~~Confidential~~

Helsinki, 27 August 2021

Addressees
Registrants of JS_6197-30-4 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
26/07/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Octocrilene
EC number: 228-250-8
CAS number: 6197-30-4

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***4 December 2023***.

The requested information must be generated using the Substance unless otherwise specified.

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

1. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

2. Identification of degradation products (Annex IX, 9.2.3.; test method: OECD TG 308)

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

4. Long-term toxicity to terrestrial plants (triggered by Annex IX, Section 9.4.3., column 2; test method: EU C.31./OECD TG 208 with at least six species or ISO 22030)

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

1. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: OECD TG 225 and OECD TG 233 and OECD TG 239)

Reasons for the request(s) are explained in the appendices entitled "Reasons to request information required under Annexes IX to X 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;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

How to comply with your information requirements

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

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". 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 can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[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 A: Reasons to request information required under Annex IX of REACH

This decision is based on the examination of the testing proposals you submitted.

1. Sediment simulation testing

Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4) if the substance has a high potential for adsorption to sediment.

Substances with a log Koc > 4 are considered to have a high potential for adsorption to sediment (ECHA Guidance R.7.9.4.3.).

Under section 5.4.1. of your technical dossier, you report on an adsorption/desorption study using a Batch Equilibrium Method according to OECD TG 106 on the Substance. The log Koc of the substance was determined to range from 4.48 to 4.90 in six different soils.

Therefore, the Substance has a high potential for adsorption to sediment and information on Sediment simulation testing must be provided.

1.1. Information provided to fulfil the information requirement

You submitted a testing proposal for an Aerobic and Anaerobic Transformation test in Aquatic Sediment Systems (test method: EU C.24./OECD TG 308) with the following justification: "*This study was already part of the CORAP testing proposal in light of the PBT/vPvB assessment but was concluded as not necessary due to the conclusion that the substance is not considered as bioaccumulative (B) or very bioaccumulative (vB). However, due to the current environmental risk assessment, this additional study was considered again as necessary for further refinement of the PEC_{water} (freshwater and marine water)*".

Your registration dossier also includes the following information on Sediment simulation testing:

1. a 24-hour study to assess the dissipation of ^{14}C-Octocrylene in water/sediment systems under aerobic conditions ([redacted], 2019);

We have assessed the available experimental data from your registration dossier and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 308 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- recoveries (i.e. mass balances) range from 90% to 110% for labelled chemicals and from 70% to 110% for non-labelled chemicals.
- the test must continue until the degradation pathway and water/sediment distribution pattern are established or when 90 % of the test substance has been removed by transformation and/or volatilisation.

Your registration dossier provides a Sediment simulation study showing the following:

- you report that "*after 24 hrs, 15.2 % of the test material remaining with the water phase and 51.6 % was associated with the within the sediment*". The test material used was radiolabelled and, based on this information, the recovery was 66.8%;
- the test duration was 24 hours. While you report some information on the water/sediment distribution pattern of the test material, you have provided no information on the degradation pathway. Further you state that no significant biodegradation was observed during the test.

Based on the above, the recovery obtained from this study was too low. Furthermore, the study duration was too short to conclude on the dissipation processes of the test material.

Therefore, the study by [redacted] (2019) does not meet the information requirement and ECHA agrees that an appropriate Sediment simulation study is needed.

1.2. Test selection and study specifications

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; ECHA Guidance R.11.4.1.).

In your comments on the draft decision you agree to perform the OECD TG 308 sediment simulation using sediments from freshwater and marine water system. You also "request to carry out both studies at an ambient temperature (i.e. 20 °C) in order to provide a more realistic scenario on the substance´s environmental fate in a water-sediment system".

ECHA reiterates that the required test temperature is 12°C for the reasons already explained above.

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

2. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Degradation (Section 9.2.) at Annex IX requires to provide information on Biotic degradation (Section 9.2.1.) and on the identity of degradation products (Section 9.2.3.) for the Substance. You have submitted a testing proposal for sediment simulation testing only. In case of data gap for the identification of degradation products, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

1.1. Information provided to fulfil the information requirement

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, the information requirement is not fulfilled.

1.2. Test selection and study specifications

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Appendix A.1. or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 308 (Appendix A.1. must be conducted at 12°C and at a test material application rate reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (*e.g.* 10 times).

1.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

3. Effects on soil micro-organisms

Effects on soil microorganisms is an information requirement under Annex IX to REACH (Section 9.4.2).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216).

Your registration dossier does not include any information on effects on soil microorganisms. ECHA agrees that an appropriate study on effects on soil microorganisms is needed.

