~~Confidential~~

Helsinki, 15 September 2022

Addressees
Registrant(s) of JS_TEA_TOFA as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/12/2013

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C18-unsatd., esters with triethanolamine
EC/List number: 939-649-8

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 ***23 June 2025***.

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

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

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)

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

2. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: EU C.47./OECD TG 210)

Information required from all the Registrants subject to Annex IX of REACH

3. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: OECD TG 408) by oral route, in rats

4. 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)

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

6. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: EU C.47./OECD TG 210)

The reasons for the requests are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed

in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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 Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

Reasons related to the information under Annex VII of REACH

1. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., Column 2)

1 Short-term toxicity testing on aquatic invertebrates is an information requirement under Column 1 of Annex VII to REACH (Section 9.1.1.). However, long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

1.1. Information provided

2 You have provided an OECD TG 202 study (2012) but no information on long-term toxicity on aquatic invertebrates for the Substance.

1.2. Assessment of the information provided

3 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

4 You have provided information which indicates that the Substance includes constituents that are poorly water soluble. In the provided EPA OPPTS 830.6302 (2012), water solubility of the components in water was determined to range from 1.42×10^{-5} g/l to 6.92×10^{-5} g/l.

5 Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

6 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 5. Also, your comments to the draft decision are considered under Request 5.

Reasons related to the information under Annex VIII of REACH

2. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., Column 2)

7 Short-term toxicity testing on fish is an information requirement under Column 1 of Annex VIII to REACH (Section 9.1.3.). However, long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

2.1. Information provided

8 You have provided an OECD TG 203 study on fish (2013) but no information on long-term toxicity on fish for the Substance.

2.2. Assessment of the information provided

9 Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (Guidance on IRs and CSA, Section R.7.8.5).

10 As already explained under Request 1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

11 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 6. Also, your comments to the draft decision are considered under Request 6.

Reasons related to the information under Annex IX of REACH

3. Sub-chronic toxicity study (90-day)

12 A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

3.1. Information provided

(i) A Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test according to OECD TG 422, in rats (2013) with the Substance

13 You have also provided an adaption in Section 7.5.1 of your dossier, and you conclude that "the DNELs derived from the OECD 422 study are relevant and appropriate for the risk assessment and in waiving a further 90 day study".

14 We understand that you have sought to adapt the standard information requirement according to Annex XI, Section 3 ('Substance-tailored exposure-driven testing').

3.2. Assessment of information provided

3.2.1. Invalid exposure waiver

15 As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a), (b) or (c) shall be met. In particular, under criteria 3.2 (a), the manufacturer or importer demontrates and documents that all of the following conditions are fulfilled:

i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
iii. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

16 This criterion 3.2(a) requires "absence of or no significant exposure in all scenarios of the manufacture and all identified uses". Moreover, relevant PNECs or DNELs are to be derived and exposure results are to be well below the derived PNECs or DNELs. However, the DNEL in your dossier is based on a combined 28day repeated dose toxicity and repro/ developmental screening study and, as specified in the footnote (1) of criteria 3.2(a), for the purpose of DNEL derivation, without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated-dose toxicity study shall not be considered appropriate to omit a 90-day repeated-dose toxicity study. Therefore, criterion 3.2(a) cannot be fulfilled and your adaptation is rejected.

3.2.2. Study not carried out in accordance with the specifications of the applicable test guideline

17 To fulfil the information requirement, the sub-chronic toxicity study (90 day) has to meet the requirements of OECD TG 408. Therefore, the following specifications must be met:

a) Dosing of the Substance daily for a minimum of 90 days (13 weeks).

18 In study (i), the following specifications are not according to the requirements of OECD TG 408:

a) An exposure duration of at least 4 weeks for males and approximately 7 weeks for females is reported.

19 Therefore, this study does not meet the information requirement.

20 Therefore, the standard information requirement is not fulfilled.

21 In your comments to the draft decision you agree that this information is required and missing. You intend to fulfil this data requirement using read-across to a similar substance (Fatty acids, tall-oil, reaction products with triethanolamine, EC No.: 267-053-1). You state that if during the Registrants analysis this read-across is not deemed appropriate, the studies will be conducted.

