~~Confidential~~

Helsinki, 27 October 2021

Addressees
Registrants of JS_952-252-4 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
17 July 2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Amines, C16-18 (even numbered)-alkyl, salts with phosphoric acid, mono- and di-C16-18 (even numbered) alkyl esters
List number: 952-252-4
CAS number: NS

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 ***1 February 2024***.

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 308)

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annexes IX of REACH".

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.) for substances with 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 IUCLID, section 5.4.1. of your technical dossier, you provided a read-across approach to meet the information requirement on adsorption/desorption screening. In support of this adaptation, you provided:

- a study according to OECD TG 106 with Octadecylamine (EC No. 204-695-3); and
- a QSAR prediction for [redacted] using KOCWIN v2.00.

The reported log Koc are 4.54 and 4.87, respectively. Furthermore, the substance is ionisable.

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

1.1. Information needed to fulfil the information requirement

You have submitted a testing proposal for an Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (test method: OECD TG 308/ EU C.24).

Your registration dossier does not include any information on aerobic and anaerobic transformation in water and sediment systems.

ECHA agrees that an appropriate degradation simulation study in sediment is needed.

In your comments on the draft decision, you state that you do not agree to perform the study as you consider that this information is not needed. You specify that "*following the* "known constituent" *approach according REACH guidance document Chapter R.11 it is therefore possible to conclude that SP674 salt is not PBT/vPvB according REACH Annex XIII*" and "*no further simulation testing in surface sediment and degradation products are required".*

In support of your statement you provided the following supporting information:

i. an adaptation under Annex XI, Section 1.5 ('read-across and grouping of substances') using information from the following source substances:
   a. [redacted])
ii. [redacted]an adaptation under Annex IX, Section 9.2., column 2 with the following justifications:
   a. "*none of the SP674 constituents (EC =952-252-4) is individually PBT nor vPvB according REACH criteria of Annex XIII*"
   b. "*risk for the aquatic and sediment compartment are RCR < 1 in every exposure scenario*"

We have assessed the information from your comments on the draft decision and identified the following issues:

A. <u>The proposed read-across adaptation does not meet the requirements of Annex XI, Section 1.5. to REACH</u>

Based on your comments on the draft decision, ECHA understand that you seek to adapt this standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5.

ECHA has considered the scientific and regulatory validity of your read-across approach(es) in general before assessing the specific standard information requirements in the following appendices.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (addressed under 'Assessment of prediction(s)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

1. Predictions for fate properties

You have some justification for the read-across in your comments on the draft decision.

You read-across between the following structurally similar substances:

[redacted]

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

i. The selected source substances are constituents of the Substance;
ii. The Substance will dissociate into individual ions upon dissolution in water (ratio 1:1) and that the "*environmental fate and ecotoxicity of* [the Substance are] *driven by properties of these dissociated alkylammonium part*";
iii. The read-across from the cation is justified as you consider that it has the most toxic effect.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on a "known component" approach. The properties of your Substance are predicted to be quantitatively equal to those of the source substances.

ECHA notes the following shortcomings with regards to prediction of degradation in sediment:

a) Read-across hypothesis contradicted by existing data

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. The ECHA Guidance[4] indicates that "*it is important to provide supporting information*

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394
[4] Guidance on information requirements and chemical safety assessment (version 6.0, July 2017), Chapter R.6, Section R.6.2.2.1.f

to strengthen the rationale for the read-across". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substances. The observation of differences in the properties between the source substances and the Substance would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substances. An explanation why such differences do not affect the read-across hypothesis needs to be provided and supported by scientific evidence.

As indicated above, your read-across hypothesis is that the information on two constituents of the Substance ([redacted]) is a sufficient basis for predicting the properties of your Substance

In your comments on the draft decision, you state that "*the primary alkylamine part of the registered substance has proved to be readily biodegradable (under OECD 301D, 75 % of biodegradation after 28 days)*" while "[redacted] *is not readily biodegradable (20% degradation after 28 days, OECD 301B)*". Finally you refer to a new ready biodegradability study according to OECD TG 301F with the Substance. You indicate that the Substance was found to be not readily biodegradable as only 11.5 % of biodegradation was observed after 28 days and 13.5% over an extended period of 60 days.

