~~Confidential~~

Helsinki, 1 September 2022

Addressees
Registrant(s) of JS_2402-58-6 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
29/07/2015

Registered substance subject to this decision ("the Substance")
Substance name: Didodecyl fumarate
EC number: 219-280-2

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

2. 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

3. 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

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

5. 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)

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

7. 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 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

0. Reasons common to several requests

0.1. Assessment of the read-across approach

1 You have adapted the following standard information requirements by using grouping and read-across approach under Annex XI, Section 1.5:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Long-term toxicity testing on fish (Annex VIII, Section 9.1.3, column 2)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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).

5 You have provided an analogue approach, which is addressed under section 0.1.1 and 0.1.2 below, and an analogue approach which is addressed under section 0.1.2 below.

0.1.1. Scope of the grouping of substances (category)

6 You provide a read-across justification document in IUCLID Section 13, and an updated version with the comments on the draft decision.

7 For the purpose of this decision, the following abbreviations are used for the category members:

1) 2-Butenedioic acid (E)-, di-C8- 18-alkyl esters EC 271-880-3
2) Didodecyl fumarate 2-Butenedioic acid (E)-, didodecyl ester, EC 219-280-2
3) 2-Butenedioic acid (2E)-, di-C12-14-alkyl esters, List 938-575-3
4) Ditetradecyl fumarate, 2-Butenedioic acid (E)-, ditetradecyl ester, EC 233-739-4
5) 2-Butenedioic acid (2E)-, di-C14-16-alkyl esters, List 695-949-6
6) 2-Butenedioic acid (E)-, di-C12-18-alkyl esters EC 272-943-8
7) 2-Butenedioic acid (E)-, diC16-18-alkyl esters EC 272-944-3
8) 2-Butenedioic acid (E)-, di-C18-22-alkyl ester, EC 272-945-9

8 You justify the grouping of the substances as: "PFAE fumarate esters have a common metabolic fate […] by which the breakdown of glycol esters results in structurally similar chemicals, the fumaric acid component and the respective alcohol".

9 You define the applicability domain of the "PFAE fumarates category" as: "diesters of the unsaturated dicarboxylic acids: fumaric acid (C4) and aliphatic alcohols with C8-C22 even and linear carbon chains."

10 Furthermore you use information from a source substance outside the category definition, Bis(2-ethylhexyl) adipate (EC 203-090-1) and you have not demonstrated how the category would be relevant to justify the read-across from that substance.

11 ECHA understands that this is the applicability domain of the grouping and your predictions are assessed on this basis.

0.1.2. Predictions for toxicological properties

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

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

1) bis(2-ethylhexyl) adipate, EC 203-090-1

14 You have provided a category approach according to which the Substance is selected for testing, which is not a read-across for the Substance itself and, in any case, misses any study on the Substance itself to fulfil the information requirement and it is thus not further addressed.

15 Furthermore, you claim that: "The toxicological properties show that all category members and the structurally related analogue substance Bis(2-ethylhexyl) adipate [source substance 1] share similar toxicokinetic behaviour (i.e. hydrolysis of the ester bond before absorption followed by absorption and metabolism of the breakdown products) and that the constant pattern consists in a lack of potency change of properties across the category, explained by the common metabolic fate of aliphatic diesters, independently of the chain length of the dicarboxylic acid moiety (C4 unsatd. or C6) and the lengths/branching of the alcohol moiety."

16 In addition, we understand that you apply an analogue approach for which your read-across hypothesis assumes that different compounds have the same type of effects. You predict the properties of your Substance to be based on a worst-case approach from source substance 2 for toxicological endpoints.

17 We have identified the following issues with the predictions of toxicological properties for the analogue approach in sections 0.3.2.

0.1.2.1. Adequacy and reliability of source study of toxicological endpoints

18 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 test method referred to in Article 13(3).

19 Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement sections 4. and 5. Therefore, no reliable predictions can be made for these information requirements.

20 In your comments on the draft decision you state your adaptation of the information requirement according to Annex XI, Section 1.5. You present a strategy relying on the generation of studies to fill all information requirements of category members 1, 2, 4, 5, 7 and 8 (Sections 8.4.1, 8.4.2, 8.4.3, 8.7.1, 8.6.2, 8.7.2, 9.1.2., 9 .1.3., and 9.1.6. from Annexes VII-IX) as requested in their respective draft decisions. These category members shall represent the lower, intermediate and upper range of members of the category and thereby enable interpolating predictions across the category. You argue that the constituent profile of these category members supports your approach, and that no further experimental information on category members (bridging studies) is required to support the predictions for human health. For ecotoxicological information requirements you indicate that further experimental information on long-term toxicity to invertebrates on all category members (bridging studies) will be provided to support the predictions. You indicate your intention to provide this in a future update of your registration dossier.

