~~Confidential~~

Helsinki, 24 May 2021

Addressees
Registrant(s) of Sodium ethylenesulphonate as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21/05/2013

Registered substance subject to this decision ("the Substance")
Substance name: Sodium ethylenesulphonate
EC number: 221-242-5
CAS number: 3039-83-6

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 in A.1, A.2., A.3. and B.1. below by ***29 August 2022*** and all other information listed below by ***29 February 2024***.

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

A. 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: EU B.13/14. / OECD TG 471)

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

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301B/C/D/F or OECD TG 310)

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

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

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

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

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) by oral route, in one species (rat or rabbit)

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: OECD TG 210)

Reasons for the request(s) are explained in the following appendices:

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to IX of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- 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;

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 testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation and bioaccumulation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency and bioaccumulation of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

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 Christel Schilliger-Musset, Director of Hazard Assessment

[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 on Reasons common to several requests

1. Assessment of your adaptation under Annex XI, Section 3.2(b)

The following issue concerns the following information requirements:
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

You have provided an adaptation according to Annex XI, section 3.2 (b) in your dossier, and you conclude that *"the substance is manufactured and used under strictly controlled conditions and no significant worker exposure occurs"*.

You have sought to adapt the standard information requirement according to Annex XI, Section 3. Substance-tailored exposure-driven testing.

As stated in Annex XI, Section 3, testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annexes IX and X may be omitted based on the exposure scenario(s) developed in the CSR, by providing an adequate and scientifically-supported justification based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and by communicating the specific conditions of use through the supply chain. Any one of the following criteria 3.2.(a), (b) or (c) shall be met.

In particular 3.2 (b) where the substance is not incorporated in an article the manufacturer or the importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Art 18(4)(a) to (f) apply.

You have sought to omit the 90-day sub-chronic toxicity study and the first species prenatal developmental toxicity study under the criteria 3.2.(b). We have assessed this information and identified the following issues:

1. Strictly controlled conditions not demonstrated

The second criterion 3.2(b) requires a demonstration that "throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)" apply.

In your dossier, in particular, exposure scenario 2, contributing scenarios 4, 5 and 6 are all presented with RCRs of [redacted]. The existence of a risk characterisation ratio of [redacted] (close to 1) is proof that strictly controlled conditions were not implemented. Otherwise, the RCR would be close to zero. Therefore, in several exposure scenarios for the combined routes, systemic long-term, the RCRs do not demonstrate strictly controlled conditions as per Annex XI, section 3.2(b) and therefore criterion 3.2(b) for exposure-based adaptation is not satisfied.

In your comments on the draft decision, you provided additional information that *"the implemented technical measures demonstrating strictly controlled conditions are described in an attachment to this document. These measures were communicated downstream and confirmed by the downstream users"*

ECHA considers that your description of the strictly controlled conditions is provided only for the exposure scenario M-1, which covers manufacture. There is no description of the strictly controlled conditions for industrial uses (IW-1 and IW-2) or any documentation that the same description applies also to other scenarios throughout the life cycle.

2. No rigorous and thorough exposure assessment

REACH Annex XI 3.2 specifies that in all cases (a, b and c), adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I. According to ECHA Guidance Chapter R.5: Adaptation of information requirements (version 2.1 December 2011) for justifying that use in strictly controlled conditions (e.g. according to Article 18(4)), is leading to no or minimised release/exposure, there should be a quantitative argumentation. In addition, in order to justify for a certain endpoint the omission of the standard information requirement, a high level of confidence is needed to demonstrate *no or no significant exposure* or *no release*.

In the information that you provided in your comments, you explained that exposure assessment is based solely on modelling. ECETOC TRA v. 3 has been used for estimating inhalation exposure and both ECETOC TRA v.3 and RiskofDerm v. 2.1 for dermal exposure. ECETOC TRA v.3 is a first tier exposure modelling tool. Rigorous and thorough exposure assessment that would justify *no or no significant exposure* cannot be done by using a tier 1 exposure modelling tool which is generally conservative, but also very uncertain. To demonstrate absence of or no significant exposure measured data or higher tier exposure modelling should be used Due to the shortcomings identified above, ECHA considers that your exposure assessment has a high uncertainty.

Therefore, ECHA considers that the information submitted in your comments on the draft decision does not cover all shortcomings identified earlier.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3 (b). Therefore, based on the information provided in your dossier and with your comments on the draft decision, your adaptation is rejected.

