-diyl dibenzoate
EC number: 224-081-9
CAS number: 4196-89-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***7 March 2025***.

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. Skin sensitisation (Annex VII, Section 8.3.; test method:

   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (EU B.71/OECD TG 442E)(Annex VII, Section 8.3.1.); and

   ii. Only if the *in vitro/in chemico* test methods specified under point i.) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429));

2. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2)

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

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

2. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: EU C.20./OECD TG 211)

3. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

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

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

Information required depends on your tonnage band

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

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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

1. Skin sensitisation

Skin sensitisation is an information requirement under Annex VII to REACH (Section 8.3.). Under Section 8.3., Column 1, the registrants must submit information allowing (1) A) a conclusion whether the substance is a skin sensitiser and B) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and (2) risk assessment, where required.

You have provided the following information in the technical dossier, based on which you conclude that the Substance is not a skin sensitiser:

i. *in vivo* Local Lymph Node Assay with Integrated Model for the Differentiation of Skin Reactions (IMDS) modification (2014) on the Substance.

You have adapted the information requirement under Section 8.3.1, Column 2 using the following justification: adequate in vivo study is already available.

In your comments to the draft decision you note that the study was carried out before 10 May 2017 and would therefore meet the column 2 adaptation criteria of Section 8.3.2.

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

A. Non-compliant study

Toxicological and eco-toxicological tests on substances must be conducted in compliance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or ECHA as being appropriate (Article 13(3) of REACH).

You have provided a study on the Substance and claimed that it is conducted according to the Local Lymph Node Assay test method (OECD TG 429) with deviations. You further explain that *"Modified LLNA (IMDS = Integrated Model for the Differentiation of Skin Reactions): The modification refers to the measurement of cell proliferation by cell counting instead of radioactive labelling."*

ECHA notes however that in the provided study the OECD TG 429 method was not followed, as IMDS modification has neither been validated nor is it included in the OECD TG 429 or in the other LLNA variants (OECD TGs 442A or 442B). More specifically, OECD TG 429 does not allow measurement of cell proliferation by cell counting instead of radioactive labelling. In addition multiple differences in the study design are noted when compared to the TG 429, such as different mouse strains use without justification, and different stimulation index cut-off value used for identification of skin sensitising substances. You did not justify the deviations from the referred OECD TG 429.

In your comments to the draft decision you refer to inter- and intra-laboratory validation studies to justify the validity of the assay, the mouse strain, and the stimulation index cut-off value used in the study (e.g. [redacted] 1998, [redacted] 2000, [redacted] 2005, [redacted] 2005, [redacted] 2008).

But ECHA notes that the investigations defined in Annex I of OECD TG 429 in order to validate the IMDS modification as a me-too test method are incomplete with regard to the Performance Standard test substances as the validation studies referred to in your comments do not cover them all. The provided information do not therefore allow the assessment of the validity of

the assay as so called me-too test. In addition, the validation of the IMDS modification according to Annex I of OECD TG 429 has not been submitted to OECD test guidelines programme and therefore the study results are not covered by Mutual Acceptance of Data.

Therefore, as the differences to the OECD TG 429 have not been justified in your comments to the draft decision nor by the OECD test guidelines programme, the provided study cannot be considered appropriate to fulfil the information requirement, or as basis for an adaptation according to Column 2 of 8.3.2.

Therefore the study does not fulfil the key parameter(s) set in the OECD TG 429 or EU Method B.42 and does not allow to make a conclusion whether the Substance causes skin sensitisation.

B. No assessment of potency

To be considered compliant and enable concluding whether the Substance causes skin sensitisation, in case the substance is considered to cause skin sensitisation the information provided must allow a conclusion whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

As the currently available data does not allow to conclude whether the Substance causes skin sensitisation (see section A above), this condition cannot be assessed.

On this basis, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance for skin sensitisation, *in vitro/in chemico* studies (OECD TG 442C, OECD TG 442D and EU Method B.71/OECD TG 442E) are considered suitable. In case *in vitro/in chemico* methods are not suitable for the Substance or the results cannot be used for classification and risk assessment an *in vivo* skin sensitisation study must be performed and the murine local lymph node assay (LLNA) (EU Method B.42/OEDC TG 429) is considered as the appropriate study.

2. 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 do 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).

In the provided OECD TG 105 study, the saturation concentration of the Substance in water was determined to be 1.16 mg/l at 20 °C.

Furthermore, you indicate that in the provided OECD TG 202 study the only nominal concentration of the Substance of 100 mg/l was used in the definitive test and that in the definitive test measured *"Effective concentrations ranged from 0.94 % to 1.07 % in the freshly prepared media and from 0.76 % to 0.84 % in the media after 24 hours of exposure."*

You indicate that in the provided OECD TG 203 study the only nominal concentration of the Substance of 100 mg/l was used in the definitive test and that in the definitive test measured "*Effective concentrations ranged from 0.33 % to 0.74 % of nominal values in the freshly medium and from 0.08 % to 0.36 % of nominal values in the medium after 24 hours of exposure."*

You also indicate that in the provided OECD TG 201 studies the measured concentrations of the Substance were between 0.021 mg/l and 0.484 mg/l.

