~~Confidential~~

Helsinki, 20 September 2021

Addressees
Registrant(s) of JS_936-610-7 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
26/03/2018

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of sodium hydrogen N-(1-oxooctadecyl)-L-glutamate and sodium hydrogen N-(1-oxohexadecyl)-L-glutamate
EC number: 936-610-7
CAS number: NS

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 ***3 January 2023***.

The scope of this compliance check is limited to physical chemistry, environmental fate and behaviour and aquatic environment.

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. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

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

1. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

Reasons for the request(s) are explained in the appendices entitled "Reasons to request information required under Annexes VII to VIII of REACH", respectively.

Information required depends on your tonnage band

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

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 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, 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. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

You have provided a key study: OECD TG 202 (2001) with the Substance.

We have assessed this information and identified the following issues:

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:

I. the test medium fulfils the following condition(s): particulate matter ≤ 20 mg/L, total organic carbon (TOC) ≤ 2 mg/L, hardness between 140 and 250 mg/L (as CaCO3);
II. adequate information on the analytical method (including performance parameters of the method) and on the results of the analytical determination of exposure concentrations are provided;
III. water hardness can influence the toxicity of ionic/anionic organic chemicals. As such hardness must be measured at least at the beginning and end of the test, renewal interval, or more frequently if changes in hardness are expected. The composition of culture and test solution require special consideration to ensure that test results correctly reflect the toxicity of the Substance (OECD GD 23, Section 7.5).

Your registration dossier provides an OECD TG 202 indicating the following:

- EC50(48h)>3.35 mg/L meas. (arithmetric mean) based on the DOC of the test solution (2.12 mg/L);
- You did not report the TOC/DOC of the test medium;
- Hardness of the test solution is reported to be 256 mg/L.

You have used DOC analysis to measure the concentration of the Substance in the test solution. The Substance is a multi-constituent and you did not describe how the effect concentrations were derived based on the DOC, nor provided the background TOC/DOC of the test solution.

In addition, the hardness of the test solution is higher than what is allowed according to the TG 202. As you describe in the algae study (OECD TG 201 (2008)), the Substance, which is an anionic surfactant, is expected to react with calcium and magnesium ions present in the test solution and precipitate out. Currently, it is not possible for ECHA to assess whether the organisms were exposed to the Substance during the test based on the available information in the dossier.

Based on the above, on the information in your dossier assessed for the initial draft decision, the Substance is difficult to test (the Substance is an anionic surfactant) and there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically, regarding point III above high hardness of the test solution and regarding point I & II insufficient/inappropriate analytical monitoring of the Substance.

In your comments to the initial draft decision, you indicate that:

1. The hardness of the test solution of 256 mg/L, slightly above what is recommended in the most recent EU guidance (OECD TG 202, 2004), i.e. between 140 and 250 mg/l (as CaCO3).
2. The study fulfilled all validity criteria of the OECD TG 202 as detailed below:

a. In the control the immobilization should be less than or equal to 10%.
    i. You state that in the control group no Daphnia were immobilised or trapped on the surface of the water.
b. The O2-concentration should be at least greater than or equal to 3 mg/L in control and test vessels.
    i. You state confirm that the dissolved O2-concentration was greater than 5.21 mg/L.
c. Analytical measurement of test concentrations was completed.
    i. The test item was analytically verified via DOC analysis.
        1. DOC was measured in the limit concentration and control after 0h (new media) and 48 h (old media) (Table 6 in an attachment confirms these results).
        2. It is also noted that DOC analysis indicates that significant amounts of test item were achieved for the saturated treatment solution.

You agree with ECHA that the requirements of OECD GD 23 for difficult test substances could have been considered more comprehensively, especially with regards to the requirement to keep water hardness low in order to reduce precipitation potential of the test item. You acknowledge that repeat testing might be provided in a more compliant manner, targeting at an optimum test item concentration achievable. However, on basis of the achieved saturation level analysed and notwithstanding deficiencies in analytical method description (lack of details including background TOC levels), the existing test data is still considered to provide a reasonable assessment of the hazard of the substance for this endpoint.

On the basis of the information provided in the dossier, ECHA concluded that, in relation to issues I and II, it is not possible for ECHA to verify whether the reported effect concentrations are adequate and, in relation to issue III, it is not possible to verify whether test results correctly reflect the toxicity of the Substance.

In your comments to the initial draft decision,

- Regarding issues I, II and III:
    - You agree the water hardness value of 256 mg/L (as CaCO3) and is slightly above what is recommended in the most recent EU guidance.
    - You do not justify the consequences of this to the validity of the test, for example where hardness values throughout the test considered; background levels.
    - You provide the results of the analytical determination of exposure concentrations and the controls but you agree that there are deficiencies in analytical method description (lack of details including background TOC levels). It is therefore difficult to benchmark, the biological concentration sample values, without having the appropriate performance parameters of the method.
    - You have not justified why you consider your analytical method adequate for this type of substance (the Substance is an anionic surfactant).