2. Assessment of the identity of the test material

The following issue concerns the following information requirements:

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)
- Ready biodegradability (Annex VII, Section 9.2.1.1.)

You have provided studies listed under each endpoint in appendices A and C that you claim were conducted with the Substance.

To comply with these information requirements, the test material in a study must be representative for the Substance (Art. 10 and Recital 19 of REACH; ECHA Guidance R.4.1).

Therefore, the unambiguous characterisation of the composition of the Substance and test material used to generate the data is required to evaluate the representativeness of the test material. The composition of the selected test material must be reported in the respective endpoint study record, under the test material section, and include details on the composition, including quantitative and qualitative information on all constituents present in the test material, or production process of the test material.

To identify the test materials you have provided the substance name, EC and/or CAS number, and/or the purity of the Substance in water. Information on the detailed composition, including quantitative and qualitative information on all constituents present in the test material, or production process of the test material has not been provided for the endpoints above.

In your comments on the draft decision you have provided additional information on the test material for the Skin sensitisation, *In vitro* gene mutation in bacteria, Short-term toxicity testing on aquatic invertebrates and fish studies and Screening for reproductive/developmental toxicity, which resulted in their removal from this section. This information is also available in your updated dossier.

Without comprehensive reporting of all constituents present in the test material (including their identity and concentrations) ECHA is unable to confirm that the test materials are representative of the Substance.

Therefore, the provided information is rejected.

Appendix A: Reasons to request information required under Annex VII of REACH

1. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is a standard information requirement in Annex VII to REACH.

You have provided a key study in your dossier:

i. *In vitro* gene mutation study in bacteria (1988) with 30% substance in water with the following strains, TA 98, TA 100, TA 1535, TA 1537, TA 1538 and E. coli WP2uvrA which all gave negative results.

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

Test guideline key parameters

To fulfil the information requirement, the study has to meet the requirements of OECD TG 471 (1997). One of the key parameters of this test guideline includes:

a) The maximum dose tested must induce 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 must correspond to 5 mg/plate or 5 ml/plate.

The reported data for the study you have provided did not include:

a) a maximum dose of 5 mg/plate or 5 ml/plate or that induced a reduction in the number of revertant colonies per plate compared to the negative control, or the precipitation of the tested substance. The concentration of the test material was 30% and the resulting high dose in the mutagenicity test 1,500 to 3000 µg/plate.

The information provided does not cover one of the key parameters required by OECD TG 471.

In your comments on the draft decision you provided additional information on the test material identity, clarifying that the purity of the test material was 30% in water. However, the submitted information still does not cover all shortcomings identified above.

Therefore, the information requirement is not fulfilled.

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

2. Growth inhibition study aquatic plants

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

You have provided key study (reliability score 1) according to OECD TG 201.

We have assessed this information and identified the following issues:

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The test material identity is provided, including information on purity, presence of impurities and compositional information;
- The results of algal biomass determined in each flask at least daily during the test

period are reported in a tabular form;
- 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;
- Adequate information on the results of the analytical determination of exposure concentrations is provided;
- The concentration series of the Substance (active ingredient) should preferably cover the range causing 5-75 % inhibition of algal growth rate or be up to limit concentration (100 mg/L or a concentration equal to the limit of solubility).

As explained in Appendix on Reasons common to several requests, identity of the test material in the key study is not sufficiently identified. Information on algal biomass in each flask throughout the test duration which would allow confirmation of fulfilment of validity criteria is not provided. The concentration series used in the test neither cover the range causing 5-75 % inhibition of algal growth rate nor the Substance (active ingredient) was tested up to limit concentration.

Finally, all reported effect concentrations are based on nominal initial concentrations. However, adequate information on the results of the analytical determination of exposure concentrations is not provided while in the reported information there are indications that the test material has not been maintained within 20 % of the nominal or measured initial concentration throughout the test, i.e. "*The mean recovery values were 97.44 % at test initiation and 67.24 % at test termination.*"

In your comments on the draft decision you agree to this request.

On this basis, the information requirement is not fulfilled.

Study design

Considering that the Substance is organic salt which is soluble in water, the Substance will be present in ionised form at environmentally relevant pHs and possesses potential for adsorption to mineral components of environmental matrixes. Due to its potential for adsorption, the Substance is difficult to test. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

3. Ready biodegradability

Ready biodegradability is a standard information requirement under Annex VII to REACH (Section 9.2.1.1.).

