~~Confidential~~

Helsinki, 23 May 2023

Addressee
Registrant of JS_105-62-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
30/11/2021

Registered substance subject to this decision ("the Substance")
Substance name: Fatty acids, C16-18 and C18-unsatd., esters with propylene glycol
EC number: 285-203-4

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 ***1 June 2026***.

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

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

1. Skin sensitisation (Annex VII, Section 8.3.; test method: (i.) in vitro/in chemico skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Annex VII, Section 8.3.1.); and (ii.) only if the in vitro/in chemico test methods specified under point i.) above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, in vivo skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429)

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: OECD TG 471, 2020) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102

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

4. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2)

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

5. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

6. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490)

7. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) by oral route, in rats

8. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

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

10. 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)

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

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

The reasons for the decision(s) 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 addressee of the decision and its corresponding information requirements based on registered tonnage band is listed in Appendix 3.

In the list of 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 below Appendix on Reasons explains why the standard information requirement is not met, as well as the specification of the design for the requested study. 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.

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 request(s)
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 request(s)

Contents

0. Reasons common to several requests

0.1. Read-across adaptation provided in the registration dossier rejected

1 In your registration dossier you have adapted the following standard information requirements by using grouping and read-across approaches under Annex XI, Section 1.5:

- Skin sensitisation (Annex VII, Section 8.3.);
- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

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 sections.

3 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.

4 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

0.1.1. Predictions for (eco)toxicological properties

5 You provide a read-across justification document in IUCLID Section 13.

6 You predict the properties of the Substance from information obtained from the following source substance(s):

Source Substance #1	Ethylene distearate, EC No. 211-014-3.
Source Substance #2	Fatty acids, C16-18, esters with ethylene glycol, EC No. 211-014-3.
Source Substance #3	Fatty acids, C18 and C18 unsatd. epoxidized, ester with ethylene glycol, EC No. N/A, CAS 151661-88-0.
Source Substance #4	Myristic acid, monoester with propane-1,2-diol, EC No. 249-395-3.
Source Substance #9	Decanoic acid, mixed diesters with octanoic acid and propylene glycol, EC No. 271-516-3.
Source Substance #10	Fatty acids, C14-18 and C16-18-unsatd., esters with propylene glycol, EC No. 284-864-6.
Source Substance #11	Butylene glycol dicaprylate / dicaprate, EC No. N/A, CAS 853947-59-8.

7 In your registration dossier, you provide the following reasoning for the prediction of (eco)toxicological properties: you claim that the Substance and the source substances are esters and the ester group is the common functional group. You state that ”the similarity is justified on basis of scope of variability and overlapping of composition, representative molecular structure, physico-chemical properties, tox-, ecotoxicological profiles and supported by various (Q)SAR methods.”

8 ECHA understands that your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be quantitatively equal to those of the source substance.

9 We have identified the following issue(s) with the prediction(s) of (eco)toxicological properties:

0.1.1.1. Missing supporting information to compare the toxicological properties of the substances

10 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

11 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s). These studies should include information on the impact of all compositional differences between the substances, to allow an assessment of the similarity between the Substance and the source substances.

12 You have provided the following experimental data:

For skin sensitisation toxicity, you have provided the following studies:

(i) Skin Sensitisation study (1982) with the Source Substance #1

(ii) Skin Sensitisation study (1989) with the Source Substance #4.

13 For genotoxicity, you have provided the following studies:

(iii) in vitro gene mutation study in bacteria (1991) with the Source Substance #10.

(iv) in vitro cytogenicity / chromosome aberration study in mammalian cells (1997) with the Source Substance #11.

(v) in vitro gene mutation study in mammalian cells (2010) with the Source Substance #2.

14 For repeated dose toxicity, you have provided the following studies:

(vi) Repeated Dose 90-Day Oral Toxicity Study (1991) with the Source Substance #3.

(vii) Repeated Dose 90-Day Oral Toxicity Study (1993) with the Source Substance #9.

15 For reproductive toxicity, you have provided the following studies:

(viii) Prenatal Developmental Toxicity Study (1997) with the Source Substance #2.

(ix) Prenatal Developmental Toxicity Study (1994) with the Source Substance #9.

