~~Confidential~~

Helsinki, 07 November 2023

Addressee
Registrant of JS_ISL_266-533-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18 June 2019

Registered substance subject to this decision ("the Substance")
Substance name: sodium 2-(1-carboxylatoethoxy)-1-methyl-2-oxoethyl isooctadecanoate
EC/List number: 266-533-8

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***14 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: OECD TG 471, 2020);

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

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

3. In vitro micronucleus study (Annex VIII, Section 8.4.2., test method: OECD TG 487). The aneugenic potential of the Substance must be assessed with an additional control group for aneugenicity on top of the control group for clastogenicity, if the Substance induces an increase in the frequency of micronuclei;

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

The reasons for the request(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 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 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)

Reasons common to several requests

0.1. Weight of evidence adaptation rejected

1 You have adapted the following standard information requirements by using Annex XI, Section 1.2. (weight of evidence):

- 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.).

2 Annex XI, Section 1.2. states that there may be sufficient weight of evidence from several independent sources of information enabling, through a reasoned justification, a conclusion on the information requirement, while the information from each single source alone is insufficient to fulfil the information requirement.

3 The justification must have regard to the information that would otherwise be obtained from the study that must normally be performed for this information requirement.

4 According to ECHA Guidance R.4, a weight of evidence adaptation involves an assessment of the relative values/weights of the different sources of information submitted. The weight given is based on the reliability of the data, consistency of results/data, nature and severity of effects, and relevance and coverage of the information for the given regulatory information requirement. Subsequently, relevance, reliability, coverage, consistency and results of these sources of information must be balanced in order to decide whether they together provide sufficient weight to conclude on the corresponding information requirement.

0.1.1. Lack of documentation justifying the weight of evidence adaptation

5 Annex XI, Section 1.2. requires that adequate and reliable documentation is provided to describe a weight of evidence approach. This documentation must include robust study summaries of the studies used as sources of information and a justification explaining why the sources of information together provide a conclusion on the information requirement.

6 You have not included a justification for your weight of evidence adaptation for each of the relevant information requirements, which would include an adequate and reliable (concise) documentation as to why the sources of information provide sufficient weight to conclude on the information requirements under consideration.

7 Beside this critical deficiency common to all information requirements under consideration, your weight of evidence approach has additional deficiencies.

8 Additional deficiencies that are specific for each of the information requirements individually are addressed under request(s) 1 and 3.

Reasons related to the information under Annex VII of REACH

1. In vitro gene mutation study in bacteria

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

1.1. Information provided

10 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following experimental data:

(i) *In vitro* gene mutation study in bacteria (1983), performed with the analogue substance calcium stearoyl lactylate (CSL) (EC: 227-335-7);

(ii) *In vitro* cytogenicity study in mammalian cells (1983), performed with the analogue substance calcium stearoyl lactylate (CSL) (EC: 227-335-7);

(iii) *In vitro* gene mutation study in mammalian cells (2018), performed with the Substance.

11 You conclude from this information that "*In all three studies, there are no indications of genetic toxicity potential of the test item as well as its read-across substance. Taking the results in a weight-of-evidence approach, there is no genetic toxicity potential of sodium isostearoyl lactylate*".

1.2. Assessment of the information provided

12 In addition to the deficiencies identified in Section 0.1., ECHA identified endpoint specific issue(s) addressed below.

13 Information that can be used to support weight of evidence adaptation for the information requirement of Annex VII, Section 8.4.1 includes similar information that is produced by the OECD TG 471. This includes:

- Detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria including data on the number of revertant colonies; and
- Data provided on 5 bacterial 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).

14 The sources of information (ii) and (iii) do not provide relevant information on the detection and quantification of gene mutations (base pairs, substitution or frame shift) in cultured bacteria and they cannot contribute to your weight of evidence.

15 More specifically, the source of information (ii) provides information on the detection and quantification of structural or numerical chromosomal aberrations in cultured mammalian cells, and the source of information (iii) provides information on the detection and quantification of gene mutations in cultured mammalian cells.

