~~Confidential~~

Helsinki, 10 November 2023

Addressee(s)
Registrants of JS_701-087-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
23 August 2017

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of sodium prop-2-enesulphonate and sodium chloride
EC / List number: 701-087-4

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***18 May 2026***.

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

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

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

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

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

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

4. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; 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 addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

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 request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the request(s)

Contents

Reasons related to the information under Annex VII of REACH

1. Growth inhibition study aquatic plants

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

1.1. Information provided

2 You have provided:

(i) Growth inhibition study on algae (1989) with the Substance;

1.2. Assessment of the information provided

1.2.1. Study not conducted according to GLP

3 (Eco)toxicological studies must comply with GLP or another recognised international standard; Art. 13(4) of REACH.

4 You have indicated that study (i) is "not GLP-compliant", without further explanation.

5 The test does not comply with GLP or another recognised international standard and is therefore rejected.

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

6 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:

Validity criteria

a) exponential growth in the control cultures is observed over the entire duration of the test;

b) at least 16-fold increase in biomass is observed in the control cultures by the end of the test;

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

d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with [*Pseudokirchneriella subcapitata / Desmodesmus subspicatus*]. For other less frequently tested species, the value is ≤ 10%;

Technical specifications impacting the sensitivity/reliability of the test

e) for *Desmodesmus subspicatus* the initial cell density is 2-5 x10^3 cells/mL;

f) the pH of the control medium does not increase by > 1.5 units;

Characterisation of exposure

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

h) the results can be based on nominal or measured initial concentration only if the concentration of the test material has been maintained within ±20 % of the nominal or measured initial concentration throughout the test;

i) if the concentration of the test material has not been maintained within ±20 % of the nominal or measured initial concentration throughout the test, results must be based on the geometric mean of measured concentrations during exposure or on a model describing the decline of the concentration of the test material over the exposure period.

7 In study (i):

Validity criteria

a) exponential growth in the control cultures was not provided nor raw data in the registration dossier;

b) the biomass at the start of the test was 10^4 cells/mL but no information on the biomass at the end of the test is reported;

c) the mean coefficient of variation for section-by-section specific growth in the control was not provided nor raw data in the registration dossier;

d) the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was not provided nor raw data in the registration dossier;

Technical specifications impacting the sensitivity/reliability of the test

e) the test was conducted on *Desmodesmus subspicatus* and the initial cell density was 10^4 cells/mL;

f) no information on pH values is reported in the registration dossier;

Characterisation of exposure

g) no analytical monitoring of exposure was conducted;

h) and i) You have expressed the effect values based on nominal concentrations. The concentrations of the test material were not proved to be within ± 20 % of nominal concentrations throughout the test.

8 Based on the above,

- the validity criteria of OECD TG 201 are not met
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, no analytical measurements have been conducted, therefore it is not possible to verify that the exposure of tested organisms to the Substance has been maintained through the study; the initial cell density is higher than that required in the OECD TG 201, this can affect the exponential growth through the incubation period due to the risk of nutrient depletion; it was not demonstrated that the pH was maintained in the acceptable interval reported in the OECD TG 201, this can impact on the growth in the control and therefore on the obtained toxicity values.

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

10 Therefore, the information requirement is not fulfilled.

11 In your comments on the draft decision, you acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study.

2. Ready biodegradability

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

2.1. Information provided

13 You have provided:

(i) a ready biodegradability study (1989) with the Substance;

2.2. Assessment of the information provided

2.2.1. Study not conducted according to GLP

14 (Eco)toxicological studies must comply with GLP or another recognised international standard; Art. 13(4) of REACH.