1.2. Test selection and study specifications

The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) is appropriate to cover the information requirement on effects on soil microorganisms (ECHA Guidance R.7.11.3.1.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

4. Long-term toxicity to terrestrial plants

Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

As specified in ECHA Guidance R.7.11.6., a substance is considered:
- to have a high potential to adsorb to soil if it has a log Kow > 5 or it is ionisable, and
- to be very persistent if it has a DT50 > 180 days in soil.

Furthermore, the guidance specifies that, in the absence of conclusive information, a substance is considered very persistent by default unless it is readily biodegradable.

Based on the information from your registration dossier:
- the Substance has a high adsorption potential to soil as you report a log Kow value of 6.1 based on EU Method A.8 (HPLC method);
- the Substance is considered to be highly persistent in soil as it is not readily biodegradable (0% biodegradation after 28 days in an EU Method C.4-D test and < 10% biodegradation after 28 days in an OECD TG 301F test).

Therefore, information on long-term toxicity to terrestrial plants must be provided for the Substance.

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Effects on terrestrial organisms at Annex IX requires to provide information on toxicity to invertebrates (Section 9.4.1, column 2), toxicity to plants (Section 9.4.3, column 2) and information on effects on soil micro-organisms (Section 9.4.2.). You have provided reliable information on long-term toxicity to invertebrates in your dossier and you have submitted a testing proposal for effects on soil micro-organisms. In case of data gap for toxicity to plants, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

1.1. Information provided to fulfil the information requirement

You have not provided any information on long-term toxicity to plants under Annex IX, Section 9.4., column 2.

Instead, you have omitted this information and you provided the following justification:
- "*a short-term study does not need to be conducted because an appropriate long-term toxicity study on terrestrial organisms is available*";
- you state that "*environmental risk assessment for cosmetic applications in sunscreen products indicate a potential risk towards soil organisms and additional study on soil microorganisms according to OECD 216 is proposed*".

Your justification does not provide any explicit reference to the general rules for adaptation set out in Annex XI or the specific rules for adaptation specified in Annex IX. However, from

the above, ECHA assumes that you intend to adapt this information under Annex IX, Section 9.4., column 2, second paragraph and have assessed your justification on that basis.

We have assessed this information and identified the following issue:

A. *The substance belongs to the soil hazard category 4 (HC4) and information on both long-term terrestrial toxicity to invertebrates and plants must be provided.*

As specified under Annex IX, Section 9.4., column 2, second paragraph, in the absence of toxicity data to soil organisms, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity, which rely on the assignment of the Substance to a "soil hazard category" and on an initial screening assessment using the EPM, in order to decide the information needed for the chemical safety assessment.

When a substance falls into soil hazard category 4 (HC4), long-term terrestrial toxicity tests according to the standard information requirements Annex X must be provided (i.e. both on terrestrial invertebrates and plants). A substance falls into HC4, if:

- it has a high potential to adsorb to soil or is very persistent, and
- it is very toxic to aquatic organisms (i.e., lowest EC/LC50 < 1 mg/L or lowest NOEC < 0.1 mg/L for algae, daphnia or fish)

As already explained above the Substance is concluded to have high potential to adsorb to soil and to be very persistent. Furthermore, the Substance is concluded to be very toxic to aquatic organisms, as your technical dossier includes a long-term toxicity study on aquatic invertebrates according to OECD TG 211 showing a $NOEC_{reproduction}$ of 2.66 µg/L. Therefore, the Substance falls into soil hazard category 4 (HC4) and your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

1.2. Test selection and study specifications

The Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208.

1.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

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

This decision is based on the examination of the testing proposals you submitted.

1. Long-term toxicity to sediment organisms

Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for:

- a Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment (test method: OECD TG 225)
- a Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218)
- a Water-Sediment *Myriophyllum Spicatum* Toxicity Test (test method: OECD TG 239)

In addition, you have provided the following justification for your testing proposal:

- *"The current environmental risk assessment indicates a potential risk towards sediment dwelling organisms in both freshwater and marine sediments due to a low $PNEC_{sediment}$ derived using the NOEC from the chronic daphnia toxicity study (OECD 211) and the equilibrium partitioning method (EPM) including an additional safety factor of 10 (due to the high logPow of 6.1)"*;
- *"This low $PNEC_{sediment}$ however, may not reflect the real toxicity towards sediment dwelling organisms as indicated by the public scientific literature ([redacted] 2017)"*;
- The Substance is listed in the CoRAP and this information is needed for the risk assessment.