16 Firstly, you have provided the above mentioned studies ((i) – (ix)) to inform on the toxicological properties of the Substance with the respective source substances. While these studies provide relevant information on the properties of the respective source substances, ECHA notes that you did not provide any experimental data, in particular bridging studies of comparable design and duration for the Substance.

17 In the absence of such information it is not possible to compare the properties of the Substance and of the source substance and to confirm your hypothesis.

18 Secondly, with the exception of source substance #10, ECHA notes that your justification does not address the structural variation of the source substances regarding the glycol group (ethylene glycol, propylene glycol, butylene glycol) and the chain length of the fatty acid moiety. More specifically:

- Source Substance #1 consists of [redacted], and as such does not cover 1,2-propylene glycol and C16 and C18 unsaturated fatty acids of the Substance.
- Source Substance #2 consists of [redacted], and as such does not cover 1,2-propylene glycol and C18 unsaturated fatty acids of the Substance.
- Source Substance #3 consists of [redacted], and as such does not cover 1,2-propylene glycol and C16 and C18 unsaturated, non-epoxidized fatty acids of the Substance.
- Source Substance #4 consists of [redacted], and as such does not cover C16 and C18 fatty acids of the Substance.
- Source Substance #9 consists of [redacted], and as such does not cover C16 and C18 fatty acids of the Substance.
- Source Substance #11 consists of [redacted], and as such does not cover 1,2-propylene glycol and C16 and C18 fatty acids of the Substance.

19 In the absence of reliable supporting information relevant for the predicted properties, you have not demonstrated that the structural variation does not affect the predicted toxicological properties.

20 Based on the above, you have not established that the Substance and the source substances are likely to have similar properties.

21 Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.2. Missing supporting information to compare the ecotoxicological properties of the substances

22 Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide supporting information to scientifically justify the read-across explanation for prediction of properties. The set of supporting information should strengthen the rationale for the read-across in allowing to verify the crucial aspects of the read-across hypothesis and establishing that the properties of the Substance can be predicted from the data on the source substance(s) (Guidance on IRs and CSA R.6, Section R.6.2.2.1.f.).

23 As indicated above, your read-across hypothesis is based on the assumption that the structurally similar source substance(s) cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the source substance(s) is necessary to confirm that the substances cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

24 In order to support your hypothesis, you have provided the following experimental data:

25 For toxicity to algae, you have provided the following studies:

(i) Algal inhibition test (1997) with the Source Substance #11.

(ii) Algal inhibition test (1995) with the Source Substance #9.

26 For long-term toxicity on aquatic invertebrates, you have provided the following study:

(iii) *Daphnia magna* reproduction test (2001) with the Source Substance #11.

27 You have also provided short-term toxicity studies on aquatic invertebrates and fish with source substances.

28 The provided information has the following deficiencies:

- Regarding the short-term studies on aquatic invertebrates and fish, as explained under requests 4 and 8 respectively, due to the Substance properties short-term studies are not considered adequate to conclude on the hazard properties.
- Regarding the source studies on toxicity to algae and long-term toxicity to aquatic invertebrates, specific reasons why these studies cannot be considered reliable are explained further below under requests 3 and 11, respectively.

29 Thus the data set reported in the technical dossier does not include relevant, reliable and adequate information for the source substance(s) to support your read-across hypothesis.

30 Furthermore, ECHA notes that your justification does not address the structural variation of the source substances regarding the glycol group (ethylene glycol, propylene glycol, butylene glycol) and the chain length of the fatty acid moiety. While the Substance contains [redacted], the Source Substance #11 contains [redacted]. In addition, while the chain lengths of the constituents of the Substance are C16-18 and C18-unsaturated, the chain length of the Source Substances #9 and #11 are C8-C10.

31 In the absence of reliable supporting information relevant for the predicted properties, you have not demonstrated that the structural variation does not affect the predicted ecotoxicological properties (i.e. toxicity to algae and long-term toxicity on aquatic invertebrates).

32 Based on the above, you have not established that the Substance and the source substances are likely to have similar properties.

33 Therefore you have not provided sufficient supporting information to scientifically justify the read-across.

0.1.1.3. Inadequate or unreliable source studies

34 According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must:

(1) be adequate for the purpose of classification and labelling and/or risk assessment;

(2) have adequate and reliable coverage of the key parameters addressed in the corresponding study that shall normally be performed for a particular information

requirement;

(3) cover an exposure duration comparable to or longer than the corresponding study that shall normally be performed for a particular information requirement if exposure duration is a relevant parameter.