Based on the information reported in the registration dossier, ECHA notes that the results of the analytical monitoring of exposure concentrations of the Substance provided in the registration dossier aquatic toxicity studies (OECD TG 202, OECD TG 203 and OECD TG 201) indicate that the Substance during duration of these tests was mostly present in the test solutions at concentrations below 1 mg/l. This indicates that the Substance may be considered poorly water soluble and that steady-state conditions may not be reached in the provided short-term toxicity studies with fish and aquatic invertebrates.

Therefore, under conditions of aquatic toxicity tests the Substance is considered to be poorly water soluble and information on long-term toxicity on aquatic organisms, including invertebrates, must be provided.

In the comments to the draft decision, you disagree with ECHA's assessment regarding the water solubility of the Substance and triggering of the long-term aquatic toxicity tests.

You provide the following information:

1. You state that REACH does not give an exact definition of the term "poor water solubility". Additionally, you mention the limit value of 1 mg/L at 20 °C given in Annex VII, Section 7.6., Column 2 (a section relevant to waiving surface tension testing);
2. You state that the relevant method for determining the water solubility of a substance is OECD TG 105. You cite Annex VII, Section 7.7. and you add "*Further guidance is given in REACh guidance document R.7.8.5: "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".* "
3. You note that the relevant method for the determination of the water solubility is OECD TG 105 where water solubility is measured "*in pure water at a defined temperature in the absence of nutrition media or electrolytes*". Further, you add: "*The Registrant has provided information on water solubility in a study performed according to OECD TG 105. The result is 1.16 mg/L at 20°C which is higher than 1 mg/L. For this reason, the substance is not poorly water soluble*." and that "*ECHA expresses clearly that the water solubility is the relevant parameter (and not solubility in a specific test medium). Further the analytical method was able to measure concentrations below the water solubility and therefore the concentrations values could be achieved.*"
4. You state that ECHA's statement ("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") is not justified for the following reasons:
    a. "*The Substance is not poorly soluble*". Rather, it "*behaves like a moderately soluble substance*", as analytical measurements of the freshly prepared test media showed 0.94 - 1.07 mg/L and 0.33 - 0.74 mg/L concentration in the

short-term Daphnia and fish toxicity studies, respectively;

b. "*Measured concentrations in test media do not reflect the water solubility*", due to the differing test conditions of the OECD TG 105 test and aquatic toxicity tests. In support of this, you reference OECD GD 23;

5. You further claim that, "*the concentration in the freshly prepared media reflects nicely the water solubility as obtained by OECD guideline 105*" and state that decrease in concentration in the aquatic toxicity tests are due to biotic or abiotic degradation and adsorption to surfaces or particles, rather than due to an effect of the water solubility.

You also acknowledge that the water solubility of the substance is *"close to the trigger value of 1 mg/L*".

In Guidance on IRs and CSA, Section R.7.8.5, the value 1 mg/L is given as an example, rather than a definitive cut-off value. It is a value that should be understood in the context of aquatic toxicity testing (i.e., reaching and maintaining a test concentration higher than 1 mg/L under the test conditions of the aquatic toxicity tests). This is further supported by the Table R.7.8-3 of the same Guidance where, in respect of definition of 'difficult property' for aquatic toxicity testing, it is noted that solubility in the test medium should be considered, i.e., "*The substance is poorly soluble in the test medium (water solubility typically < 1 mg/L)*".

ECHA agrees that the solubility of a substance measured in the purified water used in OECD TG 105 may differ from the solubility of that substance in the test medium used in aquatic toxicity tests. However, while the Substance's reported water solubility, as measured by an OECD TG 105 study (1.16 mg/L), is indeed above 1 mg/L, for the purposes of aquatic toxicity testing, it shall still be considered poorly water soluble, because this water solubility value was not reached or/and maintained under the test conditions of the fish, daphnia, and algae toxicity tests and information on long-term toxicity on aquatic organisms must be provided.

The examination of the information provided on long-term toxicity on aquatic invertebrates, as well as the selection of the requested test and the test design are addressed under Appendix C.2.

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

1. 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 issue:

As already explained under Appendix A.2., under conditions of aquatic toxicity tests the Substance is considered to be poorly water soluble and information on long-term toxicity on aquatic organisms, including fish, must be provided.

In the comments to the draft decision you disagree with ECHA's assessment regarding the water solubility of the Substance and triggering of the long-term aquatic toxicity tests.

As explained above under Appendix A.2., for the purposes of aquatic toxicity testing, the Substance shall be considered poorly water soluble and information on long-term toxicity on aquatic organisms must be provided.