The available set of data on the target and source substances indicates differences in the environmental fate properties of the substances. The available information indicates that the Substance has a lower degradation potential than any of the selected constituents used to support your read-across adaptation. This contradicts your read-across hypothesis whereby the selected constituents of the Substance and the Substance have similar environmental fate properties. Therefore, you have not demonstrated and justified that the properties of the source substance(s) provide a reliable basis to predict the properties of the Substance despite the observation of these differences.

b) Adequacy and reliability of source study

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

In your comments on the draft decision, you refer to the following information:

i. a study according to OECD TG 307 on [1-14C]-Hexadecanamine (CAS 771435-48-4) provided in Section 5.2.3. of your IUCLID dossier. A DT50 of 16.9 days was reported at 12°C. Based on this information, you report extrapolated DT50 value at 12°C of 16.9 d for the freshwater sediment (aerobic) compartments (based on the method described in ECHA Guidance R.16, Appendix A.16-3.2.2);
ii. a feasibility trial for an OECD TG 308 study on [redacted] and you reported a DT50 for the freshwater compartment as 0.93 days at 12°C. You also provided an analysis on non-extractable residues (NER) based on the MTB yield method by [redacted] (2018).

Study i. above does not provide information on degradation in sediment. Using this information you have extrapolated a DT50 for the sediment compartment. However, ECHA notes that, in the context of the PBT/vPvB assessment, ECHA Guidance R.11.4.1.1. specifies that, in general, results of a single simulation degradation study cannot be directly extrapolated to other environmental compartments unless adequate

justification is provided in the context of a weight-of-evidence. ECHA notes that you have not provided such justification.

With regard study ii., ECHA notes that this study only corresponds to a preliminary feasibility study that do not provide equivalent information for an OECD TG 308 study. Among others, OECD TG 308 specifies that for an aerobic study, two sediments differing with respect to organic carbon content and texture must be used, including:

1) a sediment with high organic carbon content (2.5-7.5%) and a fine texture, and
2) a sediment with low organic carbon content (0.5-2.5%) and a coarse texture.

However, as specifies by you this study was conducted with a single sediment sample described as neutral silt loam with a high organic carbon content.

Therefore, none of these studies provide adequate and reliable coverage of the key parameters addressed in the OECD TG 308.

c) *Supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[5]. The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

Supporting information must include:

- information to support that the selected constituents provide adequate information to predicts the properties of the Substance as a whole;
- adequate reporting of the supporting information to allow conducting an independent assessment of their reliability.

Your read-across hypothesis is that the information on two constituents of the Substance (namely Hexadecanamine and Phosphoric acid, octadecyl ester) is a sufficient basis for predicting the properties of your Substance. [redacted]

Your registration dossier includes a category justification document for long-chain (C12 to C18) primary alkyl amines and you report that all the substances included in this category were tested in ready biodegradability studies and were found to be readily biodegradable.

Phosphoric acid, alkyl ester fraction you state that "*irrespective whether the constituent is a octadecyl dihydrogen phosphate or a dioctadecyl hydrogen phosphate, the predicted half-life according EPISUITE model (Level III Fugacity Model) are the same in all compartments. Therefore the number of the alkyl chain radical is not expected to have an impact on persistence*".

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

However, you have not provided robust study summaries for the ready biodegradability studies on the selected long-chain primary alkyl amines. Therefore, ECHA cannot conduct an independent assessment of the validity of your conclusion that these substances can reliably be concluded as readily biodegradable.

With regard the phosphoric acid, alkyl ester fraction, you have not provided any documentation related to the prediction of half-life of representative structures in relevant compartment. In the absence of this information, you have not demonstrated that structural differences are unlikely to impact the degradation rates of relevant individual constituents of the Substance.