15 You have indicated that study (i) is "not GLP-compliant", without further explanation.

16 The test does not comply with GLP or another recognised international standard and is therefore rejected.

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

17 To fulfil the information requirement, a study must comply with the OECD TG 301 or 310 (Article 13(3) of REACH). Therefore, for a study according to OECD TG 301, the following specifications must be met:

Validity criteria

a) the degradation of the reference compound has reached the pass level by day 14;

b) the difference of extremes of replicate values of the removal of the test material at the plateau, at the end of the test or, if appropriate, at the end of the 10-d window is ≤ 20%;

c) in the toxicity control, the degradation of the reference substance has reached ≥ 35% (based on DOC) or ≥ 25% (based on ThOD or $ThCO_2$) by day 14;

d) the test material is the sole source of added organic carbon;

Technical specifications impacting the sensitivity/reliability of the test

e) a reference compound, which meets the criteria for ready biodegradability, is tested in parallel in all tests. Appropriate reference compounds include aniline (freshly distilled), sodium acetate and sodium benzoate;

f) determination is carried out at least in duplicate;

g) the dilution water does not contain more than 10% of the organic carbon content introduced by the test material;

h) the dilution water is checked by DOC analysis prior to use;

i) the concentration of the inoculum is set to reach a bacterial cell density of 10^7 to 10^8 cells/L in the test vessel.

j) the test temperature is 22°C ± 1°C;

k) the pH is adjusted to 7.4 ± 0.2;

Reporting of the methodology and results

l) the source of the inoculum, its concentration in the test and any pre-conditioning treatment are reported;

m) the test temperature is reported;

n) the results of measurements at each sampling point in each replicate is reported in a tabular form;

o) any observed inhibition phenomena and/or abiotic degradation are reported.

18 In study (i):

Validity criteria

a) no reference compound has been used in the test;

b) no information on the difference of extremes of replicate values of the removal of the test material was reported in the registration dossier;

c) no toxicity control has been used in the test;

d) no information on sources of added organic carbon other than the test material was reported in the registration dossier;

Technical specifications impacting the sensitivity/reliability of the test

e) a reference compound was not tested in parallel in all tests;

f) determinations were not carried out in at least duplicate;

g) no information on the organic carbon content in the dilution water was reported in the registration dossier;

h) the dilution water was not checked by DOC analysis prior to use;

i) the concentration of the inoculum is not reported in the registration dossier

j) the test temperature was not reported in the registration dossier;

k) the pH was not reported in the registration dossier;

Reporting of the methodology and results

l) pre-conditioning treatment is not reported;

m) the test temperature is not reported;

n) the results of measurements at each sampling point in each replicate is not reported in a tabular form, only a single value for each time point is available;

o) no information is provided on inhibition phenomena and/or abiotic degradation (if any).

19 Based on the above,

- the validity criteria of OECD TG 301 are not met
- there are critical methodological deficiencies resulting in the rejection of the study results. More specifically, the missing use of a reference compound does not allow to verify the correctness of the procedures; the lack of determinations in duplicates does not allow to take into account the biological variability in the biodegradation process; the lack of information on organic carbon content in the dilution water does not allow to exclude interferences in the results; the lack of information on the concentration of inoculum does not allow to verify that an

appropriate amount of microorganisms has been used in the test; the lack of information on temperature and pH does not allow to verify that the test has been conducted in suitable conditions;

- the reporting of the study is not sufficient to conduct an independent assessment of its reliability. The lack of information on the pre-conditioning treatment does not allow to verify that the inoculum has been maintained in appropriate conditions before the test; the lack of information on inhibition phenomena and/or abiotic degradation does not allow to verify that other processes, interfering with biodegradation, impacted on the results.

20 On this basis, the specifications of OECD TG 301 are not met.

21 Therefore, the information requirement is not fulfilled.

2.3. Study design and test specifications

22 To fulfil the information requirement, the test method(s) according to OECD TG 301A/B/C/D/E/F or OECD TG 310 are in general appropriate. You can choose any of these methods, but you must ensure that the Substance is within the applicability domain of the test method chosen.

23 In your comments on the draft decision, you acknowledge that the information requirement is not fulfilled for this endpoint and you agree to perform the requested study.