22 As this strategy relies on a read-across approach that has not yet been fully described and justified, no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

3.3. Specification of the study design

23 Following the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity of the Substance; Guidance on IRs and CSA, Section R.7.5.6.3.2.

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

25 Therefore, the study must be performed in rats according to the OECD TG 408, in rats and with oral administration of the Substance.

4. Pre-natal developmental toxicity study in one species

26 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

4.1. Information provided

27 You have provided the following study:

(i) A Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test according to OECD TG 422, in rats, with the Substance (Kaiser, 2013)

28 You have also provided an adaption in Section 7.8.2 of your dossier, and you state that "the DNELs derived from OECD 422 are relevant and appropriate for the risk assessment and in waiving a further pre-natal developmental toxicity study". You conclude that "The results of the OECD 422 study showed no treatment related effects in the reproductive parameters (mating performance, fertility, duration of gestation, corpora lutea count, pre-implantation loss, implantation rate, post implantation and postnatal loss or litter size) examined at the highest dose level (1000 mg/kg bw/day) tested. There is therefore no current evidence that the substance has an adverse effect on sexual function and fertility,

or on development. Based on the above information it is proposed that a pre-natal developmental toxicity study would not lead to any further relevent data to assess risk to human health and can therefore be waived as not being scientifically justifiable".

29 We understand that you have sought to adapt the standard information requirement according to Annex XI, Section 3. Substance-tailored exposure-driven testing.

4.2. Assessment of information provided

4.2.1. Invalid exposure waiver

30 As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a),(b) or (c) shall be met. In particular, for criterion 3.2 (a) the manufacturer or importer demontrates and documents that all of the following conditions are fulfilled:

i. the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
ii. a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes; and
iii. the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

31 The first criterion 3.2(a) requires "absence of or no significant exposure in all scenarios of the manufacture and all identified uses". Moreover, relevant PNECs or DNELs are to be derived and exposure results are to be well below the derived PNECs or DNELs and, as specified in the footnote (1) of criteria 3.2(a), for the purpose of DNEL derivation, without prejudice to column 2 of section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity study shall not be considered appropriate to omit a prenatal developmental toxicity study. Therefore, criterion 3.2(a) cannot be fulfilled and your adaptation is rejected.

4.2.2. Study not carried out according to the applicable test method

32 (Eco)toxicological studies must comply with a recognised test method (Art. 13(3) of REACH), in this case OECD TG 414.

33 The study (i) is described as "reproduction/ developmental toxicity screening test". This study has been conducted using OECD TG 422 which is a screening tests rather than a conclusive developmental toxicity study.

34 The study is not adequate for the information requirement and is therefore rejected.

35 Therefore, the standard information requirement is not fulfilled.

36 In your comments to the draft decision you agree that this information is required and missing. You intend to fulfil this data requirement using read-across to a similar substance (Fatty acids, tall-oil, reaction products with triethanolamine, EC No.: 267-053-1). You

state that if during the Registrants analysis this read-across is not deemed appropriate, the studies will be conducted.

37 As this strategy relies on a read-across approach that has not yet been fully described and justified, no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

4.3. Specification of the study design

38 A PNDT study according to the test method OECD TG 414 should be performed in rat or rabbit as preferred species.

39 The study shall be performed with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

40 Therefore, the study must be conducted in rats or rabbits with oral administration of the Substance.

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

42 You have provided a study according to OECD TG 211 (2013) on the Substance.

5.2. Assessment of information provided

5.2.1. Study not complying with the specifications of the test guideline

43 To fulfil the information requirement, a study must comply with the OECD TG 211 and the requirements of OECD GD 23 the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

44 Reporting of the methodology and results

a) detailed information on feeding, including amount (in mgC/daphnia/day) and schedule is reported;
b) as per OECD GD 23, the results from any preliminary studies on the solubility and stability of the test substance is reported;
c) the nominal test concentrations and the results of all analyses to determine the concentration of the test substance in the test vessels are reported;

45 However, your registration dossier provides an OECD TG 211 showing the following:

46 Your dossier indicate that the low water solubility (0.0142mg/L mg/L) and adsorptive properties (log kow in the range 2.48 to 23.1). Under the OECD GD 23, the Substance is difficult to test.