16 The source of information (i) provides relevant information on some of the key elements. More specifically, only four strains (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100) were investigated. This study is missing the fifth strain (either S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) which is capable of detecting oxidising mutagens, cross-linking agents and hydrazines. In addition, the source of information (i) is conducted on the analogue substance calcium stearoyl lactylate (EC: 227-335-7). Based on the information provided in your registration dossier, ECHA considers that information on this analogue substance can be used to inform on the properties of the Substance. However, the study on this analogue substance that you have used, i.e. the source of information (i),

has methodological deficiencies, explained below, that affect the reliability of its contribution to your weight of evidence adaptation.

1.2.1. Methodological deficiencies of study (i)

17 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

18 Study (i) is reported as *in vitro* gene mutation study in bacteria and has been performed to test protocol similar to the OECD TG 471. This test guideline requires that:

a) at least 5 doses are evaluated, in each test condition
b) the maximum dose tested induces a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test dose corresponds to 5 mg/plate or 5 µl/plate;
c) concurrent strain-specific positive controls, both with and without metabolic activation, are included in each assay and the number of revertant colonies per plate induced by the positive controls demonstrates the effective performance of the assay;

19 In the source of information (i), the following investigations/specifications are not to the requirements of OECD TG 471:

a) You did not provide information on the number of doses tested;
b) You did not report any cytotoxicity or precipitation, and the maximum dose tested was 0.3 mg/ml, which is less than required 5 mg/plate or 5 µl/plate;
c) concurrent strain-specific positive controls were not included in the study, therefore, the effective performance of the assay is not demonstrated.

20 Based on the above, the results obtained from the study (i) cannot be considered as reliable.

1.2.2. Conclusion on the weight of evidence

21 Taken together, only source of information (i) provides relevant but limited information, since it does not provide information from a strain capable of detecting oxidising mutagens, cross-linking agents and hydrazines.

22 In addition, the reliability of the contribution of the information obtained from source (i) is hampered by methodological deficiencies in the study design and/or reporting, which prevents reaching conclusion on the aspects investigated. Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for *in vitro* gene mutation study in bacteria.

23 Based on the above, your adaptation is rejected.

24 In your comments to the draft decision you provided executive summaries for two *in vitro* gene mutation in bacteria studies, performed with analogue substances L-lactic acid (2014) and calcium stearoyl lactylate (CSL) (1984), respectively. You indicate your intention to include these studies in a dossier update. You conclude that "*These tests should fulfill the endpoint in a weight of evidence approach.*"

25 Based on the summary information provided for L-lactic acid, ECHA notes that the *in vitro* gene mutation study in bacteria is performed in accordance with OECD TG 471 and gives negative results in five strains with and without metabolic activation. Therefore, ECHA considers that the data for L-lactic acid, provided in your comments provides relevant and reliable information for the *in vitro* gene mutation study in bacteria.

26 The information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should submit this information in an updated registration dossier by the deadline set out in the decision.

27 Therefore, the information requirement is not fulfilled.

1.3. Study design

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

2. Long-term toxicity testing on aquatic invertebrates

29 Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII, Column 1, Section 9.1.1. However, under Column 2, long-term toxicity testing on aquatic invertebrates may be required by the Agency if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

2.1. Triggering of the information requirement

30 You have provided a QSAR predicting that the water solubility of the Substance is 0.59 mg/L, which indicates that the Substance includes constituents that are poorly water soluble.

31 In your comments to the draft decision, you propose to perform a study according to the OECD TG 105 to determine the water solubility of the Substance. As this information is currently not available, ECHA assesses based on the available information (QSAR) indicating that the Substance has at least one constituent that is poorly water soluble.

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

2.2. Information requirement not fulfilled in the registration dossier

33 You have provided a short-term toxicity study on aquatic invertebrates but no information on long-term toxicity on aquatic invertebrates for the Substance.

34 In the absence of information on long-term toxicity on aquatic invertebrates, this information requirement is not fulfilled.

2.3. Adaptation provided in your comments to the draft decision

35 In your comments to the draft decision, you propose to apply the provided QSAR prediction (ECOSAR v. 1.11) to adapt the information requirement for long-term toxicity to aquatic invertebrates, if the Substance is considered poorly water soluble.

