EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 14 April 2021

Addressees
Registrant of 68390-58-9_269-905-8 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
14/01/2016

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, tall-oil, 1-methyl-1,2-ethanediyl esters
EC number: 269-905-8
CAS number: 68390-58-9

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 ***21 October 2022***.

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. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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

4. 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:

- Appendix entitled "Reasons common to several requests";
- 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.

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 on Reasons common to several requests

1. Assessment of your read-across approach under Annex XI, Section 1.5.

In your registration dossier, you seek to adapt the following standard information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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.

Grouping of substances and read-across approach

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."

A. Predictions for toxicological properties

You have provided a read-across justification document in IUCLID Section 13.

You read-across between the structurally similar substances, Propane-1,2-diol esters of fatty acids (E 477) (no chemical identifiers available) as source substance and the Substance as target substance.

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

- [redacted]Identical chemical composition – you state that the Substance and the source substrance are composed of [redacted]
- Same metabolic products – [redacted]
- Same, very low toxicological potential

You concluded that *"Based on this information it is concluded that read-across from safety data on the food additive E 477 is applicable. Performance of a sub-chronic oral toxicity study and of a developmental toxicity study with WS400145 is not expected to provide additional toxicological information on this substance"*.

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common (bio)transformation products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA has assessed this information and considers that your hypothesis for the prediction of

the toxicological properties of your Substance from the properties of the source substance is plausible. However, ECHA has identified the following issue:

Availability of the source studies

Under Article 10(a)(vii) of the REACH Regulation, a technical dossier must include "*robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I*". Annex I, Section 1.1.4 of REACH states that robust study summaries are "*required of all key data used in the hazard assessment*". When properties of a substance are read-across from a source study conducted with an analogue substance to fulfil an information requirement, this source study provides key data for the hazard assessment. Therefore a robust study summary providing information allowing to make an independent assessment of the study must be provided for each source study used in read-across approaches.

ECHA notes that in your technical dossier, you have not reported experimental studies to cover the information requirements for Annex IX, section 8.6.2 and section 8.7.2. with the source substance and/or with the (bio)transformation products of the target substance.

In the absence of such information, ECHA cannot conclude on its adequacy and reliability to predict the systemic toxicity and developmental toxicity properties of the Substance from data with the source substance.

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.

Reasons to request information required under Annex VII of REACH

1. 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 the following information: OECD TG 201 key study on the Substance ([redacted] 2014)

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 requirements must be met:

- 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;
- The results can be based on nominal or measured initial concentration only if the deviation in test concentration has been maintained within ±20 % of the nominal or measured initial concentration throughout the test;
- The test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (*i.e.* inoculated with algae and incubated under identical conditions);
- If the test material is poorly water soluble, evidence must be provided that the test solution preparation allowed achieving the maximum dissolved concentration under test conditions;
- A justification for, or validation of, the separation technique is provided;
- Surface-active test chemicals are tested at concentrations below their critical micelle concentration (CMC) in the test medium.

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

- Exposure levels were monitored using total organic carbon (TOC) analysis. You have not provided performance parameters of the analytical method (e.g. LOD, LOQ, recovery);
- The test media prepared specifically for analysis of exposure concentrations at the end of the test was not inoculated with algae;
- You report that the test solutions with nominal loading rates were prepared, stirred for 24 h, left to stand for additional 24 h and syphoned from a mid-vessel location of each preparation vessel to give the Water Accommodated Fractions;
- You have not provided any justification for the methods used to prepare the test solutions.
- Nominal loading rates at which test was conducted ranged from 0.298 mg/L to 100 mg/L. The CMC is 0.1 mg/L as determined in the provided water solubility test.

Based on the above,

- There are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you used the total organic carbon (TOC) method for analytical monitoring of exposure concentrations. Although you did not provide performance parameters for this method, TOC is considered as a nonspecific method

with low sensitivity. Therefore, you have not demonstrated that exposure concentrations were maintained within 20 % of the nominal concentration throughout the test, hence it is not possible to conclude if the algae were exposed to the test material nor if the exposure was satisfactorily maintained during the test.