Reporting of the methodology and results

a) information on feeding rate is not provided;
b) results from preliminary studies on the solubility and stability of the test substance is not reported;
c) the results of all analyses to determine the concentration of the test substance in the test vessels are not reported.

47 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. Missing Information includes details on feeding amount per *Daphnia* per day, solubility and stability of the test substance in any preliminary studies, detailed reporting of concentrations of test substance in the test vessels.

48 In your comments to the draft decision, you submitted the following further details on the listed defieciencies in the reporting:

- Feeding rate: *"Each daphnid received approximately 2 to 7 µL of an algal suspension (Desmodesmus subspicatus) and approximately 10 to 32 µL of* [redacted] *flake food suspension daily. Feeding was at a level of 0.1 to 0.2 mg carbon/daphnid/day dependent on the age and size of the animals."*

- Solubility and stability from a preliminary study: *"the stirring period* [up to 96 hours] *did not significantly increase the amount of carbon in the WAF and so preparation of the WAF was maintained at 24 hours."* In addition you state that *"At both the start and end of the mixing period, and following a 1 hour standing period the 32, 100 and 320 mg/L loading rates were observed to be clear colorless water columns with globules of test item floating on the surface* [noting that the WAF was taken from the centre of the water columns]*. Microscopic inspection of the WAFs showed no micro-dispersions or undissolved test item to be present. After siphoning and for the duration of the test, the loading rates 32, 100 and 320 mg/L were observed to be clear, colorless solutions."*

- Concentrations of test substance in the test vessels are provided in a tabular format.

49 In addition to these clarifications, you suggest to do a statistical reanalysis of test concentrations using a time weighted average.

50 ECHA has assessed the information against the requirement in OECD TG 211. The detailed information you have provided in your comments addresses the incompliances 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.

5.3. Study design and test specifications

51 The Substance is difficult to test. OECD TG 211 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 211. 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.

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

53 If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

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

6. Long-term toxicity testing on fish

54 Long-term toxicity testing on fish is an information requirement under Annex IX to REACH (Section 9.1.6.).

6.1. Information provided

55 You have provided a justification to omit the study which you consider to be based on Annex IX, Section 9.1., Column 2. In support of your adaptation, you provided the following justification: *"In accordance with column 2 of REACH Annex IX (9.1. Aquatic toxicity), long-term testing on fish shall be proposed if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. An assessment of the need for long-term testing has therefore been made based on the available information.* […] *Releases of the substance to the environment are anticipated to be minimal from its use. Any potential releases, if any, would be through release of waste water. However, the amount and concentration of substance, if any, in the waste water is anticipated to be below levels of concern. Based on the above data, it is considered that a long-term study in fish is not required."*

56 We understand that you have sought to adapt the standard information requirement according to Annex IX, Section 9.1., Column 2.

6.2. Assessment of the information provided

6.2.1. Annex IX, Section 9.1., Column 2 is not a valid basis to omit the study

57 Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

58 Your adaptation is therefore rejected and the information is not fulfilled.

59 In your comments to the draft decision, you state that "The Registrant agrees that this information is required and missing. The Registrant intends to fulfil this data requirement using read-across to a similar substance (Fatty acids, tall-oil, reaction products with triethanolamine, EC No.: 267-053-1)." You also provide some general information and reasoning to support the suggested read-across approach. In addition you state, "If during the Registrant's analysis this read-across is not deemed appropriate, the study will be conducted."

60 As this strategy relies on a read-across approach that has not yet been fully described and justified, no conclusion on the compliance of the proposed adaptation can be made. You remain responsible for complying with this decision by the set deadline.

6.4. Study design and test specifications

61 To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (Guidance on IRs and CSA, Section R.7.8.2.).

62 OECD TG 210 specifies 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 'Study design' under Request 5.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; (ECHA 2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: 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 19 April 2021.

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.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

Appendix 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- 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;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

1.2. 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:

   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.

2. *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 careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,
   c) The reported composition must also include other parameters relevant for the property to be tested, in this case the distribution of C-chain length of constituents and the ratio between saturated and unsaturated constituents.

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

With that detailed information, ECHA can confirm 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. General recommendations for conducting and reporting new tests

2.1. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, 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.

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[3] https://echa.europa.eu/manuals