2.3.1. Assessment of the information provided

2.3.1.1. (Q)SAR adaptation rejected

a) Under Annex XI, Section 1.3., the following conditions must be fulfilled whenever a (Q)SAR approach is used:

(1) the prediction needs to be derived from a scientifically valid model,
(2) the substance must fall within the applicability domain of the model,
(3) results need to be adequate for the purpose of risk assessment or

classification and labelling, and
(4) adequate and reliable documentation of the method must be provided.

2.3.1.2. The prediction does not cover all constituents of the Substance

36 Under Guidance on IRs and CSA R.6.1.7.3. a prediction is adequate for the purpose of classification and labelling and/or risk assessment if the following condition sare met:

- the composition of the substance is clearly defined, and
- different constituents of the same substance are predicted individually.

37 Your registration dossier provides the following information:

- In Section 1.1. of your technical dossier, you define the Substance as a UVCB with three constituents ([redacted]).
- For the assessment, you provided predictions based on the structure of the following constituent: [redacted]

38 As you have used only one structure for the prediction while the Substance is composed of three constituents. You have not covered all constituents of the Substance.

39 Therefore, you have not demonstrated that the prediction is adequate for the purpose of classification and labelling and/or risk assessment.

2.3.1.3. Inadequate documentation of the model (QMRF)

40 Under Appendix C of the OECD Guidance document on the validation of (Q)SAR models (ENV/JM/MONO(2007)2) and Guidance on IRs and CSA R.6.1.6.3., adequate and reliable documentation must include a (Q)SAR Model Reporting Format document (QMRF) which reports, among others, the following information:

- the predicted endpoint, including information on experimental protocol and data quality for the data used to develop the model;
- an unambiguous definition of the algorithm, the descriptor(s) of the model and its applicability domain,
- an estimate of the goodness-of-fit and of the predictivity of the model, including information on training set and validation statistics.

41 The documentation provided on the model (ECOSAR, Special class: Anionic Surfactant) does not include:

- information on experimental protocol and data quality for the data used to develop the Special Class: Anionic Surfactant model;
- information on applicability domain of the Special class: Anionic Surfactant model;
- an estimate of goodness-of-fit and of the predictivity of the Special class: Anionic Surfactant model, including information on trating set and relevant validation statistics

42 In absence of such information, ECHA cannot establish that the model can be used to meet this information requirement.

2.3.1.4. Inadequate documentation of the prediction (QPRF)

43 Guidance on IRs and CSA R.6.1.6.3. states that the information specified in or equivalent to the (Q)SAR Prediction Reporting Format document (QPRF) must be provided to have adequate and reliable documentation of the applied method. For a QPRF this includes, among others the identities of close analogues, including considerations on how predicted and experimental data for analogues support the prediction.

44 You provided the following information about the prediction: the model prediction(s), including the endpoint, and a precise identification of the substance modelled. In addition, you describe the relationship between the modelled substance and the high level applicability domain of the model (as described in Section 2.3.1.3, detailed information about the applicability domain as defined by the model developer of the Special class: Anionic Surfactant model was not included in the QMRF provided). The information you provided about the prediction lacks the following elements: the close analogues have not been identified, and considerations on how predicted and experimental data for analogues support the prediction have not been provided.

45 In absence of such information, ECHA cannot establish that the prediction can be used to meet this information requirement.

46 Based on the above, your adaptation is rejected.

47 Therefore, based on the information in the dossier and in your comments, the information requirement is not fulfilled.

2.4. Study design

48 The Substance is difficult to test due to the low water solubility (0.59 mg/L) and surface activity (surface tension 28.5 mN/m). OECD TG 211 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

49 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).

50 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.

Reasons related to the information under Annex VIII of REACH

3. *In vitro* micronucleus study

51 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.

3.1. Information provided

52 You have adapted this information requirement by using Annex XI, Section 1.2. (weight of evidence) based on the following:

(i) *In vitro* gene mutation study in bacteria (1983), performed with the analogue substance calcium stearoyl lactylate (CSL) (EC: 227-335-7);

(ii) *In vitro* cytogenicity study in mammalian cells (1983), performed with the analogue substance calcium stearoyl lactylate (CSL) (EC: 227-335-7);

(iii)In vitro gene mutation study in mammalian cells (2018), performed with the Substance.

