~~Confidential~~

Helsinki, 27 August 2021

Addressees
Registrant(s) of JS_68815_51_0 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21/06/2018

Registered substance subject to this decision ("the Substance")
Substance name: 9-Octadecenoic acid (Z)-, reaction products with 2-[(2-aminoethyl)amino]ethanol
EC number: 272-379-2
CAS number: 68815-51-0

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 ***6 March 2023***.

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

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

1. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

B. 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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

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

Failure to comply

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

Authorised[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

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

1. Growth inhibition study aquatic plants

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test] (Article 13(3) of REACH). Therefore, the following specifications must be met:

- The results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;
- Test validity criteria for increase in biomass in the controls (>16-fold), mean coefficient of variation for sector-by-sector growth rates (<35%), and coefficient of variation of average specific growth rates in replicate controls (<7%) must be met;
- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include: (1) an analytical method validation report demonstrating that the analytical method is appropriate, and (2) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;
- a justification for, or validation of, the separation technique is provided, in particular when filtration is used as this technique can cause potential for losses due to adsorption onto the filter matrix;
- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided. This justification should confirm that the analytical methods attempted were state of the art, and include a justification as to why detection lower limits were not feasible (any preliminary analytical efforts should also be described in the report);
- chemical specific analysis of the test solutions is required to demonstrate stability of exposure concentrations during the test;
- the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within 20% of the nominal or measured initial concentration throughout the test;

You have submitted an OECD TG 201 showing the following:

- In your registration dossier, tabulated data on the algal biomass determined daily for each treatment group and control are not reported and you have not specified whether the study meets the validity criteria (i.e. section-by-section growth rates in the control cultures; the increase in biomass during the test period; the mean coefficient of variation for section-by-section specific growth; and the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures). In the comments on the draft decision you state that tabulated data will be provided in the next dossier update. In addition, in the comments you provide the following information regarding the validity criteria: increase in biomass in the controls was 58-fold; mean coefficient of variation for sector-by-sector growth rates was 15.1%; and coefficient of variation of average specific growth rates in replicate controls was 2.27%;
- No analytical method validation report or results of a preliminary solubility experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution are provided in your registration dossier. In the comments on the draft decision you argue that a pre-study was conducted in line with OECD GD 23 and that the application of an ultrasonic bath and stirring period of one day ensured that a maximized Water Accommodated Fraction (WAF) was tested.

However, no analytical method validation report is provided and you do not provide analytical confirmation of test concentrations from this pre-study to establish that the preparation methods were adequate to maximise the test material concentrations;

- In your registration dossier, you used a separation technique (filtration with pore width 0.2µm) to prepare the test solutions but you did not provide a justification for, or validation of, this separation technique. In the comments on the draft decision you indicate that you first used centrifugation as a separation technique, which did not allow for a strict separation of (non-)dissolved testing material. You reiterate that you then used filtration to prepare the test solutions without providing additional justification that validates the separation techniques used. In your registration dossier, you state that a method for analytical monitoring is not available. But you do not provide detailed information of the methods attempted, confirmation that these were state of the art, or details of the results obtained from these efforts. You do not provide detailed justification for why the analytical monitoring of exposure concentrations is not technically feasible. In the comments on the draft decision you provide a basic listing of analytical techniques attempted and state that none of these techniques led to the development of a reliable method to analyse the concentration of the Substance in algal medium with reasonable effort. No additional detailed information on the techniques used, the results obtained, or evidence that the techniques attempted were state of the art are provided;
- No analytical monitoring was conducted to confirm exposure concentrations;
- You based the EC50 on nominal concentrations, but you did not demonstrate that concentration of the test material was maintained within 20% of the nominal or measured initial concentration throughout the test;

Based on the above,

- in the absence of tabulated data on the algal biomass determined daily, the reporting of the study is not sufficient to conduct an independent assessment of its reliability and determine if the validity criteria of OECD TG 201 are met. The comments on the draft decision indicate that the validity criteria for increase in biomass in the controls (>16-fold), mean coefficient of variation for sector-by-sector growth rates (<35%), and coefficient of variation of average specific growth rates in replicate controls (<7%) are met. However, the information is currently not available in your registration dossier. 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).