Reasons related to the information under Annex IX of REACH

3. Long-term toxicity testing on aquatic invertebrates

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

3.1. Information provided

25 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) *"In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of the test substance reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance. The short-term toxicity tests indicate that the substance is not harmful to aquatic organisms. In addition, the ready biodegradability and low log Pow and log Koc values do not indicate a risk of chronic exposure or bioaccumulation in aquatic organisms. Therefore, a long-term toxicity study with aquatic invertebrates is not provided."*

26 With your comments on the initial draft decision, you have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). To support the adaptation, you have provided the following information:

(ii) A prediction from ECOSAR v2.2QSAR for the main constituent sodium prop-2-enesulphonate.

3.2. Assessment of the information provided

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

27 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to aquatic invertebrates referred to under Column 1, Section 9.1.5.

3.2.2. (Q)SAR adaptation rejected

28 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.

29 With regard to these conditions, we have identified the following issue(s):

3.2.2.1. The substance is outside the applicability domain of the model

30 Under Guidance on IRs and CSA R.6.1.5.3, a substance must fall within the applicability domain specified by the model developer. The substance is outside the applicability domain of the ECOSAR neutral organic model, as specified in the documentation in ECOSAR. The documentation states that the model is applicable to non-ionizable substances, while the Substance is ionised.

31 Your adaptations are therefore rejected.

32 Therefore, the information requirement is not fulfilled.

4. Long-term toxicity testing on fish

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

4.1. Information provided

34 You have adapted this information requirement by using Column 2 of Annex IX, Section 9.1. To support the adaptation, you have provided following information:

(i) "*In Annex IX of Regulation (EC) No 1907/2006, it is laid down that long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to Annex I of this regulation, the chemical safety assessment triggers further action when the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB. The hazard assessment of the test substance reveals neither a need to classify the substance as dangerous for the environment, nor is it a PBT or vPvB substance. The short-term toxicity tests indicate that the substance is not harmful to aquatic organisms. In addition, the ready biodegradability and low log Pow and log Koc values do not indicate a risk of chronic expsoure or bioaccumulation in aquatic organisms. Therefore, and for reasons of animal welfare, a long-term toxicity study in fish is not provided.*"

35 With your comments on the initial draft decision, you have adapted this information requirement by using Annex XI, Section 1.3. (Qualitative or Quantitative Structure-Activity Relationships, (Q)SARs). To support the adaptation, you have provided the following information:

(ii) A prediction from ECOSAR v2.2QSAR for the main constituent sodium prop-2-enesulphonate.Assessment of the information provided

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

36 Under Annex IX, Section 9.1., Column 2 is not a basis for omitting information on long-term toxicity to fish referred to under Column 1, Section 9.1.6.

4.1.3. (Q)SAR adaptation rejected

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

(5) the prediction needs to be derived from a scientifically valid model,

(6) the substance must fall within the applicability domain of the model,

(7) results need to be adequate for the purpose of risk assessment or classification and labelling, and

(8) adequate and reliable documentation of the method must be provided.

38 With regard to these conditions, we have identified the following issue:

4.1.3.1. The substance is outside the applicability domain of the model

39 Under Guidance on IRs and CSA R.6.1.5.3, a substance must fall within the applicability domain specified by the model developer. The substance is outside the applicability domain of the ECOSAR neutral organic model, as specified in the documentation in ECOSAR. The documentation states that the model is applicable to non-ionizable substances, while the Substance is ionised.

40 Your adaptations are therefore rejected.

41 Therefore, the information requirement is not fulfilled.

4.2. Study design and test specifications

42 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.).

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 03 August 2022.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and amended the requests and the deadline.

As a result of one or more changes of registration tonnage band or registration type, the requests for Pre-natal developmental toxicity study in a second species and Extended one-generation reproductive toxicity study were removed from the decision.

As a result of the submission of information considered sufficient and relevant, the request for Adsorption/desorption screening study was removed from the decision.

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 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]
[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

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.

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (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 Appendix 1.