21 We acknowledge your intentions to improve the (eco)toxicological profile of the Substance and your plans to refine your read-across approach. It relies on data which is yet to be generated. Therefore no conclusion on the compliance can currently be made, because only the future study results will determine whether the (eco)toxicological profiles of the category members are coherent and support your hypothesis. You remain responsible for complying with this decision by the set deadline.

22 Related deficiencies are addressed under the corresponding Appendix below.

0.1.3. Conclusion on the read-across approach

23 For the reasons above, you have not established that relevant properties of the Substance can be predicted from data on the source substances. Your read-across approach under Annex XI, Section 1.5. is rejected.

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

25 You have provided the following information:

- Study(ies) on the Substance:

  (i) a study according to OECD TG 201 (a limit test conducted with the Substance)

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

1.2. Assessment of the information provided

27 We have assessed this information and identified the following issue[s]:

1.2.1. The provided study does not meet the information requirement

28 To fulfil the information requirement, a study must comply with OECD TG 201 (Article 13(3) of REACH). Therefore, the following specifications must be met:

29 Characterisation of exposure

a) analytical monitoring must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

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

31 Characterisation of exposure

a) no analytical monitoring of exposure was conducted; In addition to this, you have not provided a justification as to why the analytical monitoring of exposure concentrations is not technically feasible.

32 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More, specifically, because no analytical monitoring has been performed, the exposure concentrations cannot be confirmed.

33 Therefore, the requirements of OECD TG 201 are not met.

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

1.3. Study design and test specifications

35 The Substance is difficult to test due to the low water solubility (< 0.15 mg/L) and the high potential for adsorption (Log Koc > 5). OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and

maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

2. Long-term toxicity testing on aquatic invertebrates

36 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.

37 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).

38 In the provided OECD TG 105 (2012), the saturation concentration of the Substance in water was determined to be below the limit of detection of the analytical method (i.e. 0.15 mg/L).

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

2.1. Information provided

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

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

2.2. Assessment of the information provided

42 We have assessed this information and identified the following issues:

43 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix 1, Section 6.

Reasons related to the information under Annex VIII of REACH

3. Long-term toxicity testing on fish

44 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.

45 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).

46 As already explained under Appendix 1, Section 3, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

3.1. Information provided

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

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

3.2. Assessment of the information provided

49 We have assessed this information and identified the following issues:

50 The examination of the information provided, as well as the selection of the requested test and the test design are addressed under Appendix 1, Section 7.

Reasons related to the information under Annex IX of REACH

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

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

4.1. Information provided

52 You have adapted this information requirement by using a Grouping of substances and read-across approach.

53 You have provided the following studies performed with these source substances:

1) 1982 NTP carcinogenesis study in F344 rats (feed study) with reference to OECD 408, with an analogue substance substance, bis(2-ethylhexyl) adipate, EC No. 203-090-1, (CAS No. 103-23-1)
2) 1982 NTP carcinogenesis study in B6C3F1 mice (feed study), with reference to OECD 408, with an analogue substance, bis(2-ethylhexyl) adipate, EC No. 203-090-1, (CAS No. 103-23-1)
3) 2013 Study according to OECD TG 422 study, with the Substance
4) 2006 Study according to OECD TG 407, with an analogue substance, bis(2-ethylhexyl) adipate, EC No. 203-090-1, (CAS No. 103-23-1)
5) 1988 Study according to OECD TG 415, with an analogue substance, bis(2-ethylhexyl) adipate, EC No. 203-090-1, (CAS No. 103-23-1)

54 In the comments to the draft decision, you indicate your intention of adapting this information requirement through grouping and read-across. Please see our detailed reply in section 0.

4.2. Assessment of the information provided

55 We have assessed this information and identified the following issue(s):

56 As explained above 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, we have identified the following endpoint-specific issue.

57 As explained in Section 0.1.2.1, 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 408. Therefore, the following specifications must be met:

a. Dosing of the Substance daily for a minimum of 90 days.
b. Haematological and clinical biochemistry tests as specified in paragraphs 30-38 of the test guideline.
c. The oestrus cycle in females at necropsy
d. Terminal organ and body weights.

