~~Confidential~~

Helsinki, 15 November 2023

Addressee
Registrant of Epofloc L-1R as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
11 January 2023

Registered substance subject to this decision ("the Substance")
Substance name: Reaction product of tetraethylene pentamine, carbon disulphide and sodium hydroxide
EC number/List number: 939-782-1

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 ***24 November 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. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, OECD TG 471 (2020))

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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

4. *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: EU B.17./OECD TG 476 or EU B.67./OECD TG 490)

5. Screening study 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

6. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: EU C.11./OECD TG 203)

7. Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method: EU C.1./OECD TG 209)

8. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111)

9. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: EU C.18./OECD TG 106)

The reasons for the requests are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressee of the decision and its corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 requests
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

Reasons common to several requests

1 For the information requirements of:

- Short-term toxicity testing on aquatic invertebrates (request 2)
- Growth inhibition study on aquatic plants (request 3)
- Short-term toxicity testing on fish (request 6)
- Hydrolysis as a function of pH (request 7)

2 We have analysed the information provided and found a recurring issue.

Test material not representative of the Substance

3 To comply with this information requirement, the test material in a study must be representative for the Substance; Article 10 and Recital 19 of REACH; Guidance on IRs and CSA, Section R.4.1.). The Test Methods Regulation (EU) 440/2008, as amended by Regulation (EU) 2016/266, requires that "*if the test method is used for the testing of a [...] UVCB [...] sufficient information on its composition should be made available, as far as possible, e.g. by the chemical identity of its constituents, their quantitative occurrence, and relevant properties of the constituents*". For the Substance, the information on the test material must include purity and composition (including the presence of impurities and, if relevant, of diluent).

4 The provided studies have been conducted with a test material referred to as "*Epofloc L-1R*". You specify that purity was approximately [redacted]%. However, no information on composition is provided.

5 In the absence of detailed information on the UVCB test material, the identity of the test material cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

6 In your comments to the draft decision, you state that "[t]*he purity is* [redacted]*% (solid content determination).* [redacted]*% refers to the content of EC#939-782-1 (Reaction product of tetraethylene pentamine, carbon disulphide and sodium hydroxide). The additional* [redacted]*% are water. The substance EC# 939-782-1 is marketed in this form. EPOFLOC L-1R (purity* [redacted]*%) is chemical compound created from chemical reaction by using* [redacted]*, and the finishing product is liquid type product. The extraction of the only pure substance EC# 939-782-1 from water is difficult. Thus, only EPOFLOC L-1R (purity* [redacted]*%) and not the pure substance EC#939-782-1* [can be tested]."

7 ECHA acknowledges your comments clarifying that the purity corresponds to the relative amount of active ingredient in the test material (the reminder being water). However, ECHA notes that you have not provided information on the composition of the test material in your comments allowing to verify that it falls within the boundary composition of the Substance as described by you in Section 1.2. of IUCLID. Therefore, the deficiency remains.

Reasons related to the information under Annex VII of REACH

1. *In vitro* gene mutation study in bacteria

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

1.1. Information provided

9 You have provided an *in vitro* gene mutation study in bacteria (1995) with the Substance.

1.2. Assessment of the information provided

1.2.1. The provided study does not meet the specifications of the test guideline

10 To fulfil the information requirement, a study must comply with OECD TG 471 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) the mean number of revertant colonies per plate is reported for the treated doses and the controls.

11 However, in the provided study, the mean number of revertant colonies per plate for the treated doses and the controls is not reported.

12 The information provided does not cover the specification(s) required by the OECD TG 471.

13 Therefore, the information requirement is not fulfilled.

14 In your comments to the draft decision, you state that *"an additional study was already conducted (12/2018)".* However, you have not provided this study as part of your comments on the draft decision. Therefore, no assessment of the compliance of this information can be made. You remain responsible for complying with this decision by the set deadline.