35 Specific reasons why the studies on the source substances do not meet these criteria are explained further below under the applicable information requirement sections 2, 3 and 11.

36 Therefore, no reliable predictions can be made for these information requirements.

0.1.2. Conclusion on the read-across approach in the registration dossier

37 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substance(s). Your read-across approach under Annex XI, Section 1.5. provided in your registration dossier is rejected.

0.2. New read-across approach provided in the comments to the draft decision

38 In the comments on the draft decision you have indicated your intentions to rely on a new category approach in accordance with Annex XI, Section 1.5. to fulfil the following information requirements:

- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2 and Annex IX, Section 9.1.5.)
- Long-term toxicity testing on fish (Annex VIII, Section 9.1.3, column 2 and Annex IX, Section 9.1.6.1.)

39 You intend to provide a new read-across adaptation based on a 'Glycol Esters Category'. You consider that such a category approach "*allows a more comprehensive characterisation of the glycol esters and thus does more appropriately account for the impact of differences in composition and the structural variation of the whole group*". You have provided in your comments a version of the read-across justification document for the glycol esters category approach 'Category concept Document Glycol Esters Category'.

40 You report that work on this category is currently ongoing, and that "*further testing is considered necessary to meet the data requirements. Thus additional studies are planned*". You explain that you intend to follow a tiered testing strategy with the Substance: "*By generating substance-specific data, the registrant intends to increase the robustness of the proposed category approach of glycol esters. The newly generated data on the Substance together with data on the category members that will become available shall serve as bridging studies to support the read-across approach by demonstrating consistency in the toxicological as well as ecotoxicological profile across the category members*". You outline that "*The decision whether this approach can be maintained or has to be adapted can only be made on the basis of adequate and reliable studies that are going to be conducted in the near future*."

41 Because this strategy relies essentially on data which is yet to be generated for the Substance and the proposed category members, no conclusion on the compliance can currently be made.

42 As far as you further request "additional time to gather sufficient data to prove the adequacy of the read-across approach", we point you out at the objectives of compliance checks and also at the extension of the deadline compared to the initial draft decision, as further explained in Appendix 2 to this decision.

Reasons related to the information under Annex VII of REACH

1. Skin sensitisation

43 Skin sensitisation is an information requirement under Annex VII, Section 8.3. Under Section 8.3., Column 1, the registrants must submit information allowing (1) a conclusion whether the substance is a skin sensitiser and (2) whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A).

1.1. Information provided

44 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

i. Skin Sensitisation study, Buehler test (1982) with the Source Substance #1.

ii. Skin Sensitisation study, guinea pig maximisation test, (1989) with the Source Substance #4.

1.2. Assessment of the information provided

Read-across adaptation rejected

45 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

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

1.1. Specification of the study design

47 To fulfil the information requirement for the Substance, information on molecular interaction with skin proteins and inflammatory response in keratinocytes and activation of dendritic cells (OECD TG 442C and OECD TG 442D and OECD TG 442E) must be provided. Furthermore, an appropriate risk assessment is required if a classification of the Substance as a skin sensitiser (Cat 1A or 1B) is warranted.

48 In case no conclusion on the skin sensitisation potency can be made for the Substance based on the existing data or newly generated data, in vivo skin sensitisation study must be performed and the murine local lymph node assay (EU Method B.42/OECD TG 429) is considered as the appropriate study for the potency estimation.

49 Since some data are already available, you should consider whether the Defined Approaches to Skin Sensitisation can be applied based on the information already available or to be generated (https://echa.europa.eu/support/oecd-eu-test-guidelines).

50 In the comments to the draft decision, you agree to perform the requested study.

2. In vitro gene mutation study in bacteria

51 An in vitro gene mutation study in bacteria is an information requirement under Annex VII, Section 8.4.1.

2.1. Information provided

52 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

i. in vitro gene mutation study in bacteria (1991) with the Source Substance #10.

2.2. Assessment of the information provided

2.2.1. Read-across adaptation rejected

53 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

54 In addition, ECHA identified endpoint specific issue(s) addressed below.

2.2.1.1. Source study not adequate for the information requirement

55 As already mentioned under 0.1.1.3 above, under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 471. Therefore, the following specifications must be met:

a) the test is performed with 5 strains: four strains of *S. typhimurium* (TA98; TA100; TA1535; TA1537 or TA97a or TA97) and one strain which is either *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).