58 Your registration dossier provides the studies 1-5 listed above. The following specifications are not according to the requirements of OECD TG 408:

a. In studies 3, 4 and 5, the exposure duration was 48 (male) / 54 (female), 28 and 70 days instead of 90 days.
b. Data on haematology and clinical biochemistry findings: incidence and severity with relevant base-line values were not reported in studies 1, 2 and 3.
c. Data on oestrus cycle was missing in studies 1, 2, 3 and 5;
d. Data on terminal organ weights and organ/body weight ratios were not addressed

in studies 1 and 2.

59 Based on the above, the studies 1 to 5 do not provide an adequate and reliable coverage of the key parameter(s) addressed by the OECD TG 408 and these studies are not an adequate basis for your read-across predictions. Because of these deviations from the requirements of an OECD TG 408 the study 3, which was conducted with the Substance, does not fulfil the information requirement in itself.

60 Based on the above, the information you provided does not fulfil the information requirement.

4.3. Specification of the study design

61 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.

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

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

5. Pre-natal developmental toxicity study in one species

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

5.1. Information provided

65 You have adapted this information requirement by using a Grouping of substances and read-across approach.

66 You have provided the following study performed with this source substance:

1) 1988 OECD TG 414 with an analogue substance, bis(2-ethylhexyl) adipate, EC No.203-090-1, CAS No. 103-23-1

67 In the comments to the draft decision, you indicate your intention of adapting this information requirement through grouping and read-across. Please see our detailed reply in section 0.1.

5.2. Assessment of the information provided

68 As explained above 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, we have identified the following endpoint-specific issue.

69 As explained in Section 0.1.2.1, 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 414. Therefore, the following specifications must be met:

a. examination of the dams: thyroid hormone measurements, and

b. examination of the foetuses: measurement of anogenital distance in all live rodent foetuses.

70 Your registration dossier provides the study listed above which is described as OECD TG 414. However, the following specifications are not according to the requirements of OECD TG 414:

a. thyroid hormone measurements,

b. measurement of anogenital distance in all live rodent foetuses.

71 Based on the above, the study 1 does not provide an adequate and reliable coverage of the key parameters addressed by the OECD TG 414 and this study is not an adequate basis for your read-across predictions.

72 Based on the above, the information you provided does not fulfil the information requirement.

5.3. Specification of the study design

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

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

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

6. Long-term toxicity testing on aquatic invertebrates

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

6.1. Information provided

- You have provided the following justification to omit the study:
    1. Short-term aquatic toxicity tests conducted with some substances of the "*PFAE fumarates*" category showed no effects up to the limit of water solubility.
    2. Chronic exposure of aquatic organisms is unlikely because of the environmental fate properties (i.e., biodegradability, adorption, water solubility) of substances of the "PFAE fumarates" category.
    3. On the basis of existing data, substances of the "PFAE fumarates" category are not bioaccumulative.
    4. Minimisation of animal testing.

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

6.2. Assessment of the information provided

78 We have assessed this information and identified the following issues:

6.2.1. Your justification to omit the study has no legal basis

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

80 In addition to this, 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).

81 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

82 Therefore, you have not demonstrated that this information can be omitted. Minimisation of animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

83 Your adaptation is therefore rejected.

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

6.3. Study design and test specifications

85 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' under Appendix 1, Section 1.

7. Long-term toxicity testing on fish

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

7.1. Information provided

- You have provided the following justification to omit the study:
    1. Short-term aquatic toxicity tests conducted with some substances of the "*PFAE fumarates*" category showed no effects up to the limit of water solubility.
    2. Chronic exposure of aquatic organisms is unlikely because of the environmental fate properties (i.e., biodegradability, adorption, water solubility) of substances of the "PFAE fumarates" category.
    3. On the basis of existing data, substances of the "PFAE fumarates" category do not fulfil the P and B criteria set out in Annex XIII of REACH.
    4. Minimisation of animal testing.

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

7.2. Assessment of the information provided

88 We have assessed this information and identified the following issues:

7.2.1. Your justification to omit the study has no legal basis

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

90 In addition to this, 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).

91 Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

92 Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

93 Your adaptation is therefore rejected.

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

7.3. Study design and test specifications

95 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.).

96 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 Appendix 1, Section 1.

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 4 May 2021.

ECHA notified you of the draft decision and invited you to provide comments.
ECHA took into account your comments and amended the deadline.

In your comments on the draft decision, you requested an extension of the deadline to provide information from 24 to 30 months from the date of adoption of the decision.

In alignment with the deadline given in the compliance check decisions on other members of your category, ECHA has extended the deadline to 30 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]

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:
- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

(2) Information on the Test Material needed in the updated dossier
- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[3].

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