~~Confidential~~

Helsinki, 15 September 2022

Addressees
Registrants of JS_FA-DEA_91032-08-5 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
27/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C16-18, reaction products with diethanolamine
EC number: 293-014-3

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 ***7 January 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)

2. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: EU C.4. C/D/E/F/OECD TG 301B/C/D/F or EU C.29./OECD TG 310)

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

3. 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

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

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 (2013) but no information on long-term toxicity on aquatic invertebrates for the Substance.

1.2. Assessment of the information provided

3 We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests do 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 In the provided OECD TG 105 (2013), the saturation concentration of the Substance in water was determined to be < 4 mg/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.

7 In your comments to the draft decision, you agree with the request.

2. Ready biodegradability

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

2.1. Information provided

(i) A study according to OECD TG 301B (2006) on the Substance
(ii) A study according to OECD TG 302B (2003) on the Substance

2.2. Assessment of information provided

2.2.1. The provided study (i) does not meet the information requirement

9 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 301B, the following requirements must be met:

10 Reporting of the methodology and results

a) the test temperature is reported.
b) the inorganic carbon content (IC) and total carbon content (TC) of the test material

suspension in the mineral medium at the beginning of the test is reported.
c) the calculation of the $ThCO_2$ is described and justified.
d) the results of measurements at each sampling point in each replicate is reported in a tabular form.

11 Your registration dossier provides an OECD TG 301B showing the following:

12 Reporting of the methodology and results

a) the test temperature is not reported.
b) the inorganic carbon content (IC) and total carbon content (TC) of the test material suspension in the mineral medium at the beginning of the test is not reported.
c) the calculation of the $ThCO_2$ is not described.
d) the results of measurements at each sampling point in each replicate are not reported.

13 Based on the above, the reporting of all studies is not sufficient to conduct an independent assessment of its reliability. More, specifically:

- you have not provided information on the test temperature, inorganic carbon content (IC) and total carbon content (TC) and therefore, it is not possible to verify whether the test was conducted under conditions that are consistent with the specifications of the OECD TG 301B;
- you have not described and justified how the ThCO2 was calculated. In this absence of this information, it is not possible to assess whether the interpretation of the results is correct.
- the results of measurements at each sampling point in each replicate is not provided. Therefore, it is not possible to verify that the validity criteria of the test guideline were met and to verify the results of these studies and their interpretation.

14 Therefore, the requirements of OECD 301B are not met.

15 In your comments to the draft decision, you submitted further details on all the listed deficiencies in the reporting. ECHA has assessed the information against the requirements in OECD TG 301. The 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.

2.2.1. The provided study (ii) does not qualify for a ready biodegradability test

16 The supporting study (study ii) was conducted according to OECD TG 302B. Therefore, this study is not a ready biodegradability test but an inherent biodegradability test. Study ii cannot fulfil the information requirement.

17 On this basis, the information requirement is not fulfilled.

Reasons related to the information under Annex VIII of REACH

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

18 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.

3.1. Information provided

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

3.2. Assessment of the information provided

20 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).

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

22 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 6.

23 In your comments to the draft decision, you agree with the request.

Reasons related to the information under Annex IX of REACH

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

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

4.1. Information provided

25 You have adapted this information requirement by using weight of evidence based on the following sources of information:

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

(ii) A statement that, based on physico-chemical properties of the Substance, low absorption is assumed. In addition, you state that during manufacturing the worker exposure is avoided due to production procedures or appropriate RMM measures like a closed batch process. The submitted statement does not provide any new information that could contribute to the applied adaptation, since key investigations of the required endpoint are not met (in particular, an exposure period of 90 days).

26 Based on the presented sources of information, you argue that the available data gives sufficient information to conclude on the sub-chronic toxicity (90-day) of the Substance.

4.2. Assessment of the information provided

27 Annex XI, Section 1.2 states that there may be sufficient weight of evidence from several independent sources of information leading to assumption/conclusion that a substance has or has not a particular dangerous (hazardous) property, while information from a single source alone is insufficient to support this notion.

28 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude that the Substance has or has not the (dangerous) property investigated by the required study.

29 Annex XI, section 1.2 requires that adequate and reliable documentation is provided to describe your weight of evidence approach.

30 However, for each relevant information requirement, you have not submitted any explanation why the sources of information provide sufficient weight of evidence leading to the conclusion/assumption that the Substance has or has not a particular dangerous property.