You have provided:
i. Key study (reliability score 2) according to OECD TG 301E.
ii. Supporting study (reliability score 2); test method: "*Biodegradation was determined by COD-degradation in a Sapromat*".

We have assessed this information and identified the following issues:

To comply with this information requirement, a study must fulfil the requirements of the corresponding OECD test guideline or EU method (Article 13(3) of REACH), in this case OECD TG 301, in general and OECD TG 301E, specifically for the key study. Therefore, the following requirements must be met:

1. The test material identity is provided, including information on purity, presence of impurities and compositional information;
2. The OECD TG 301E is not applicable to adsorbing substances unless appropriate adsorption control are included in the test design; when the substance is suspected to be adsorptive, a preliminary assessment of the extent of adsorption must be conducted using an adsorption control (*i.e.* containing the test substance, inoculum and sterilising agent);
3. The dilution water does not contain more than 10% of the organic carbon content introduced by the test material;
4. The concentration of the inoculum is set to reach a bacterial cell density of approx. 10^5 cells/L in the test vessel. The concentration of added inoculum is ≤ 0.5 mL/L;
5. The information on the study design details (the source of the inoculum and its cells concentration/density in the test, oxygen conditions, temperature, initial test substance/material concentration, number of used replicates for test substance and controls, information on used controls, details on analytical method) is reported.

Considering that the Substance is organic salt which is well soluble in water, the Substance will be present in ionised forms at environmentally relevant pHs and possesses potential for adsorption to mineral components of environmental matrixes.

As explained in Appendix on Reasons common to several requests, identity of the test material in the key and supporting studies is not sufficiently identified. Furthermore, the information to verify fulfilment of above listed requirements 2-4 is missing for the key study.

The information on the study design details is missing for the supporting study.

In your comments on the draft decision you agree to this request.

On this basis, the information requirement is not fulfilled.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Screening for reproductive/developmental toxicity

A Screening for reproductive/developmental toxicity study (test method: EU B.63/OECD TG 421 or EU B.64/OECD TG 422) is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided a key study for this endpoint in your dossier:

i. Combined sub-acute repeated dose-toxicity and screening for reproductive/developmental toxicity study (2010, OECD TG 422) with 25% substance in water.

The following endpoint-specific deficiency has been identified:

Test guideline key parameters

To be considered compliant and to generate information concerning the effects of the Substance on male and female reproductive performance, the study has to meet the requirements of EU B.63/OECD TG 421 or EU B.64/OECD TG 422. The key parameter(s) of this test guideline include, among others:

- The highest dose level should aim to induce some systemic toxicity, but not death or severe suffering, or be tested up to a limit dose of 1000 mg/kg bw/d of the Substance.

The highest dose level in the study (500 mg/kg bw/day) did not induce any toxicity and you have not shown that the aim was to induce toxicity. Therefore, the dose level selection was too low, and the study does not fulfil the criterion set in EU B.63/OECD TG 421 or EU B.64/OECD TG 422.

In your comments on the draft decision you provided additional information. However, the submitted information does not cover all shortcomings identified above. Specifically, you explain that "*There were absolutely no adverse effects in all parameters observed up to 2000 mg/kg bw/d based on the 25% aqueous solution. This corresponds to 500 mg/kg bw/d water-free substance. Based on the absence of any adverse effects it is quite unlikely that severe effects would have been detected with a test dose of 1000 mg/kg bw/d based on the water-free substance.The DNELs and consequently the risk assessment is based on a NOAEL of 500 mg/kg bw/d (water-free substance) which is a worst case NOAEL.*"

ECHA considers that effects observed up to the limit dose/effective concentration of 1000 mg/kg bw/d might require classification as "toxic to reproduction" according to the CLP Regulation (EC/1272/2008). Therefore, the highest test dose of effectively 500 mg/kg bw/d is not a worst-case. The stabilising function of water is superseded by its function as vehicle in the administration as a test material, and you have not demonstrated that effective doses up to 1000 mg/kg bw/d could not be achieved. Furthermore, ECHA considers that you agree that the highest dose did not induce any toxicity and you have not shown that the aim was to induce toxicity.

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

Information on study design

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 with oral[2] administration of the Substance.