1.3. Specification of the study design

15 To fulfil the information requirement for the Substance, the in vitro gene mutation study in bacteria (OECD TG 471) is considered suitable.

2. Short-term toxicity testing on aquatic invertebrates

16 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.).

2.1. Information provided

17 You have provided a short-term toxicity study on *Daphnia magna* according to OECD TG 202 (2014) with the Substance.

2.2. Assessment of the information provided

2.2.1. Test material not representative of the Substance

18 As explained in the section "Reasons common to several requests", in the absence of detailed information on the UVCB test material, the identity of the test material cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

2.2.2. The provided study does not meet the specifications of the test guideline

19 To fulfil the information requirement, a study must comply with OECD TG 202 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Characterisation of exposure

a) analytical monitoring must be conducted. 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.

20 However, in the provided study, no analytical monitoring of exposure was conducted.

21 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical verification of exposure concentration over the exposure period, you have not demonstrated that test animals were adequately exposed to the test material.

22 In your comments to the draft decision, you state that "[t]*he actual substance is not expected to be altered within the test duration of 48 hours*" and "[t]*he substance is not readily biodegradable (7% in 7 day)*".

23 ECHA takes note of your comment and emphasizes that analytical monitoring of exposure concentrations is a mandatory requirement:

(i) to assess the stability of exposure concentrations in a particular study, and

(ii) to support that the test medium preparation method was adequate (i.e. measured concentrations at t = 0h are consistent with nominal concentrations).

24 In the absence of experimental evidence, your comments on the draft decision does not change the assessment outcome.

25 On this basis, the specifications of OECD TG 202 are not met.

26 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

27 The Substance is difficult to test due to fast hydrolysis (at pH 7, the DT50 of the Substance was found to be 8.2h and 3.75h at 15 and 25°C, respectively). OECD TG 202 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 202. 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.

28 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).

29 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.

3. Growth inhibition study aquatic plants

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

3.1. Information provided

31 You have provided a growth inhibition study on aquatic plants/algae according to OECD TG 201 (2014) with the Substance.

3.2. Assessment of the information provided

3.2.1. Test material not representative of the Substance

32 As explained in the section "Reasons common to several requests", in the absence of detailed information on the UVCB test material, the identity of the test material cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

3.2.2. The provided study does not meet the specifications of the test guideline

33 To fulfil the information requirement, a study must comply with OECD TG 201 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

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;

Reporting of the methodology and results

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

34 In the provided study:

Characterisation of exposure

a) no analytical monitoring of exposure was conducted;

Reporting of the methodology and results

b) tabulated data on the algal biomass determined daily for each treatment group and control are not reported.

35 Based on the above,

- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, in the absence of analytical verification of exposure concentration over the exposure period, you have not demonstrated that test organisms were adequately exposed to the test material.

  In your comments to the draft decision, you state that "[t]*he actual substance is not expected to be altered within the test duration of 72 hours*" and "[t]*he substance is not readily biodegradable (7% in 7 day)*".

  ECHA takes note of your comment and emphasizes that analytical monitoring of exposure concentrations is a mandatory requirement:

  (i) to assess the stability of exposure concentrations in a particular study, and

  (ii) to support that the test medium preparation method was adequate (i.e. measured concentrations at t = 0h are consistent with nominal concentrations).

  In the absence of experimental evidence, your comments on the draft decision does not change the assessment outcome.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, as you have not provided the results of algal biomass determinations during the test, ECHA cannot conduct an independent assessment as to whether the validity criteria of the test guideline were met and cannot verify the interpretation of the study results.

  In your comments you also state that "[t]*he cell density is available in the test report of the provided study for 24, 48 and 72 hours and can be completed to the dossier.*"

  However, as the information is currently not available in your registration dossier, the deficiency remains. You must submit this information in an updated registration dossier by the deadline set in the decision.