56 The study (a.) is described as in vitro gene mutation study in bacteria.

57 However, the following specifications are not according to the requirements of OECD TG 471:

a) the test was performed with the strains *S. typhimurium* (TA98; TA100; TA1535; TA1537, TA1538) (i.e., the strains *S. typhimurium* TA102 or *E. coli* WP2 uvrA or *E. coli* WP2 uvrA (pKM101).are missing).

58 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 471 and this study is not an adequate basis for your read-across predictions.

59 Therefore, the information requirement is not fulfilled.

2.3. Specification of the study design

60 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471, 2020) should be performed using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

61 In the comments to the draft decision, you agree to perform the requested study. In addition, you indicate your plan to conduct the full study including all bacterial strains as recommended by OECD TG 471. This is in your discretion.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

63 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

i. Algal inhibition test (1997) with the Source Substance #11.

ii. Algal inhibition test (1995) with the Source Substance #9.

3.2. Assessment of the information provided

3.2.1. Read-across adaptation rejected

64 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

65 In addition, ECHA identified endpoint specific issue(s) addressed below.

3.2.1.1. Source study not adequate for the information requirement

66 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 201 and OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

67 Reporting of the methodology and results

a) the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

68 Validity criteria

b) the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
c) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7%;

69 Characterisation of exposure

d) 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;
e) 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);

70 Additional requirements applicable to difficult to test substances

f) 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;
g) a justification for, or validation of, the separation technique is provided, especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix.

71 In studies (i.) and (ii.) described as algal inhibition tests:

72 Reporting of the methodology and results

a) tabulated data on the algal biomass determined daily for each treatment group

and control are not reported for any of the studies;

73 Validity criteria

b) the mean coefficient of variation for section-by-section specific growth in the control is not reported for any of the studies, therefore you have not demonstrated that it is ≤ 35%;
c) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is not reported for any of the studies, therefore you have not demonstrated that it is ≤ 7%;

74 Characterisation of exposure

d) total organic carbon (TOC) analyses were carried out in both studies to determine exposure concentrations, and performance parameters of the analytical methods are not reported (e.g. LOD, LOQ, recovery);
e) you have not reported if the test media prepared specifically for analysis of exposure concentrations was inoculated with algae for any of the studies;

75 Additional requirements applicable to difficult to test substances

f) the water solubility of the test materials is reported to be below 0.01 mg/L (Source Substance #11) and below 0.05 mg/L (Source Substance #9) in the read-across justification document. For both studies, the stock solution (1000 mg/L nominal) was prepared, stirred for 18 h and filtered;
g) you have not provided any justification for the methods used to prepare the test solutions for any of the studies.

76 Based on the above,

- the reporting of the studies is not sufficient to conduct an independent assessment of its reliability. More specifically, for both studies in the absence of data related to biomass and on coefficients of variations, you have not demonstrated that the validity criteria are met.
- the source substances are difficult to test due to the low water solubility and there are critical methodological deficiencies resulting in the rejection of the study results. First, for both studies you used the total organic carbon (TOC) method for analytical monitoring of exposure concentrations. You did not provide performance parameters for this method, including limit of detection. While the performance of the method cannot be currently assessed based on the information submitted, the TOC is considered as a non-specific method with low sensitivity. Therefore the TOC method used may not be reliable for analysing the concentration of the test material in the test solution. Hence it is not possible to conclude to what extent the test organisms were exposed to the test material nor if the exposure was satisfactorly maintained during the test. Second, you have not justified nor demonstrated for any of the studies that the method applied in test solution preparation allowed achieving maximum dissolved concentrations, including the use of filtration as a separation method.

77 Based on the above, the studies do not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 201 and these studies are not an adequate basis for your read-across predictions.

78 Therefore, the information requirement is not fulfilled.

3.3. Study design and test specifications

79 The Substance is difficult to test due to the low water solubility (< 1 mg/L) and/or adsorptive properties (Log Kow 5.353-8.474). 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.

80 Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results.

81 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.

82 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.

83 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).

84 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.

85 In the comments to the draft decision, you agree to perform the requested study.

4. Long-term toxicity testing on aquatic invertebrates

86 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, 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.