[2] ECHA Guidance R.7a, Section R.7.6.2.3.2.

Appendix C: Reasons to request information required under Annex IX of REACH

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

A Sub-chronic toxicity study (90 day) is a standard information requirement in Annex IX to REACH.

You have provided a key study for this endpoint in your dossier:

ii. Combined sub-acute repeated dose-toxicity and screening for reproductive/developmental toxicity study (2010, OECD TG 422) with 25% substance in water AND

You have provided an adaptation according to Annex XI, section 3.2 (b)in your dossier, and you conclude that "*the substance is manufactured and used under strictly controlled conditions and no significant worker exposure occurs*".

Adaptation according to Annex XI

As explained in Section 1 in the Appendix on Reasons common to several requests your adaptation according to Annex XI Section 3.2(b), as submitted in the dossier and supported with further information in the comments on the draft decision, is rejected.

Test material characterisation

As explained in Section 2 in the Appendix on Reasons common to several requests the test material characterisation, as submitted in the dossier and supported with your comments on the draft decision, does not fulfil the requirements of REACH. The study is therefore rejected. In addition, the following endpoint-specific deficiency has been identified:

Test guideline key parameters

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others

- The highest dose level should aim to induce some systemic toxicity, but not death or severe suffering, or be tested up to a limit dose of 1000 mg/kg bw/d of the Substance;
- At least 10 female and 10 male animals should be used at each dose level (including control group);
- Dosing of the Substance daily for a period of 90 days until the scheduled termination of the study.

The highest dose level in the study (500 mg/kg bw/day) did not induce any systemic toxicity. Therefore, the dose level selection was too low, and the study does not fulfil the criterion set in OECD TG 408. Please refer to ECHAs reasoning for considering water as vehicle in addition to stabiliser, in order to reach higher effective doses, in request B.1 of this decision.

The Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) you have submitted does not have the required exposure duration of 90 days as required in OECD TG 408, because the exposure duration of the screening test as you reported is 39-47 days (for females) and 28 days (for males). Furthermore the organ weight and histopathological investigations in OECD TG 422 are only conducted using 5 animals per sex per group and not 10 per sex per group as in OECD TG 408.

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

Information on the design of the study to be performed

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the substance is a liquid of very low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance

2. Pre-natal developmental toxicity study in one species

A Pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX to REACH.

You have provided a key study for this endpoint in your dossier:

iii. Combined repeated dose-toxicity with the reproduction/developmental toxicity screening test (2010, OECD TG 422) with 25% substance in water AND

You have provided an adaptation according to Annex XI, section 3.2 (b)in your dossier, and you conclude that "*the substance is manufactured and used under strictly controlled conditions and no significant worker exposure occurs*".

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

Adaptation according to Annex XI

As explained in Section 1 in the Appendix on Reasons common to several requests your adaptation according to Annex XI Section 3.2(b), as submitted in the dossier and supported with your comments on the draft decision, is rejected.

Test material characterisation

As explained in Section 2 in the Appendix on Reasons common to several requests the test material characterisation, as submitted in the dossier and in the comments on the draft decision, does not fulfil the requirements of REACH. The study is therefore rejected. In addition, the following endpoint-specific deficiency has been identified:

Key parameters of the test guideline

In order to be considered compliant and enable assessing if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in one species. According to this test guideline structural malformations and variations must be investigated and the highest dose level should aim to induce some developmental and/or maternal toxicity.

You have not provided information following OECD TG 414. Instead, you have provided a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (OECD TG 422). In this study, structural malformations and variations are not investigated as required in the PNDT study (OECD TG 414) and the number of test anmials is too low. Furthermore, the highest dose level in the study (500 mg/kg bw/day) did not induce any developmental and/or maternal toxicity and you have not shown that the aim was to induce toxicity. Therefore, the dose level selection was too low, and the study does not fulfil the criterion set in OECD TG 414. Please refer to ECHAs reasoning for considering water as vehicle in addition to stabiliser, in order to reach higher effective doses, in request B.1 of this decision.

Therefore, this study does not fulfil the information requirement.

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

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[3] administration of the Substance.