Your registration dossier also includes:

1. a study according to OECD TG 218 with the Substance ([redacted], 2017)

We have assessed the available experimental data from your registration dossier and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 218 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- fish-food (e.g., for example Tetra-Min) in the amount of 0.25-0.5 mg per larvae per day is added for young larvae for the first 10 days. 0.5- 1 mg per larvae per day is added for the rest of the test. When testing strongly adsorbing substances (e.g. with log Kow > 5), plant material must be used instead of fish food, for example by addition of 0.5% (dry weight) alpha-cellulose;
- twenty first instar larvae are used in each replicate;
- with at least four replicates must be used. If short-term investigations are conducted to assess the effects of the test material on growth, additional replicates must be included in the test design;
- if the LOEC or NOEC are to be estimated, five test concentrations must be used.

You have provided a study according to OECD TG 218 showing the following:

- you report that chironomid larvae were fed a suspension of macerated Tetramin® (0.5 mg per organism per day). However, you also report that the artificial sediment mixture also included 5% alpha-cellulose. Therefore, the feed ration (and likely the carbon content of the sediment mixture) was higher than specified in the test

guideline;
- you report that twelve replicates with five larvae each were used. Furthermore, short-term investigations on the effects of the test material on growth after 10 days were conducted. Therefore, the number of test animals used in this study is lower than specified in the test guideline which may have resulted in a lower sensitivity of the test;
- only three concentrations were stated which is lower than the minimum of five test concentrations required by the test guideline for LOEC/NOEC identification;
- you report that the growth of *C. riparius* (expressed based on body length) after 10 days was significantly reduced at 2.33 mg test mat./kg sediment. However, considering the deficiencies listed above, this study cannot be considered as a reliable basis to identity the NOEC of the test material.

Therefore, this study does not meet the information requirement and ECHA agrees that an appropriate information on long-term toxicity to sediment is needed.

1.2. Test selection and study specifications

Annex X, Section 9.5.1., Column 2 deals with the choice of the most appropriate test(s) and thereby implies that more than one test may be needed to fulfil the information requirement (ECHA Guidance R.7.8.12.).

The Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218 or 233), the Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment (test method: OECD TG 225) and the Water-Sediment *Myriophyllum Spicatum* Toxicity Test (test method: OECD TG 239) are most relevant when generating new data for REACH purposes (ECHA Guidance R.7.8.9.1.).

For strongly adsorbing or binding substances (e.g. log Kow > 5) sediment-dwelling organisms that feed on sediment particles (e.g. *Lumbriculus variegatus*, *Tubifex tubifex*) are considered of particular relevance. However, if a specific mode of action cannot be excluded other species may also provide useful information (ECHA Guidance R.7.8.10.1).

For substances that have an equilibration time (time to reach steady state in the body) that is anticipated to be very long (e.g. highly lipophilic substance such as substance with Kow > 5), studies with longer test duration are preferred. For such substance, the Sediment-water chironomid life-cycle test using spiked water or spiked sediment (test method: OECD TG 233), which is an extension of the Sediment-Water Chironomid Toxicity Using Spiked Sediment (test method: OECD 218), is preferred (ECHA Guidance R.7.8.9.1. and R.7.8.14.2.). Furthermore, the OECD TG 233 specifies, that when testing strongly adsorbing substances (typically with log Kow > 5), the test material must be added to the formulated sediment before the stabilisation period.

1.3. Outcome

Your testing proposals for Sediment-Water *Lumbriculus* Toxicity Test Using Spiked Sediment and Water-Sediment *Myriophyllum Spicatum* Toxicity Test are accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above. Your testing proposal for Sediment-Water Chironomid Toxicity Using Spiked Sediment is rejected under Article 40(3) (d) of REACH. Under Article 40(3)(c) you are requested to carry out the additional Sediment-water chironomid life-cycle test using spiked water or spiked sediment with the Substance, as specified above.

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[2].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

   The Test material used to generate the new data must be selected taking into account the following:
   - the variation in compositions reported by all members of the joint submission,
   - 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 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[3].

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

Appendix D: Procedure

The Substance was listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2012.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 17 December 2018.

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

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

In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 30 months from the date of adoption of the decision.

You argue that more time is needed for planning, method development, conductance of pre-test, development of extraction and results evaluation. ECHA notes that the current deadline already allows time for these aspects and consequently further extension is not justified.

You also argue that more time is needed due to technical issues with synthesis of a radiolabelled substance. ECHA considers such an extension justified. ECHA also notes your request regarding the sampling under ideal environmental conditions and considers that this can be accommodated under the time already granted for the synthesis of the radiolabelled substance.

On this basis, ECHA has extended the deadline to 24 months.

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

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

Appendix E: List of references - ECHA Guidance[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 multi-constituent 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.

[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

OECD Guidance documents[7]
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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix F: Addressees of this decision and the corresponding information requirements applicable to them

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.