4.1. Triggering of the information requirement

87 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).

88 In the provided EU method A.6 study (2015), the saturation concentration of the Substance in water was below the limit of detection of the analytical method (i.e. < 10 mg/L). You

also provide water solubility studies conducted with analogue substances and conclude that the water solubility of the Substance is <1 mg/L based on trend analysis.

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

90 In the comments to the draft decision, you agree that the performance of a long-term toxicity study on aquatic invertebrates is more appropriate than a short-term aquatic toxicity test because the Substance is poorly soluble.

91 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Request 11.

Reasons related to the information under Annex VIII of REACH

5. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

92 An in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study is an information requirement under Annex VIII, Section 8.4.2..

5.1. Information provided

93 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

i. in vitro cytogenicity / chromosome aberration study in mammalian cells (1997) with the Source Substance #11.

5.2. Assessment of the information provided

Read-across adaptation rejected

94 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

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

Specification of the study design

96 To fulfil the information requirement for the Substance, either in vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

97 In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to provide a new, 'Glycol Esters Category' based read-across approach according to Annex XI, Section 1.5.

98 As explained under Section 0.2, no conclusion on the compliance of the proposed adaptation can currently be made.

6. In vitro gene mutation study in mammalian cells

99 An in vitro gene mutation study in mammalian cells is an information requirement under Annex VIII, Section 8.4.3., in case of a negative result in the in vitro gene mutation test in bacteria and the in vitro cytogenicity test.

6.1. Triggering of the information requirement

100 Your dossier contains an adaptation for an in vitro gene mutation study in bacteria, and an adaptation for an in vitro cytogenicity study in mammalian cells or in vitro micronucleus study.

101 The information for the in vitro gene mutation study in bacteria and for the in vitro cytogenicity study in mammalian cells provided in the dossier are rejected for the reasons provided in the in the reasons for requests 2 and 5.

102 The result of the requests for an in vitro gene mutation study in bacteria and for an in vitro cytogenicity study in mammalian cells will determine whether the present requirement for an in vitro mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

~~103~~ Consequently, you are required to provide information for this information requirement, if the in vitro gene mutation study in bacteria / the in vitro cytogenicity study in mammalian cells or an in vitro micronucleus study provide a negative result.

6.2. Information provided

104 You have adapted this information by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

i. in vitro gene mutation study in mammalian cells (2010) with the Source Substance #2.

6.3. Assessment of the information provided

6.3.1. Read-across adaptation rejected

105 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

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

6.4. Specification of the study design

107 To fulfil the information requirement for the Substance, either the in vitro mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) or the thymidine kinase gene (OECD TG 490) are considered suitable.

108 In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to provide a new, 'Glycol Esters Category' based read-across approach according to Annex XI, Section 1.5.

109 As explained under Section 0.2, no conclusion on the compliance of the proposed adaptation can currently be made.

7. Screening for reproductive/developmental toxicity

110 A screening for reproductive/developmental toxicity study (OECD 421 or OECD 422) is an information requirement under Annex VIII, Section 8.7.1., if there is no evidence from analogue substances, QSAR or in vitro methods that the substance may be a developmental toxicant.

7.1. Information provided

111 Your dossier does not contain a screening for reproductive/developmental toxicity study with the Substance.

112 Under the Developmental toxicity/teratogenicity section of your technical dossier (IUCLID 7.8.2), you have provided the following studies

(i) Prenatal Developmental Toxicity Study (1997) with the Source Substance #2.

(ii) Prenatal Developmental Toxicity Study (1994) with the Source Substance #9.

113 Although you do not explicitly claim an adaptation, ECHA understands that the information provided was submitted in order to meet the required information by way of adaptation under Annex VIII, Section 8.7.1., column 2, of REACH in conjunction with Annex XI, section 1.5.

7.2. Assessment of information provided

114 We have identified the following issues:

115 Under Section 8.7., Column 2 of Annex VIII to REACH, the current information requirement can be adapted if a pre-natal developmental toxicity study (OECD TG 414) is already available.

116 Studies (i) and (ii) are a prenatal developmental toxicity studies, performed with analogue substances.

117 However, as explained in the Appendix of Reasons common to several requests, your read-acorss approach based on Annex XI, Section 1.5. is rejected.