36 On this basis, the specifications of OECD TG 201 are not met.

37 Therefore, the information requirement is not fulfilled.

3.3. Study design and test specifications

38 OECD TG 201 specifies y 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 2.

Reasons related to the information under Annex VIII of REACH

4. *In vitro* gene mutation study in mammalian cells

39 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.

4.1. Triggering of the information requirement

40 Your dossier contains (I) a negative result for in vitro cytogenicity study in mammalian cells or in vitro micronucleus study, and (II) inadequate data for the other study (in vitro gene mutation study in bacteria).

41 However, the in vitro gene mutation study in bacteria, provided in the dossier is rejected for the reasons provided in request 1.

42 The result of the request 1 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.

43 Consequently, you are required to provide information for this information requirement, if the in vitro gene mutation study in bacteria provides a negative result.

4.2. Information provided

44 You have provided an *in vitro* gene mutation study in mammalian cells according to OECD TG 476 (2014) with the Substance.

4.3. Assessment of the information provided

4.3.1. The provided study does not meet the specifications of the test guideline(s)

45 To fulfil the information requirement, a study must comply with the OECD TG 476 or the OECD TG 490 (Guidance on IRs and CSA, Table.7.7-2) (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) data on the cytotoxicity and the mutation frequency for the treated and control cultures are reported.

46 However, in the provided study, data on the cytotoxicity and the mutation frequency for the treated and control cultures were not reported.

47 The information provided does not cover the specification(s) required by the OECD TG 476.

48 Therefore, the information requirement is not fulfilled.

49 In your comments to the draft decision, you state that *"data on the cytotoxicity and the mutation frequency for the treated and control cultures are available in the test report of the provided study and can be completed to the dossier".* However, you have not provided this information as part of your comments on the draft decision. Therefore, no assessment of the compliance of this information can be made. You remain responsible for complying with this decision by the set deadline.

4.4. Specification of the study design

50 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.

5. Screening study for reproductive/developmental toxicity

51 A screening study 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.

5.1. Information provided

52 You have provided a screening study for reproductive/developmental toxicity (2015) with the Substance.

5.2. Assessment of the information provided

5.2.1. The provided study does not meet the specifications of the test guideline(s)

53 To fulfil the information requirement, a study must comply with EU B.63/OECD TG 421 or EU B.64/OECD TG 422 (Article 13(3) of REACH). Therefore, the following specifications must be met:

a) body weights are measured at least weekly;

b) terminal organ and body weights are reported;

c) parameters for sexual function and fertility such as those for mating and fertility/duration of gestation, parturition and lactation are reported;

d) oestrous cycles are monitored;

e) offspring parameters such as number and sex of pups/stillbirths and live births/ pup body weight/litter weight/anogenital distance/nipple retention in male pups are reported.

54 In the provided study:

a) data on body weights, body weight changes are missing;

b) terminal organ weights and organ/body weight ratios are not reported;

c) data on parameters for sexual function and fertility such as those for mating and fertility/duration of gestation, parturition and lactation are missing;

d) data on oestrous cycles is missing;

e) data on number and sex of pups, stillbirths and live births, pup body weight, litter weight, anogenital distance and nipple retention in male pups are missing.

55 The information provided does not cover the specification(s) required by the OECD TG 422.

56 Therefore, the information requirement is not fulfilled.

57 In your comments to the draft decision, you state that further information on the study result is available. However, you have not provided this information as part of your comments on the draft decision. Therefore, no assessment of the compliance of this

information can be made. You remain responsible for complying with this decision by the set deadline.

5.3. Specification of the study design

58 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.

59 As the Substance is a liquid, the study must be conducted with oral administration of the Substance (Annex VIII, Section 8.7.1, Column 1).

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

6. Short-term toxicity testing on fish

61 Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.).