3. Long-term toxicity testing on aquatic invertebrates

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

You have adapted this information requirement based on Annex IX, Section 9.1., Column 2, stating that "*According to column 2 of Annex IX of Regulation (EC) 1907/2006 this study has not been conducted since the chemical safety assessment indicates no need to further investigate the effects on aquatic organisms.*"

Under Section 9.1., Column 2, Annex IX to REACH, the study may be omitted if the CSA demonstrates that risks towards the aquatic compartment arising from the manufacture and use of the substance are controlled (Annex I, Section 0.1). The justification for this adaptation must be documented in the Chemical Safety Report (CSR) and include all the following elements:

- the predicted no effect concentrations (PNEC) for the aquatic compartment which must be based on:
  - reliable information on the hazardous properties of the Substance on at least three trophic levels,
  - an appropriate assessment factor (AF) (ECHA Guidance R.10, Section R.10.3),
- a quantitative exposure assessment which leads to derivation of predicted environmental concentrations (PECs),
- the outcome of the risk characterisation ratio (RCR) which demonstrates that the risks are adequately controlled (*i.e.* PEC < PNEC).

As concluded in the respective sections above and below, the information requirement for the growth inhibition study aquatic plants is not fulfilled. Hence your dossier currently does not include adequate information for the Substance on at least three trophic levels to characterize the hazard property (aquatic toxicity) of the Substance.

Therefore, a reliable PNEC cannot be derived and your CSA does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

In your comments on the draft decision you note that the need to conduct long-term ecotoxicological studies with the Substance is not justified for the following reasons:

- the dataset from acute toxicity data is or will be sufficient for evaluation of environmental risk;
- the Algae toxicity test is proposed to be redone, as Algae proofed to be the most sensitive species based on the acute dataset. The Algae NOEC (no-observed effect concentration) also represents a long-term toxicity value as more than one generation of Algae is exposed during the test duration of 72 hours. It is thus not expected based on the acute dataset that long-term fish or long-term *Daphnia* studies will result in lower NOECs as compared to the Algae toxicity test and will in conclusion neither affect the classification nor risk assessment of the substance;
- PNECs will be updated as soon as the new Algae test result is available. With these PNECs and considering the strictly controlled conditions under which the substance is used only very low risk characterisation values (below 0.1) were calculated. Thus, an exposure based waiving due to the strictly controlled conditions as described in the document provided together with comments on the draft decision is valid. A waiving

[3] ECHA Guidance R.7a, Section R.7.6.2.3.2.

of this endpoint is thus possible in accordance with REACH Annex XI, Section 3.2(b) (exposure based waiving);
- Based on its physical/chemical parameters like low Kow (-1.01) and high water solubility (completely miscible in water), the substance is not expected to cause long-term ecotoxicological effects. If reaching the environment, which is highly unlikely due to the strictly controlled conditions, it is quickly distributed and diluted. Bioaccumulation and absorption to sediment and soil can be excluded. In addition, based on the available biodegrdation results (which are proposed to be redone) the substance shows at least inherent biodegradation which further supports the fact that long-term ecotoxicity is not to be expected.

As already noted above in the Appendix on Reasons common to several requests, section 1, the second criterion of Annex XI, Section 3.2(b) requires a demonstration that "throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f)" (including the waste stage as explained in ECHA Guidance, R.5) apply. Your description of the strictly controlled conditions is provided only for the manufacture stage of the life-cycle of the Substance. There is, at least, following information missing in respect of potential releases to environment to justify application of SCCs for manufacture life-cycle stage of the Substance:
- efficiency of removal of residual gases from the "*off gas of reaction step 1*" by scrubber with supporting documented evidence of efficiency of such removal for the Substance;
- how water from the cleaning operations is inspected and what are quantitative results of such inspections;
- it is not clear: if the waste containing the Substance is generated (e.g. whether by-product contains the Substance or filters from the process would be contaminated with the Substance etc.); and how such waste is treated/disposed as only reference to disposal "*according to the permission of the local authorities*", but not the conditions which would justify implementation of SSCs, is given.

For other identified uses of the Substance reported in the CSR attached to your comments on the draft decision you have provided exposure scenarios with emission estimation section which includes justification for release factors to water, air and non-agricultural soil. However, there is no detailed description provided to justify application of SCCs as set in Article 18(4)(a) to (f) for these other uses as well as there is no justification why no release of the Substance is possible from matrix of the polymer. Specific information in relation to fulfilling regulatory requirements concerning SCCs and support documentation reporting SCCs in a registration dossier can be found in the ECHA Guidance on intermediates and Practical Guide 16 on How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID.