However, all of these issues (I – III) are of more importance in particular due to the type of substance involved. The Substance, which is an anionic surfactant, is expected to react with calcium and magnesium ions present in the test solution and precipitate out. Based on the information provided and for the reasons above, it is not possible for ECHA to assess whether the organisms were exposed to the Substance during the test.

Therefore, it is not possible for ECHA to verify whether the reported effect concentrations are adequate and meet the OECD TG specifications.

So this information does not change the overall outcome of ECHA's assessment.

Therefore, the requirements of OECD TG 202 are not met.

On this basis, the information requirement is not fulfilled.

Study design

The Substance is difficult to test due to the surface active properties (Surface tension= 50.5 mN/m). OECD TG 202 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 202. 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. For example, by keeping the hardness of the test solution low.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2).

You have provided a key study: OECD TG 201 (2008) with the Substance.

We have assessed this information and identified the following issues:

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:

I. If concentrations cannot be quantified, direct addition approaches with defined nominal concentrations should be used to prepare testing solutions (OECD GD 23, Section 9).
II. 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;
III. if the concentration of the test material has not been maintained within 20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material.
IV. water hardness can influence the toxicity of ionic/anionic organic chemicals. As such hardness must be measured at least at the beginning and end of the test, renewal interval, or more frequently if changes in hardness are expected. The composition of culture and test solution require special consideration to ensure that test results correctly reflect the toxicity of the Substance (OECD GD 23, Section 7.5).
V. Data from tests in which complexation has been judged to have had a significant bearing on the result are likely to be of questionable value for classifying test chemicals and for extrapolating to a predicted no effect concentration for risk assessment unless additional tests are conducted to attempt to determine the nature and extent of the effect. The extent to which complexation affects toxicity therefore must be determined where possible (OECD GD 23).

Your registration dossier provides an OECD TG 201 showing the following:

- You stated that measured test concentrations were below the limit of quantification (LOQ) of the analytical method (0.56 mg/L) after serial dilution of the saturation solution. Despite this, you did not use direct addition approaches with defined nominal concentrations to prepare testing solutions.
- The measured concentrations after 72hr were below the limit of quantitation (LOQ) of the analytical method at all the test concentrations. However the effect concentrations were reported based on the nominal concentrations (EC50(72h)=100 % saturated solution (nominal).
- You did not report hardness of the test solution although precipitation of the Substance was observed during the preliminary stability analysis.
- You stated that precipitation was formed in culture medium due to the formation of insoluble complexes with the magnesium and calcium ions present in the medium. You have not addressed the issue of the extent to which complexation may affect toxicity.

In your comments to the initial draft decision, you indicate that the study fulfilled the validity criteria as detailed below:

1. Cell density in the controls should increase by at least a factor of 16 in 72-hours.
    a. In the test cell density increased by a factor of 54 after 72 hours.
    b. The coefficient of variation of sectional (daily) growth rates in the controls should be less than or equal to 35%.
        i. In the test this was 19%.
    c. The coefficient of variation of average growth between control replicates should be less than or equal to 7% in tests with Desmodesmus subspicatus.
        i. In the test this was 5%.

Therefore, the test is considered by you to be valid and results are considered relevant for the saturation level achieved for testing.

However, as outlined in this section certain critical methodological deficiencies have been observed, which need to be considered before accepting the observed validity criteria as accurately reflecting the study.

In your comments to the initial draft decision, you have not provided any justification why the requirements of OECD GD 23 for difficult test substances were not considered regarding:

- Preparation of your test concentrations - use of direct addition approaches with defined nominal concentrations to prepare testing solutions.
- The reporting of the effect concentrations on the nominal concentrations (EC50(72h)=100 % saturated solution (nominal). OECD 23 outlines various options to consider.
- You did not report hardness of the test solution although precipitation of the Substance was observed during the preliminary stability analysis.
- You further state that precipitation of the test item occurs also in dependence of the test conditions. However, the reasoning/justification for this precipitation observed both in the preliminary stability analysis and the definitive study was not further investigated or its effects on the validity of the definitive study.

So this information does not change the outcome of ECHA's assessment.

Based on the above,
- the Substance is difficult to test (the Substance is an anionic surfactant) and there are critical methodological deficiencies resulting in the rejection of the study results.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, in A.1. the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

3. Ready biodegradability

Ready biodegradability is an information requirement under Annex VII to REACH (Section 9.2.1.1.).

You have provided a key study: OECD TG 301B (2008) with the Substance.

To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following requirement must be met:

1. The inoculum is not pre-adapted to the test material;

In the technical dossier, you indicated that adapted inoculum was used for the study.

In addition, you did not report the bacterial cell density of inoculum as specified for the TG 301.

In your comments to the initial draft decision, you indicate that the study fulfilled the validity criteria as detailed below:

1. the IUCLID dossier will be updated be corrected to reflect accurately the test conditions from [redacted] (2008) by selecting the following description for the inoculum/test system: "activated sludge, domestic, non-adapted".
2. You do not agree with the premise that "these are critical methodological deficiencies affecting the reliability of the test results" and that "the information requirement is not fulfilled". You consider that existing study data valid and that there is no need to undertake a new study to address this endpoint.