6.1. Information provided

62 You have provided a short-term toxicity study on fish according to OECD TG 203 (2014) with the Substance.

6.2. Assessment of the information provided

6.2.1. Test material not representative of the Substance

63 As explained in the section "Reasons common to several requests", in the absence of detailed information on the UVCB test material, the identity of the test material cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

6.2.2. The provided study does not meet the specifications of the test guideline

64 To fulfil the information requirement, a study must comply with OECD TG 203 and the specifications of OECD GD 23 if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Validity criteria

a) the analytical measurement of test concentrations is conducted;

Reporting of the methodology and results

b) the test procedure is reported (e.g. size of fish to verify that juveniles were

65 In the provided study:

Validity criteria

a) no analytical measurement of test concentrations was conducted;

Reporting of the methodology and results

b) on the test procedure, you have not provided information on fish size or on the life-stage of tested animals.

66 Based on the above,

- the validity criteria of OECD TG 203 are not met

  In your comments to the draft decision, you state that "[t]*he actual substance is not expected to be altered within the test duration of 48 hours*" and "[t]*he substance is not readily biodegradable (7% in 7 day)*".
  ECHA takes note of your comment and emphasizes that analytical monitoring of exposure concentrations is a mandatory requirement:

  (i) to assess the stability of exposure concentrations in a particular study, and

  (ii) to support that the test medium preparation method was adequate (i.e. measured concentrations at t = 0h are consistent with nominal concentrations).

  In the absence of experimental evidence, your comments on the draft decision does not change the assessment outcome.

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. More specifically, you have not provided adequate information to demonstrate that the test was conducted on juveniles as required by the test guideline.

  In your comments you also state that "[m]*ean length and weight of the fish are available in the test report of the provided study and can be completed to the dossier*."

  However, as the information is currently not available in your registration dossier, the deficiency remains. You must submit this information in an updated registration dossier by the deadline set in the decision.

67 On this basis, the specifications of OECD TG 203 are not met.

68 Therefore, the information requirement is not fulfilled.

6.3. Study design and test specifications

69 OECD TG 203 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 2.

7. Activated sludge respiration inhibition testing

70 Activated sludge respiration inhibition testing is an information requirement under Annex VIII to REACH (Section 9.1.4.).

7.1. Information provided

71 You have provided an activated sludge respiration inhibition study according to OECD TG 209 (2014) with the Substance.

7.2. Assessment of the information provided

7.2.1. Test material not representative of the Substance

72 As explained in the section "Reasons common to several requests", in the absence of detailed information on the UVCB test material, the identity of the test material cannot be

assessed, and you have not demonstrated that the test material is representative for the Substance.

73 Therefore, the information requirement is not fulfilled.

74 ECHA understands from your comments to the draft decision that you agree to conduct the requested study.

8. Hydrolysis as a function of pH

75 Hydrolysis as a function of pH is an information requirement under Annex VIII to REACH (Section 9.2.2.1.).

8.1. Information provided

76 You have provided a hydrolysis study according to OECD TG 111 (2015) with the Substance.

8.2. Assessment of the information provided

8.2.1. Test material not representative of the Substance

77 As explained in the section "Reasons common to several requests", in the absence of detailed information on the UVCB test material, the identity of the test material cannot be assessed, and you have not demonstrated that the test material is representative for the Substance.

8.2.2. The provided study does not meet the specifications of the test guideline

78 To fulfil the information requirement, a study must comply with OECD TG 111 (Article 13(3) of REACH). This TG is designed as a tiered approach and each tier is triggered by the results of the previous tier. Therefore, the following specifications must be met:

Identification of hydrolysis products (Tier 3)

a) all major hydrolysis products observed in Tier 2 testing (i.e. at least those representing > 10% of the applied dose) must be identified using an appropriate analytical method (Tier 3);

Technical specifications impacting the sensitivity/reliability of the test

b) sterility confirmation tests should be conducted at the end of the higher Tier test (i.e. at 90% hydrolysis or 30 days).

79 In the provided study:

Identification of hydrolysis products (Tier 3)

a) Rapid hydrolysis was observed at pH 4 and 7 (and to a lesser extent at pH 9). However, no quantitative information on the formation of hydrolysis products or their identity is provided.