On this basis, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

2. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

B. Your adaptation under Annex IX, Section 9.2., column 2 is not adequately justified.

ECHA has assessed the proposed adaptation under Annex IX, Section 9.2., column 2 and identified the following issues:

a) The information provided in your comments does not allow to conclude that all constituents of the Substance are not PBT/vPvB

A substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4.) if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as it is not readily biodegradable, and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier and your comments on the draft decision provide the following:

- In your comments on the draft decision, you refer to a new OECD TG 301F study on the Substance indicating that it is not readily biodegradable 11.5 % of biodegradation was observed after 28 days and 13.5% over an extended period of 60 day);
- In your comments on the draft decision, you have state that the log Kow values of [redacted] and of [redacted] are below 4.5. You conclude that therefore these constituents are not B or vB. However, the constituents of the Substance are ionisable and therefore high potential for bioaccumulation cannot be excluded based on available information;

- The Substance may meet the T criteria as you self-classify the Substance as STOR RE 2. ECHA note however, that in the context of this testing proposal evaluation ECHA has not conducted an exhaustive assessment of all toxicological and ecotoxicological endpoints relevant to reach a conclusion on T.

The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance has low water solubility (you report a water solubility estimate < 0.162 based on OECD TG 105 for [redacted] in your dossier and you refer to a new study conducted on the Substance in your comments where the solubility limit of primary amine C16:0 and primary amine C18:0 was determined to be < 0.031 mg/L and < 0.248 mg/L, respectively) and high adsorption potential (as it is ionisable)], indicating high potential to adsorb to soil.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, sediment represents a relevant environmental compartment.

b) The risk characterization described in Annex I cannot be conducted with reliability for substances satisfying the PBT/vPvB criteria

Annex I, Section 4.0.1. specifies that a hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5, Step 2 cannot be accrued out with sufficient reliability for substances satisfying the PBT and vPvB criteria of Annex XIII. Therefore, a separate PBT and vPvB assessment is required.

In your comments on the draft decision you state that RCR are < 1 for the aquatic and sediment compartment and you therefore consider that a simulation study in sediment is not needed. However, as already explained above, the information currently available on the Substance does not allow excluding that the Substance may be PBT/vPvB. Therefore, in the absence of adequate information to conclude that the Substance is not PBT/vPvB, the outcome of risk characterisation as described under Section 6 of Annex I cannot be used to omit this information requirement.

On this basis, your adaptation under Annex IX, Section 9.2, column 2 is rejected.

For the reasons explained above, the justification provided in your comments on the draft decision does not provide an adequate basis to omit this information requirement.

1.2. Test selection and study specifications

The proposed Aerobic and Anaerobic Transformation in Aquatic Sediment Systems test (test method: OECD TG 308/ EU C.24) is appropriate to cover the information requirement for degradation/biodegradation (ECHA Guidance R.7.9.4.1).

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.).

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 needed 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 and an identification of degradation products is needed.

1.2. Specification of the study design

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).

You may also use other appropriate and suitable test method(s) to provide information on the identity of the transformation/degradation products, for example an enhanced screening level degradation test or modelling tools. You will need to provide a scientifically valid justification for the chosen method. The provided information should include, identification, stability, behaviour, molar quantity of transformation/degradation products relative to the parent compound. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated.

1.3. Outcome

Based on the above, according to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the proposed test as per OECD TG 308 and perform analysis to provide information on the identity of the transformation/degradation products.

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

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[6].

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[7].

[6] https://echa.europa.eu/practical-guides
[7] https://echa.europa.eu/manuals

Appendix C: Procedure

ECHA received your testing proposal(s) on 23 July 2020 and started the testing proposal evaluation in accordance with Article 40(1).

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 however amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 18 to 24 months from the date of adoption of the decision. You provided a justification for your request for extension "*on the nature of the test substance and the radiolabeling processes of all constituents of the UVCB or selected the surrogate compound(s*)"

On this basis, ECHA has granted the request and 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 D: List of references - ECHA Guidance[8] 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)[9]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[10]

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.

[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316

OECD Guidance documents[11]
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.

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

Appendix E: 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]
[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.