Furthermore, the Substance is difficult to test (based on OECD GD 23 indicator values of Log Kow >4, saturation concentration in aqueous media expected to be <100 mg/L and surface tension <60 mN/m) and there are critical methodological deficiencies resulting in the rejection of the study results. Specifically:

- In the absence of analytical method validation report or results of a preliminary solubility experiment providing evidence that the test material preparation techniques were adequate to maximise test concentrations there is no evidence that all reasonable efforts have been taken to achieve maximum saturation concentration of the test substance.
- Your approach used filtration of undissolved Substance (filter pore width 0.2µm) which can result in potential losses due to adsorption onto the filter matrix. In the absence of appropriate justifications and validation for the separation technique, there is no evidence that the technique used for separation did not cause losses of the test substance.
- In the absence of a detailed justification as to why analytical detection was not feasible

(including descriptions confirming that the analytical methods attempted were state of the art, as well as providing detailed results from preliminary efforts), the lack of analytical monitoring is not justified;
- You did not provide any analytical monitoring of the test concentrations to confirm that the concentration of the test material was maintained within 20 % of the nominal or measured initial concentration throughout the test.

Therefore, the requirements of OECD TG 201 are not met.

Study design

OECD TG 201 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 201. 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.

If analytical monitoring of exposure concentrations is not technically feasible, a justification must be provided. This justification should confirm that the analytical methods attempted were state of the art, and include a justification as to why detection lower limits were not feasible (any preliminary analytical efforts should also be described in the report).

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the WAF approach, in addition to the above, you must:
- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

Appendix B: 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 in Annex IX to REACH.

You have provided an adaptation for this information requirement in your dossier under the endpoint study record:

- Justification for not providing the sub-chronic (90-day) toxicty study.

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

You have provided the following reasoning for not providing the Sub-chronic toxicity study: "*There is an enhanced combined repeated dose toxicity and reproductive/developmental toxicity screening test (enhanced OECD 422) in rats available which is considered to be sufficient to assess the repeated dose toxicity of the substance. […] . No adverse effects of systemic toxicity were observed up to the limit dose of 1000 mg/kg bw/d, and the NOAEL for general, systemic toxicity of the test substance was determined to be 1000 mg/kg body weight/day for the F0 parental animals, the highest dose tested. Therefore, and for the sake of animal welfare, the performance of an additional subchronic (90-day) repeated dose toxicity study is not warranted".*

ECHA understands this statement as an attempt to adapt the requirement for a Sub-chronic toxicity study according to Annex IX, Section 8.6.2, Column 2, fourth indent. This provision sets out several (cumulative) criteria in order to adapt the informaton, including: the Substance is unreactive and there is no evidence of absorption/ of toxicity in a 28-day 'limit test'.

However, these criteria are not met, because:

- The substance is corrosive to the skin and a skin sensitizer, therefore, it cannot be considered unreactive; and
- There are statistically significant effects in haematology, clinical chemistry, urinalysis, histopathology reported in the OECD TG 422 study. These effects can only occur if the substance is absorbed. In addition, the Substance is self-classified as Repro 1B (H360).

ECHA concludes that the criteria for adaptation of the standard information set out in Annex IX, Section 8.6.2, Column 2, fourth indent are not met.

On this basis, the information requirement is not met.

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

Information on the design of the study to be performed

Following 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[2], because your substance is solid. 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

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

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: *'In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore a long-term toxicity study in aquatic invertebrates is not provided*.'

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.

In your comments on the draft decision, you agree to perform the Daphnia magna Reproduction test (OECD TG 211) "*in order to improve the robustness of the assessment*". In this regard, you recognise that the hazard assessment of the Substance is currently based exclusively on acute aquatic toxicity data. You also note that "*the water solubility of the substance is relatively low (although above the regulatorily relevant threshold of 1mg/L)*" and therefore acute aquatic toxicity data "*may not be suited to fully appraise the (potential) aquatic toxicity with sufficient confidence*".

Study design

To fulfil the information requirement for long-term toxicity testing on invertebrates, the Daphnia magna Reproduction Test (test method OECD TG 211) is the most appropriate (ECHA Guidance R.7.8.4.).

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained in A.1, the Substance is difficult to test. Therefore, you must fulfil the requirements for difficult to test UVCBs as described in 'Study design' under A.1.