31 Irrespective of the above-mentioned deficiencies on the documentation, which in itself could lead to the rejection of the adaptation, ECHA has assessed the provided sources of information.

32 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.6.2 at Annex IX includes, at general level, information on systemic toxicity in intact, non-pregnant and young adult males and

females from: 1) in-life observations, 2) blood chemistry, 3) organ and tissue toxicity. Information should address effects on the following physiological systems: circulatory system, digestive/excretory system, endocrine system, immune system, integumentary system, musculoskeletal system, nervous system, renal/urinary system, reproductive system, and respiratory system.

33 You have provided a single repeated dose toxicity study conducted with the Substance (study (i) above). This source of information provides relevant information for sub-chronic toxicity. However, we have identified the following deficiencies affecting your adaptation:

4.2.1. Only one source of information

34 Annex XI, Section 1.2 states that there may be sufficient weight of evidence "from several independent sources of information".

35 You have provided only one source of information in the form of a robust study summary and the statement referring to information on physico-chemical properties and worker exposure.

36 However, the sources of information that can be considered as part of a weight of evidence adaptation must be scientific information enabling to conclude that the Substance has or has not the property investigated by the study normally required. Therefore, a source of information must be submitted in the form of a robust study summary. The statement you provided cannot therefore be considered per se as "source of information".

37 A statement may however provide an explanation as to why the different sources would together enable concluding that the Substance has or has not the property investigated by the study normally required. However, the statement you provided does contain any explanation relating to the unique source of information you provided. In any case, neither the physico-chemical data or worker exposure data included in your statement provide information on the intrinsic properties investigated.

38 Therefore, your weight of evidence adaptation relies only on one source of information.

4.2.2. The study provided does not comply with applicable test guideline

39 To fulfil the information requirement, normally a sub-chronic toxicity study (90 day) according to OECD TG 408 needs to be provided. The OECD TG 408 requires that the following specification is met:

- Dosing of the Substance daily for a minimum of 90 days.

40 However, in study (i), the exposure duration was of up to 54 days for females and minimum of 28 days for males.

41 This condition of exposure is essential, as the effects observed in a sub-chronic study might be considerably more pronounced compared to a shorter study duration. You have not demonstrated that the effects of the Substance generated over the exposure of 90 days will not be different to that over the exposure duration of the provided study. Therefore, these studies (i) do not inform on the properties of the Substance after a 90 days exposure period.

42 As a conclusion, for the single source of information you provided essential parts of information on the dangerous property is lacking (in particular, adequate exposure duration).

43 Accordingly, it is not possible to conclude whether your Substance has or has not the particular dangerous properties foreseen to be investigated in an OECD TG 408 study. Therefore, your adaptation is rejected, and the information requirements is not fulfilled.

4.3. Specification of the study design

44 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.

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

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

47 In your comments to the draft decision, you agree with the request.

5. Long-term toxicity testing on aquatic invertebrates

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

5.1. Information provided

48 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: "*Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006 (CSA does not indicate need for further investigations)*".

5.2. Assessment of the information provided

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

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

50 Your adaptation is therefore rejected.

51 On this basis, the information requirement is not fulfilled.

5.3. Study design and test specifications

52 The Substance is difficult to test due to the low water solubility (<4 mg/L). 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.

53 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).

54 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.

55 In your comments to the draft decision, you agree with the request.

6. Long-term toxicity testing on fish

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

6.1. Information provided

57 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: "*Waiving according to "column 2" in Annex IX of REGULATION (EC) No 1907/2006 (CSA does not indicate need for further investigations)*".

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

58 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).

59 Your adaptation is therefore rejected.

6.3. Study design and test specifications

60 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.).

61 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.

62 In your comments to the draft decision, you agree with the request.

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).

However, in your comments on the draft decision, you requested an extension of the deadline to provide information from 12 to 18 months from the date of adoption of the decision. You justify the extension by stating that *"the substance is difficult to test due to the low water solubility and more time is needed as development of analytical methods and detailed discussion on test design is very time consuming".*

ECHA acknowledges that the properties of the Substance may require additional preliminary steps before conducting the requested studies. On this basis, ECHA has granted the request to extended the deadline to 18 months.

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

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

The deadline of the decision has been exceptionally extended by additional 6 months from the 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]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]
[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

[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