The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix C.3.

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

1. Sub-chronic toxicity study (90-day)

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

You have provided an adaptation according to Column 2 of Annex IX, Section 8.6.2 in your dossier.

In support of this adaptation of the information requirement, you have provided the following information for this endpoint:

i. Sub-acute repeated dose toxicity study (2015) on the Substance

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

As provided in Annex IX, Section 8.6.2, Column 2, you may adapt the information requirement, provided you fulfil the criterion including:

- the Substance is insoluble and not inhalable and there is no evidence of absorption, particularly if it is coupled with limited human exposure.

You stated that *"2,2-Dimethylpropane-1,3-diyl dibenzoate is an unreactive white or yellowish solid with mild odor and a melting point of 49 °C. 2,2-Dimethyl-1,3-diyl dibenzoate is not inhalable, because it is a waxy solid with a low vapor pressure, which is estimated to be < 0.0001 hPa at 25 °C. Additionally it is nearly insoluble in water (1.16 mg/l). 2,2-Dimethylpropane-1,3-diyl dibenzoate is used* [redacted] *and thus provides only limited human exposure. Furthermore, in the available 28 day study (OECD TG 407 and GLP) male and female rats were given daily doses up to and including 1000 mg/kg bw/day (limit dose) resulting in a NOAEL of 1000 mg/kg bw/day due to the lack of adverse effects. Based on these considerations the requirements of Regulation (EC) No.1907/2006 (REACH), ANNEX IX, section 8.6, column 2 (Specific rules for adaption from column 1) are fulfilled."*

You have not demonstrated that the Substance is insoluble, not inhalable, that there is no evidence of absorption, or that there is limited human exposure because of the below reasons.

The Substance is not demonstrated to be not absorbed because no study investigating absorption specifically is available in your dossier. ECHA notes also that lack of adverse effects up to limit dose in the available OECD TG 407 study is not indication of no absorption.

The substance is not insoluble according to your waiver justification.

The substance is reported having uses indicative of exposure via inhalation (PROCs 7 and 11 industrial and non-industrial spraying applications). In the absence of an exposure assessment demonstrating the contrary, you have not demonstrated that the Substance is not inhalable.

The Substance is reported with wide spread uses (PROCs 7 and 11) which are not indicative of limited human exposure.

Therefore, you did not meet the adaptation criteria and your adaptation is rejected.

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

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

Information on the design of the study to be performed

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because even though the information indicates that human exposure to the Substance by the inhalation route is likely, potential inhalation-specific effects are already addressed by performing a qualitative assessment for inhalation, local effects. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

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

2. Long-term toxicity testing on aquatic invertebrates

Long-term toxicity testing on aquatic invertebrates is an information requirement under Annex IX to REACH (Section 9.1.5.).

You have provided the following information: a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: *"According to column 2 of REACH Annex IX, a long-term test shall be proposed by the Registrant if the chemical safety assessment (CSA) shows the need to further investigate the effects in aquatic organisms. In this case, no effects have been observed in acute tests. A long-term test would be required for substances with poor water solubility (<1 mg/L). However, the water solubility of 2,2-dimethylpropane-1,3-diyl dibenzoate is higher than 1 mg/L (1.16 mg/L)."*.

We have assessed this information and identified the following issues:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1. It must be understood as a trigger for providing further information on aquatic invertebrates if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you acknowledge the Decision of the Board of Appeal in case A-011-2018 and you agree to performing the requested OECD TG 211 study.

Study design

The Substance is difficult to test due to the low water solubility. 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 solution.

3. Long-term toxicity testing on fish

Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

You have provided the following information:

i. *a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: "According to column 2 of REACH Annex IX, a long-term test shall be proposed by the registrant if the chemical safety assessment (CSA) shows the need to further investigate the effects in aquatic organisms. In this case, no effects have been observed in acute tests. A long-term test would be required for substances with poor water solubility (<1 mg/L). However, the water solubility of 2,2-dimethylpropane-1,3-diyl dibenzoate is higher than 1 mg/L (1.16 mg/L)."*

We have assessed this information and identified the following issues:

Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

In the comments to the draft decision, you refer to the Board of Appeal's decision in case A-011-2018 and, on this basis, you acknowledge that under Annex IX, long-term toxicity studies on invertebrates and fish are standard information requirements.

You also mention estimates derived using ECOSAR's neutral organics QSAR model. However, the latter does not provide any further substantiated adaptation under the general rules set out in Annex XI.

On this basis, the information requirement is not fulfilled.

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 C.2.

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

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[2].

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[3].

[2] https://echa.europa.eu/practical-guides
[3] https://echa.europa.eu/manuals

Appendix E: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 17 September 2020.

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

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

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

Appendix F: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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[7]

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

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

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

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

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

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

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

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

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.