- Furthermore, the test media prepared for analysis of exposure concentrations was not treated identically to those used for testing i.e., it was not inoculated with algae;
- The Substance is difficult to test (low water solubility of 0.1 mg/L and surface active properties as demonstrated by the formation of CMC in water solubility study) and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in this study all the test concentrations were prepared at concentrations above the CMC. Therefore you have not demonstrated that test organisms were exposed to the freely dissolved chemical species and not the micelle form, which is considered to be biologically unavailable. Also, you have not justified nor demonstrated that the method applied in the aquatic toxicity test allowed achieving maximum dissolved concentrations.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision you indicate your intention to adapt Annex VII, Section 9.1.2 information requirement by means of weight of evidence.

You indicate that performance of the requested algae growth inhibition test with the Substance is not necessary because you consider that sufficient information is available from analogue substances CAS no 68583-51-7, CAS no 84988-75-0, and CAS no 1323-39-3.

However, while you have described your intentions, you have not provided in your comments any new scientific information addressing the information requirement. Therefore, the data gap remains. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to the dossier evaluation.

Study design

The Substance is difficult to test due to the low water solubility (0.1 mg/L) and adsorptive properties (Substance is surface active as indicated by formation of CMC in water solubility test). 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.

Appendix A: 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 the following key study with the Substance:

(i) Screening for reproductive/developmental toxicity study in rats (according to OECD TG 422, GLP)

In addition, you propose to adapt the information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. ECHA aknowledges that your hypothesis for the prediction of the toxicological properties of your Substance from the properties of the source substance is plausible. However for the reasons explained in Appendix of reasons common to several requests, your read-across is rejected.

Furthermore, ECHA has assessed the information, provided with the Substance and identified the following issue(s):

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others:

- dosing of the Substance daily for a period of 90 days until the scheduled termination of the study;
- histopathological investigations of all organs, performed on at least 10 animals per sex/dose.

The Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) you have submitted does not have the required exposure duration of 90 days as required in OECD TG 408, because the exposure duration reported is 45 days (for females) and 28 days (for males). Furthermore the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 408.Therefore, the provided study does not fulfil the information requirement.

In the comments on the draft decision you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation.

You propose to provide the information used by EFSA for the safety evaluation of E477 food additive or an appropriate analogue including CAS no 68583-51-7, CAS no 84988-75-0, and CAS no 1323-39-3. You also indicate that you will provide the robust study summaries when available.

However, while you have described your intentions, you have not provided in your comments any new scientific information addressing the information requirement. Therefore, the data gap remains. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to the dossier evaluation.

Information on the study design

According to the OECD TG 408 rat is the preferred species.

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because although the information indicate that human exposure to the Substance by the inhalation route is likely, there is no concern for severe local effects following inhalation exposure.

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. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided the following key study with the Substance:

(i) Screening for reproductive/developmental toxicity study in rats (according to OECD TG 422, GLP)

In addition, you propose to adapt the information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. ECHA aknowledges that your hypothesis for the prediction of the toxicological properties of your Substance from the properties of the source substance is plausible. However for the reasons explained in Appendix of reasons common to several requests, your read-across is rejected.

Furthermore, ECHA has assessed the information, provided with the Substance and identified the following issue(s):

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species, e.g external, skeletal and visceral malformations and variations has to be investigated as described in OECD TG 414.

You have not provided information following OECD TG 414. Instead, you have provided a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). This study does not inform on skeletal and visceral malformations and variations as required by OECD TG 414. Therefore, this study does not fulfil the information requirement.

In the comments on the draft decision you indicate your intention to adapt this information requirement by means of weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation.