118 Therefore, your adaptation under Annex VIII, Section 8.7. column 2 in conjunction with Annex XI, Section 1.5. is also rejected.

119 Based on the above, the information requirement is not fulfilled.

7.3. Specification of the study design

120 A study according to the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422 must be performed in rats.

121 The study must be conducted with oral administration of the Substance (Guidance on IRs and CSA, Section R.7.6.2.3.2.).

122 Therefore, the study must be conducted in rats with oral administration of the Substance.

123 In the comments to the draft decision, you propose to conduct a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test according to OECD TG 422. As specified above, you may indeed choose between the test method EU B.63/OECD TG 421 or EU B.64/OECD TG 422. You agree to conduct the study in rats with the substance administration via the oral route.

8. Long-term toxicity testing on fish

124 Short-term toxicity testing on fish is an information requirement under Annex VIII, Column 1, 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.

8.1. Triggering of the information requirement

125 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).

126 In the comments to the draft decision, you principally agree that the performance of a long-term toxicity study is more appropriate than a short-term toxicity test when the Substance is poorly soluble.

127 As already explained in Request 4, the Substance is poorly water soluble and therefore information on long-term toxicity on fish must be provided.

128 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under section 12.

Reasons related to the information under Annex IX of REACH

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

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

9.1. Information provided

130 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) Repeated Dose 90-Day Oral Toxicity Study (1991) with the Source Substance #3.

(ii) Repeated Dose 90-Day Oral Toxicity Study (1993) with the Source Substance #9.

9.2. Assessment of the information provided

9.2.1. Read-across adaptation rejected

131 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

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

9.3. Specification of the study design

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

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

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

136 In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to provide a new, 'Glycol Esters Category' based read-across approach according to Annex XI, Section 1.5.

137 As explained under Section 0.2, no conclusion on the compliance of the proposed adaptation can currently be made.

10. Pre-natal developmental toxicity study in one species

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

10.1. Information provided

139 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substances:

(i) Prenatal Developmental Toxicity Study (1997) with the Source Substance #2.

(ii) Prenatal Developmental Toxicity Study (1994) with the Source Substance #9.

10.2. Assessment of the information provided

10.2.1. Read-across adaptation rejected

140 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected.

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

10.3. Specification of the study design

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

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

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

145 In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to provide a new, 'Glycol Esters Category' based read-across approach according to Annex XI, Section 1.5.

146 As explained under Section 0.2.1, no conclusion on the compliance of the proposed adaptation can currently be made.

11. Long-term toxicity testing on aquatic invertebrates

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

11.1. Information provided

148 You have adapted this information requirement by using Annex XI, Section 1.5. (Grouping of substances and read-across approach) based on experimental data from the following substance:

i. Daphnia magna reproduction test (2001) with the Source Substance #11.

11.2. Assessment of the information provided

11.2.1. Read-across adaptation rejected

149 As explained in Section 0.1., your adaptation based on grouping of substances and read-across approach under Annex XI, Section 1.5. is rejected. In addition, ECHA identified endpoint specific issue(s) addressed below.

11.2.1.1. Source study not adequate for the information requirement

150 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 211 and OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

151 Reporting of the methodology and results

a) the full record of the daily production of living offspring during the test by each parent animal is provided;

152 Validity criteria

b) the mean number of living offspring produced per surviving parent animal in the control is ≥ 60 at the end of the test;

153 Additional requirements applicable to difficult to test substances

c) 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;
d) A justification for, or validation of, the separation technique is provided, especially if filtration is used, as it can cause losses due to adsorption onto the filter matrix.

154 In study (i.) described as Daphnia magna reproduction test:

155 Reporting of the methodology and results

a) the full record of the daily production of living offspring during the test by each parent animal is not provided;

156 Validity criteria

b) the mean number of living offspring produced per surviving parent animal in the control is not reported, therefore you have not demonstrated that it is ≥ 60 at the end of the test;

157 Additional requirements applicable to difficult to test substances

c) the water solubility of the test material (Source Substance #11) is reported to be below 0.01 mg/L in the read-across justification document. The stock solution (100 mg/L nominal) was prepared by addition of the test substance to test water, followed by ultrasonication for 15 minutes, stirring for 48-73 h and filtration using a cellulose nitrate filter (pore size 0.45 µm). The test solutions of the lower test concentrations were prepared by diluting the stock solution with test water;
d) you have not provided any justification for the methods used to prepare the test solutions.