Based on the information in the dossier, ECHA concluded that there is a critical methodological deficiency affecting the reliability of the test results for the inoculum/test system.

In your comments to the initial draft decision, you have provided the requested information for the inoculum/test system. ECHA has assessed the information against the requirement in OECD TG 301B / 310. The information you have provided in your comments addresses the incompliance identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision."

On this basis, the information requirement is not fulfilled.

Please note that ECHA agrees that the information relating to the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel was addressed in the dossier assessed for the initial draft decision.

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

1. Short-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

You have provided the following information:

i. OECD TG 203 key study (2013) with the Substance

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 203 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 analytical measurement of test concentrations is conducted (Validity criteria)
- the test medium fulfils the following condition(s): particulate matter ≤ 5 mg/L, total organic carbon (TOC) ≤ 2 mg/L or carbon oxygen demand (COD) ≤ 5 mg/L.

Your registration dossier provides an OECD TG 203 showing the following:

- You stated that "A suitable analytical method could not be derived due to the properties of the test material" without any substantiation/justification
- No information on the test medium provided
- LC50(96h)>100 % saturated solution.

Although no effect was observed during the study, no analytical monitoring was conducted to confirm the exposure concentration of the Substance. Hence it is not possible to confirm whether the lack of effect seen is due to the lack of toxicity of the Substance or if it is due to the absence of the Substance in the test solution (e.g. by precipitation of the Substance as you described in the algae study). In addition, the analytical monitoring is a validity criterion of the TG 203. As already pointed out in the Requests A.1. - A.2., the analytical monitoring of the exposure concentrations is particularly important for this type of substances. In addition, there is no information on the test medium methodology.

In your comments to the initial draft decision, you indicate that two of the three validity criteria have been met and are detailed below:

1. Control mortality should be less than or equal to 10% (or 1 fish if less than 10 control fish are tested) by the end of the test.
    a. 0% control mortality was observed in the study.
2. Dissolved oxygen concentrations should be less than or equal to 60% of the air saturation value in all test vessels throughout the exposure.
    a. Greater than or equal to 62% was observed throughout the exposure period.
3. However, you agree that analytical measurement of test concentrations was not performed due to the properties of the test material.
    a. The only information available on the test medium is that is aquarium water with a hardness of 54 mg/L (as CaCO3).
    b. The analytical measurement of test concentrations is not due to the properties of the test material.
    c. You agree with ECHA that the requirements of OECD GD 23 for difficult test substances have not been considered but in acknowledgement of the fact no effects have been observed at the saturated test item solution (NOEC greater than the limit concentration achieved), you consider that the study is adequate for hazard assessment. This is because with reference to the fact that the relevant endpoint from acute fish testing is the median lethal concentration,

the achieved results provide a margin of safety also allowing for a range of differing test conditions still resulting in the conclusion of an LD50 of greater than the solubility limit of the test item. You are of the opinion, that the deficiencies of the available test would not warrant additional vertebrate testing because further testing would not enhance the hazard assessment. In conclusion, for animal welfare reasons and with the reported low toxicity for fish, the available data are considered to be acceptable.

Based on the information in the dossier, the validity criterion of OECD TG 203 is not met and there are critical methodological deficiencies resulting in the rejection of the study results.

Regarding points 1 and 2 of your comments to the initial draft decsion above, you have confirmed two validity criteria.

Regarding point 3 of your comments to the initial draft decsion,

- You stated that, no analytical monitoring was conducted to confirm the exposure concentration of the Substance, due to the properties for the Substance. However, for the other aquatic tests (see sections above), some level of analytical monitoring was performed, and you have not justified why the situation would be different, here.
- You provide the water hardness but not the other medium aspects; particulate matter ≤ 5 mg/L, total organic carbon (TOC) ≤ 2 mg/L or carbon oxygen demand (COD) ≤ 5 mg/L.
- You agree with ECHA that the requirements of OECD GD 23 for difficult test substances have not been considered comprehensively.
- You state no effects observed at the saturated test item solution, the reported low toxicity for fish. This statement is not substantiated. You have not provided information on the test medium methodology, for example.

As stated above, it is currently not possible to confirm whether the lack of effect seen is due to the lack of toxicity of the Substance or if it is due to the absence of the Substance in the test solution (e.g. by precipitation of the Substance as you described in the algae study, perhaps there was loss observed in the stock and/or test concentration preparations).

In addition, the analytical monitoring is a validity criterion of the TG 203, which has not been met or sufficiently justified. As already pointed out in the Requests A.1. - A.2., the analytical monitoring of the exposure concentrations is particularly important for this type of substances.

In addition you invoke animal welfare, as a reason to avoid testing. It does not constitute as such a valid justification to omit the standard information requirements of Annexes VII – IX or a valid adaptation to these information requirements.

So this information does not change the overall outcome of ECHA's assessment.

On this basis, the information requirement is not fulfilled.

Study design

OECD TG 203 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, in A.1. the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A.1.

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

A. Test methods, GLP requirements and reporting

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

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

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[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: 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 9 April 2020.

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

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

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

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

Appendix F: List of references - ECHA Guidance[4] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[5]

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

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[6]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[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] 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]
[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.