You indicate that you will provide the information used by EFSA for the safety evaluation of E477 food additive or an appropriate analogue including CAS no 68583-51-7, CAS no 84988-75-0, and CAS no 1323-39-3. You also indicate that you will provide the robust study summaries when available.

However, while you have described your intentions, you have not provided in your comments any new scientific information addressing the information requirement. Therefore, the data gap remains. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to the dossier evaluation.

Information on the study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[2] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates

and

4. Long-term toxicity testing on fish

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

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH (Section 9.1.6.).

You have provided the following information: a justification to omit the study. In support of your adaptation, you provided the following justification: "*The substance WS400145 is readily biodegradable and thus will be quickly eliminated from the aquatic environment by micro-organisms. In addition, the water solubility of WS400145 is very low, i.e. < 0.1 mg/l. No toxic effects were observed in algae, daphnia, and fish in acute tests with water accommodated fractions (WAF) of WS400145; loading rates amounted to up to 100 mg/l. Furthermore, accumulation of WS400145 is unlikely. The chemical composition of WS400145, i.e. fatty acid esters of propylene glycol, is identical with that of the food additive E 477. For the food additive an ADI value (Acceptable Daily Intake) has been established for the safe lifelong exposure of consumers. The metabolism of fatty acid esters of propylene glycol is very similar to that of fatty acid esters of glycerol (lipids, triglycerides) starting with hydrolysis of the ester bonds (a detailed discussion and justification of the read-across approach from safety data of the food additive E 477 is provided in the attachment in section 13). Lipids are produced and contained in all plants including algae; plant material and lipids are consumed by all organisms of the food web. Accordingly, metabolism of triglycerides is common in all animals. Since WS400145, i.e. fatty acid esters of propylene glycol, is metabolized in mammals in the same way as fatty acid esters of glycerol (lipids) it is assumed that WS400145 also will be metabolized in other organisms similarly to lipids. Taking this information together it is concluded that performance of long-term toxicity testing in aquatic invertebrates and fish is not necessary. WS400145 is not expected to exhibit long-term toxicity in the aquatic environment.*"

We have assessed this information and identified the following issue:

In general, a registrant may adapt the standard testing regime in accordance with the specific rules set out in column 2 of Annexes VII to X (if applicable) or the general rules set out in Annex XI. For the present information requirements, column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish and long-term toxicity to Daphnia under Column 1 (Decision of the Board of Appeal in case A-011-2018). Your adaptation does not refer to any of the general adaptation possibilities under Annex XI. It is therefore unclear what adaptation possibility you refer to under Annex XI.

Your adaptation is therefore rejected. On this basis, the information requirements are not fulfilled.

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

In the comments on the draft decision you indicate your intention to adapt these information requirements by means of weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation.

You indicate that performance of the two long-term aquatic toxicity tests with the registered substance is not necessary because you consider that sufficient information is available to conclude absence of long-term aquatic toxicity. You also indicate that you will provide the reasons for the absence of long-term toxicity in more detail.

However, while you have described your intentions, you have not provided in your comments any new scientific information addressing the information requirement. Therefore, the data gap remains. Should you decide to pursue the strategy presented in your comments, ECHA will assess its compliance in the follow-up to the dossier evaluation.

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 211 and OECD TG 210 specify that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in in 'Study design' under Section A.1.

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[3].

B. Test material

Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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.

1. *Information on the Test Material needed in the updated dossier*

a) 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.
b) The reported composition must include The reported composition must identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm 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 C: 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 16 April 2020.

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

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

In your comments, you stated that you will use weight of evidence according to Annex XI, Section 1.2, of the REACH Regulation to adapt standard information requirements addressed in the draft decision and that you will provide this information in an update of your registration dossier. The information in your comments is not sufficient for ECHA to make an assessment.

Please note that as indicated in the notification letter accompanying the draft decision sent to you on 20 August 2020, 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, including changes in the annual or total quantities manufactured or imported (Article 22(1)(c)) or change of type of your registration (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation)."

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[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 E: 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.