158 Based on the above,

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, in the absence of data on the daily production of living offspring, you have not demonstrated that the validity criteria are met.
- the source substance is difficult to test due to the low water solubility and there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, you have not justified nor demonstrated that the method applied in test solution preparation allowed achieving maximum dissolved concentrations, including the use of filtration as a separation method.

159 Based on the above, the study does not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 211 and this study is not an adequate basis for your read-across predictions.

160 Therefore, the information requirement is not fulfilled.

11.3. Study design and test specifications

161 OECD TG 211 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 and test specifications' under Request 3.

162 In your comments to the draft decision, you do not agree to perfom the requested study. Instead, you indicate your intention to provide a new 'Glycol Esters Category'-based read-across approach according to Annex XI, Section 1.5.

163 Nevertheless, you indicate your possible agreement to perform the requested study if the data generated on algae growth inhibition (request 3 in this decision) would be "*considered as not sufficient for supporting the read-across on ecotoxicity*".

164 As explained under Section 0.2, no conclusion on the compliance of the proposed adaptation can currently be made.

12. Long-term toxicity testing on fish

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

12.1. Information provided

166 ECHA understands that you have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided the following information in your registration dossier:

(i) "*No experimental data on long-term toxicity to fish are available for the test substance.The chemical safety assessment according to Annex I of Regulation (EC) 1907/2006 does not indicate the need to investigate further the long-term toxicity to fish. No effects were observed in a chronic study with Daphnia magna according to OECD 211 (NOELR ≥ 0.02 mg/L) with the read-across substance butylene glycol dicaprylate / dicaprate (CAS 853947-59-8). Moreover, no effects were observed with structurally related substances in short-term studies with fish and aquatic invertebrates. As there was no sign that invertebrates are less sensitive than fish in the short term tests, it can not be expected that a long-term test with fish will generate different results than the existing long-term test with invertebrates. Furthermore, it is not likely that aquatic organisms are exposed to the test substance since it will be ultimately degraded in sewage treatment plants, due to its ready biodegradability. Thus, based on the above mentioned results, it can be concluded that the test substance does not show any chronic toxicity to fish up to the limit of water solubility. Hence due to animal welfare reasons and to avoid unnecessary vertebrate tests, no further long-term test with fish is required for the test substance.*"

167 In your comments to the draft decision, you do not agree to perfom the requested study and you restate the considerations provided in your dossier by claiming that "*it is scientifically not necessary and not justifiable to perform a long-term toxicity study with fish for further hazard evaluation at this stage of registration*" and that "*If the T-criterion is fulfilled by the algae and/or the chronic Daphnia data, a chronic fish test is not necessary*

and should therefore not be carried out to avoid unnecessary testing on vertebrate animals".

12.2. Assessment of the information provided

168 A registrant may only adapt this information requirement based on the general rules set out in Annex XI. 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).

169 Your adaptation using Column 2 of Annex IX, Section 9.1., as provided in your registration dossier and supported by your above comments, is therefore rejected.

170 ECHA further notes that your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

12.3. Assessment of the read-across adaptation provided in the comments to the draft decision

171 In the comments to the draft decision you have also indicated your intention to fulfil this information requirement according to Annex XI, Section 1.5. In support to your adaptation you provide a justification document for the 'Glycol Esters Category'.

172 As explained under Section 0.2, no conclusion on the compliance of the proposed adaptation can currently be made.

173 Therefore, the information requirement is not fulfilled.

12.4. Study design and test specifications

174 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.).

175 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 and test specifications' under Request 3.

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).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are 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 17 December 2021.

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.

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).

With a view to your comments to the draft decision regarding "*additional time to gather sufficient data to prove the adequacy of the read-across approach*" concerning the required information on mutagenicity, reproductive and repeated dose toxicity, we further point out that the deadline set in this decision allows for generating the data on the Substance as required by law and as a result of incompliances identified in the dossier submission. The objective of this compliance check is for you to fulfil the standard information requirements by the set deadline. Therefore, an even further extension of the deadline set in the decision to develop an adaptation is considered unjustified.

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 3: Addressee 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.

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.

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].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. Test material

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

a) the boundary composition(s) of the Substance,
b) 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.

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.

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 (https://echa.europa.eu/manuals).

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