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:

- In the dossier you provide 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: *'In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms.*

According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance, nor are there any further indications that the substance may be hazardous to the environment. Therefore, and for reasons of animal welfare, a long-term toxicity study in fish is not provided. '

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 based on Annex IX, Section 9.1., Column 2 is therefore rejected.

In the comments on the draft decision you have adapted this information requirement under Annex XI Section 3. Substance-tailored exposure-driven testing. In particular, ECHA understands that you rely on Annex XI, Section 3.2(a) in the context of your adaptation.

ECHA has therefore evaluated your adaptation under Annex XI, Section 3.2(a) (Substance-tailored exposure-driven testing).

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria 3.2.(a),(b) or (c). In particular:

3.2 (a) It can be demonstrated that all the following conditions are met:

i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5.;

ii. a PNEC can be derived from available data, which:

- must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
- must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.

iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

In the comments on the draft decision, you provide the following justification for your adaptation: (i) the Substance is (exclusively) used as a fuel additive and is incinerated during its application(s) hence long-term exposure to the environment is generally not anticipated, and (ii) that the highest RCR obtained from the environmental risk assessment for all

compartments is [redacted] On that basis, you conclude that the Substance does not pose a risk to the environment and long-term aquatic toxicity testing is not considered necessary.

To support your adaptation, in the comments on the draft decision (in Annex I) you provide an exposure assessment and risk characterisation for the freshwater and marine water compartments.

In addition, you emphasize that by carrying out the Daphnia magna Reproduction test (OECD TG 211), as requested above under section B.2, the long-term aquatic effects of the Substance are already being investigated.

As stated in Annex XI Section 3(a)(ii) the PNEC used in the risk assessment must be based on reliable data from at least three trophic levels.

In addition, 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 tests are required for a reliable hazard assessment, including PNEC derivation. 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., Section R.7.8.5).

In your registration dossier, you provide the following aquatic toxicity studies for the Substance: algal growth inhibition, short-term toxicity to fish and short-term toxicity to aquatic invertebrates. Furthermore, you provide a water solubility test (OECD TG 105) that estimates the water solubility of the Substance as 3-6 mg/L using measurement of total organic carbon (TOC) for analytical determination.

In your registration dossier you also state that '*the test item is a mixture of different compounds. Every constituent contributes to a different degree to overall solubility, depending on its own individual solubility and its mass fraction in the test item'.*

In addition, as also pointed out above under section B.2., in your comments on the draft decision you state that '*the water solubility of the substance is relatively low (although above the regulatorily relevant threshold of 1 mg/L). Therefore, short-term aquatic studies may not be suited to fully appraise the (potential) aquatic toxicity with sufficient confidence.'*
As already described in Appendix A.1. the algal toxicity test provided is considered unreliable. A critical methodological deficiency in the algal toxicity test is that no analytical monitoring of test concentrations was conducted to confirm exposure concentrations.

In addition you have acknowledged in the dossier that each constituent of the Substance '*…contributes to a different degree to overall solubility, depending on its own individual solubility'*; while in your comments on the draft decision you noted that the water solubility of the Substance is relatively low. In this regard, ECHA notes that the water solubility data provided in the dossier does not provide unambiguous information on the water solubility of the Substance as it is based on the non-specific measurement of TOC. Since the Substance is a UVCB, information on the water solubilities of the individual constituents is required for unambiguous determination of the water solubility.

Short-term aquatic toxicity tests are considered inadequate to assess the hazards of poorly water soluble substances and long-term aquatic toxicity testing is therefore required for this Substance. Currently, there are no reliable long-term aquatic toxicity test results available for aquatic invertebrates and for fish (Section B.2.-3). Therefore, reliable data from at least three trophic levels is not available for the derivation of a reliable PNEC.

Therefore, your adaptation is rejected.

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 in A.1, the Substance is difficult to test. Therefore, you must fulfil the requirements for difficult to test UVCBs as described in 'Study design' under 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[3].

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 the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

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[4].

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

Appendix D: General recommendations when conducting and reporting new tests for REACH purposes

A. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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 22 July 2020.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account the comments and did not amend the requests.

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 F: List of references - ECHA Guidance[5] 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)[6]

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

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