53 You conclude from this information that "*In all three studies, there are no indications of genetic toxicity potential of the test item as well as its read-across substance. Taking the results in a weight-of-evidence approach, there is no genetic toxicity potential of sodium isostearoyl lactylate*".

3.2. Assessment of the information provided

54 In addition to the deficiency identified in Section 0.1., ECHA identified endpoint specific issue(s) addressed below.

55 Relevant information that can be used to support weight of evidence adaptation for information requirement of Section 8.4.2. at Annex VIII includes:

- Detection and quantification of cytotoxicity and the frequency of cells with structural chromosomal aberration(s) or the frequency of micronuclei in cultured mammalian cells *(in vitro*) or in mammals (*in vivo*).

56 A level of information on these aspects similar to that obtained from *in vitro/in vivo* chromosomal aberration tests (OECD TG 473/OECD TG 475) or *in vitro/in vivo* micronucleus tests (OECD TG 487/OECD TG 474) is required.

57 The sources of information (i) and (iii) do not provide relevant information on the detection and quantification of cytotoxicity and the frequency of cells with structural chromosomal aberration(s) or the frequency of micronuclei in cultured mammalian cells and they cannot contribute to your weight of evidence.

58 More specifically, the source of information (i) and (iii) provide information on the detection and quantification of gene mutations in cultured bacteria and in cultured mammalian cells, respectively.

59 The source of information (ii) provides relevant information on the detection and quantification of structural or numerical chromosomal aberrations in cultured mammalian cells. The source of information (ii) informs on the properties of the analogue substance calcium stearoyl lactylate (EC: 227-335-7). Based on the information provided in your registration dossier, ECHA considers that information on this analogue substance can be used to inform on the properties of the Substance. However, the study on this analogue substance that you have used, i.e. the source of information (ii), has methodological deficiencies, explained below, that affect the reliability of its contribution to your weight of evidence adaptation.

3.2.1. Methodological deficiencies of study (ii)

60 The evaluation of the reliability of the contribution of each relevant line of information to the weight of evidence approach includes an assessment of each source of information against the specifications of the test guideline followed.

61 Study (ii) refers to *in vitro* chromosomal aberration tests performed equivalent to the OECD TG 473. This test guideline requires that:

a) two separate test conditions are assessed: in absence of metabolic activation and in presence of metabolic activation

b) the maximum concentration tested induces 55+5% of cytotoxicity compared to the negative control, or the precipitation of the tested substance. If no precipitate or limiting cytotoxicity is observed, the highest test concentration corresponds to 10 mM, 2 mg/mL or 2 µL/mL, whichever is the lowest;

c) One positive control must be included in the study. The positive control substance must produce a statistically significant increase in the response compared with the concurrent negative control.

d) Data on the cytotoxicity and the frequency of cells with structural chromosomal aberration(s) for the treated and control cultures must be reported.

62 In study (ii), the following investigations/specifications are not to the requirements of OECD TG 473:

a) the test was performed only in absence of metabolic activation;
b) You did not report any cytotoxicity or precipitation and the maximum dose tested was 0.063 mg/ml which is less than required 2 mg/mL;
c) no positive control was reported in the study, therefore, the effective performance of the assay is not demonstrated;
d) No details on the extent of the cytotoxicity observed in study are provided.

63 Based on the above, the results obtained from the study (ii) cannot be considered as reliable.

3.2.2. Conclusion on the weight of evidence

64 Taken together, only source of information (ii) provides relevant information on the detection and quantification of structural or numerical chromosomal aberrations in cultured mammalian cells. However, the reliability of the contribution of the information is hampered by methodological deficiencies in the study design and/or reporting, which prevents reaching conclusion on the aspects investigated.Therefore, it is not possible to conclude, based on any source of information alone or considered together, on the information requirement for in vitro cytogenicity in mammalian cells.