Technical specifications impacting the sensitivity/reliability of the test

b) sterility confirmation tests at the end of the higher Tier test are not provided.

80 Based on the above, there are critical methodological deficiencies resulting in the rejection of the study results. More specifically:

- the Substance showed fast hydrolysis under the conditions of the Tier 2 test. However you have provided no information on the quantity and identity of formed hydrolysis products;

  In your comments to the draft decision, you state that "[t]*he result of the reaction of EC# 939-782-1 (Reaction product of tetraethylene pentamine, carbon disulphide and sodium hydroxide) with water is just a dissociation into the anion and sodium cation in combination with effects on the pH. For the anion C13H25NS6 – no subsequent dissociation in the aqueous solution is expected*".

  ECHA emphasizes that hydrolysis is defined as the reaction of a substance RX with water, with the net exchange of the group X with OH at the reaction centre (OECD TG 111, 2004). ECHA takes note of your comment and understands that the results you have reported refer to the dissociation of the salt into individual ions and not to hydrolysis as defined in the OECD TG 111. You must provide this clarification in an update of your registration dossier by the deadline set out in this decision.

- in the absence of sterility controls at the end of the higher Tier test, it cannot be excluded that the dissipation of the parent substance may be due, at least partly, to biodegradation.

  In your comments to the draft decision, you explain that "[t]*he actual substance is not expected to be altered within the test duration of 48 hours. The substance is not readily biodegradable (7% in 7 day). The potential uncertainty resulting from a potential biodegradation is within test duration of the tier 2 approach neglectable."*

  ECHA takes note of your comment which addresses the deficiency identified above. You must provide this justification in an update of your registration dossier by the deadline set out in this decision.

81 On this basis, the specifications of OECD TG 111 are currently not met.

82 Therefore, the information requirement is not fulfilled.

9. Adsorption/desorption screening

83 Adsorption/desorption screening is an information requirement under Annex VIII to REACH (Section 9.3.1).

9.1. Information provided

84 You have adapted this information requirement by using Column 2 of Annex VIII, Section 9.3.1. To support the adaptation, you have provided following justification: "*In accordance with column 2 of annex viii, this study has not been undertaken because it has a low partition coefficient, Log Pow -2.45*".

9.2. Assessment of the information provided

9.2.1. The conditions set out in Annex VIII, Section 9.3.1, Column 2 are not met

85 Under Annex VIII, Section 9.3.1, Column 2, first indent, the study may be omitted if the substance can be expected to have a low potential for adsorption (e.g. the substance has

a low octanol-water partition coefficient). In order to adapt this information requirement based on low octanol-water partition coefficient (log K_{ow}), lipophilicity must be the sole characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

86 You claim that the Substance has a low octanol-water partition coefficient and has therefore low potential for adsorption/desorption.

87 However, you have not provided any relevant evidence or argument that the Substance can be expected to have a low potential for adsorption.

88 The substance includes various salts and its constituents are therefore ionised under environmentally relevant pH. Furthermore, in section 4.4. of your IUCLID dossier, you have not provided information on surface tension as you consider this is not "*a desired property of this substance*".

89 The information in your dossier indicates that the Substance is ionisable. Furthermore, in the absence of substantiating information it cannot be excluded that the Substance is surface active. Therefore, other mechanisms than lipophilicity may drive absorption.

90 You have not demonstrated that lipophilicity is the sole characteristic driving adsorption potential and that log K_{ow} is not a valid descriptor for assessing the adsorption potential of the Substance.

91 Based on the above, your adaptation is rejected.

92 Therefore, the information requirement is not fulfilled.

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

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 14 June 2022.

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 requests.

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;
- 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]

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

(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 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.

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

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. General recommendations for conducting and reporting new tests

2.2. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in Guidance on IRs & CSA, Section R.11.4.2.2, you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

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