Furthermore, as noted on ECHA dissemination website[4] there are other uses than those described in the CSR attached to your comments on the draft decision, including by professional workers and consumers, identified in the registration dossier of one of adressees of the decision, for which application of the SCCs is not claimed and not justified.

Finally, it is not further explained how from the physico-chemical properties of the substance (e.g. high water solubility) it is predicted that "*the substance is not expected to cause long-term ecotoxicological effects*", as for instance there are well soluble in water substances which are toxic to aquatic organisms and have harmonised classification of Aquatic Chronic 1.

Thus, the information requirement is not fulfilled.

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As

[4] https://echa.europa.eu/substance-information/-/substanceinfo/100.019.312

already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section on Growth inhibition study aquatic plants.

4. Long-term toxicity testing on fish

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

You have adapted this information requirement based on Annex IX, Section 9.1., Column 2, stating that "*According to column 2 of Annex IX of Regulation (EC) No 1907/2006 this study has not been conducted since the chemical safety assessment indicates no need to further investigate the effects on aquatic organisms.*"

Under Section 9.1., Column 2, Annex IX to REACH, the study may be omitted if the CSA demonstrates that risks towards the aquatic compartment arising from the manufacture and use of the substance are controlled (Annex I, Section 0.1). The justification for this adaptation must be documented in the CSR and include all the following elements:

- PNEC for the aquatic compartment which must be based on:
  - reliable information on the hazardous properties of the Substance on at least three trophic levels,
  - an appropriate assessment factor (AF) (ECHA Guidance R.10, Section R.10.3),
- a quantitative exposure assessment which leads to derivation of PECs,
- the outcome of RCR which demonstrates that the risks are adequately controlled (*i.e.* PEC < PNEC).

As concluded in the respective sections above, the information requirement for the growth inhibition study aquatic plants is not fulfilled. Hence your dossier currently does not include adequate information for the Substance on at least three trophic levels to characterize the hazard property (aquatic toxicity) of the Substance.

Therefore, a reliable PNEC cannot be derived and your CSA does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

In your comments on the draft decision you provide the same comments as for Long-term toxicity testing on aquatic invertebrates which are addressed in the section above.

Thus, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Section on Growth inhibition study aquatic plants.

Appendix D: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[5].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

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

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

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[6].

[5] https://echa.europa.eu/practical-guides
[6] https://echa.europa.eu/manuals

Appendix E: General recommendations when conducting and reporting new tests for REACH purposes

A. Testing strategy for aquatic toxicity testing

You are advised to consult ECHA Guidance R.7b, (Section R.7.8.5) which describes the Integrated Testing Strategy, to determine the sequence of aquatic toxicity tests and testing needed.

Appendix F: 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 10 April 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA took into account your comments and amended the request(s) and the deadline.

You have provided comments on the draft decision on the substance identity of the test material for the following endpoints: Skin sensitisation (Annex VII, Section 8.3; test methods OECD TGs 442C-E or 429), Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202), *In vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or *In vitro* micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487), *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) and Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203) which has resulted in the original requests being removed from this decision. This information is also available in your updated dossier.

Deadline to submit the requested information in this decision

The timelines indicated in the initial draft decision to provide the information requested in the sections A.1, A.2., B.1. B.2., B.3., C.1 is 12 months and for all the other information is 24 months from the date of adoption of the decision.
In your comments on the draft decision, you requested an extension of the timeline to 30 months. You justified your request with the following arguments, which ECHA has evaluated:

- *"If ECHA should decide to insist on the performance of all(eco-) toxicity studies the Registrant proposes to extend the overall deadline to at least 30 months including the deadline for dossier update."*
- *"Based on our experience CROs are currently very busy with higher tier (eco)toxicological studies (e.g. OECD 408/414, OECD 211/210). It is thus very challenging to find a CRO which can immediately start with the tests after availability of a final decision.In addition, the current situation with the Coronavirus makes it difficult to plan and schedule new tests."*

ECHA considers, you have provided partial justification to extend the deadline, based on laboratory capacity grounds. The deadline of the decision has been amended to 30 months for Sub-chronic toxicity study (90-day), Long-term toxicity testing on aquatic invertebrates and the Long-term toxicity testing on fish.

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 G: List of references - ECHA Guidance[7] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[8]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[9]
Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[7] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[8] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[9] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix H: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

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.