65 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

66 In your comments to the draft decision you provided executive summaries for two *in vitro* chromosomal aberration studies, performed with analogue substances L(+)-lactic acid (2014) and calcium stearoyl lactylate (CSL) (1984), respectively. You indicate your intention to include these studies in a dossier update. You conclude that "*These tests should fulfill the endpoint in a weight of evidence approach although they are not micronucleus studies.*"

67 Based on the summary information provided for L(+)-lactic acid, ECHA notes that the *in vitro* chromosomal aberration study is performed in accordance with the OECD TG 473 and gives negative results with and without metabolic activation when tested to the maximum

non-cytotoxic concentration. Therefore, ECHA considers that the data for L(+)-lactic acid, provided in your comments provides relevant and reliable information for the *in vitro* chromosomal aberration study.

68 Therefore, the information you have provided in your comments addresses the incompliances identified in this decision for this information requirement. However, as the information is currently not available in your registration dossier, the data gap remains. You should therefore submit this information in an updated registration dossier by the deadline set out in the decision.

3.3. Study design

69 According to the Guidance on IR & CSA, Section R.7.7.6.3., either the in vitro mammalian chromosomal aberration ("CA") test (test method OECD TG 473) or the in vitro mammalian cell micronucleus ("MN") test (test method OECD TG 487) can be used to investigate chromosomal aberrations in vitro. However, while the MN test detects both structural chromosomal aberrations (clastogenicity) and numerical chromosomal aberrations (aneuploidy), the CA test detects only clastogenicity, as OECD TG 473 is not designed to measure aneuploidy (see OECD TG 473, paragraph 2).Therefore, you must perform the MN test (test method OECD TG 487), as it enables a more comprehensive investigation of the chromosome damaging potential in vitro.Moreover, in order to demonstrate the ability of the study to identify clastogens and aneugens, you must include two concurrent positive controls, one known clastogen and one known aneugen [1] (OECD TG 487, paragraphs 33 to 35).

3.3.1. Assessment of aneugenicity potential

70 If the result of the MN test is positive, i.e. your Substance induces an increase in the frequency of micronuclei, you must assess the aneugenic potential of the Substance.

71 In line with the OECD TG 487 (paragraph 4), you should use one of the centromere labelling or hybridisation procedures to determine whether the increase in the number of micronuclei is the result of clastogenic events (i.e. micronuclei contain chromosome fragment(s)) and/or aneugenic events (i.e. micronuclei contain whole chromosome(s)).

[1] According to the TG 487 (2016) "At the present time, no aneugens are known that require metabolic activation for their genotoxic activity" (paragraph 34).

4. Long-term toxicity testing on fish

72 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 may be required by the Agency (Section 9.1.3., Column 2) if the substance is poorly water soluble, i.e. solubility below 1 mg/L.

4.1. Triggering of the information requirement

73 As already explained in request 2, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

74 Therefore, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

4.2. Information requirement not fulfilled in the registration dossier

75 You have provided a short-term toxicity study on fish but no information on long-term toxicity on fish for the Substance.

76 In the absence of information on long-term toxicity on fish , this information requirement is not fulfilled.

4.3. Adaptation provided in your comments to the draft decision

77 In your comments to the draft decision, you propose to apply the provided QSAR prediction (ECOSAR v. 1.11) to adapt the information requirement for long-term toxicity to fish, if the Substance is considered poorly water soluble.

78 For the same reasons as already explained under Section 2.3.1.2., 2.3.1.3., and 2.3.1.4., your adaptation under Annex XI, section 1.3 is rejected.

79 Therefore, based on the information in the dossier and in your comments, the information requirement is not fulfilled.

4.4. Study design

80 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.).

81 The OECD TG 210 specifies that, for difficult to test substances, the OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in "Study design" under request 2.

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 02 May 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 request(s).

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

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

Appendix 3: Addressee(s) 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 (https://echa.europa.eu/practical-guides).

(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 boundary composition(s) of the Substance,
- the impact of each constituent/group of constituents on the test results for the endpoint to be assessed. For example, if a constituent/group of constituents of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/group of constituents.

(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.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).