EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 03 June 2021

Addressees
Registrants of Nadiisobutylnaphthalenesulpho as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
16/12/2016

Registered substance subject to this decision ("the Substance")
Substance name: Reaction product of naphthalene, butanol, sulfonated and neutralized by caustic soda
List number: 939-707-2
CAS number: NS

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***11 December 2023***.

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

A. 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

2. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2.)

3. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)

4. Bioaccumulation in aquatic species also requested below (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.)

B. 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 413) by inhalation 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)

5. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: EU C.25./OECD TG 309) at a temperature of 12 °C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

6. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305, aqueous exposure)

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 VIII and 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 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.

For certain endpoints, ECHA requests the same study from registrants at different tonnages. In such cases, only the reasoning why the information is required at lower tonnages is provided in the corresponding Appendices. For the tonnage where the study is a standard information requirement, the full reasoning for the request including study design is given. Only one study is to be conducted; the registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the other registrants under Article 53 of REACH.

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 read-across approach under Annex XI, Section 1.5.

In your comments to the draft decision, you indicate that you intend to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; Annex IX, Section 9.2.1.2.)
- Identification of degradation products (triggered by Annex VIII, Section 9.2.; Annex IX, Section 9.2.1.2.)
- Bioaccumulation in aquatic species (triggered by Annex I, Sections 0.6.1. and 4; Annex XIII, Section 2.1.; Annex IX, Section 9.3.2.)

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

Predictions for environmental fate properties

You propose to predict the degradation and bioaccumulation propertie of the Substance from studies yet to be conducted on the source substance EC No. 939-368-0, which has been requested by ECHA in a separate compliance check decision.

As your strategy relies on a read-across approach and on other information (e.g. *degradation and bioaccumulation studies*) that has not yet been generated, no assessment or conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

However, based on your intention presented in the comments to the draft decisions, the following shortcomings on the read-across and grouping of the approach are noted.

Absence of read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[4]
You intend to provide the above mentioned studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394
[4] ECHA Guidance R.6, Section R.6.2.6.1

provided documentation in your comments on the draft decision as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

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

1. Screening for reproductive/developmental toxicity

Screening for reproductive/developmental toxicity is a standard information requirement in Annex VIII to REACH.

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 adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5 using the following study:

- Combined repeted dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) conducted with Reaction product of naphthalene, propan-2-ol, sulfonated and neutralized by caustic soda, EC No. 939-368-0 ([redacted] 2012)

ECHA has assessed this information and identified the following issue(s):

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have provided a read-across justification document in IUCLID Section 13.

You predict the properties of the Substance from the structurally similar substance: Reaction product of naphthalene, propan-2-ol, sulfonated and neutralized by caustic soda, EC No. 939-368-0, hereafter "the source substance".

You have provided the following reasoning for the prediction of toxicological properties:
"*the main assumption is that the difference of alkyl length of the naphthalene substituent's is not significant in respect of the physico-chemical, ecotoxicological and toxicological properties under consideration based on the fact these two lengths of alkyl chains are short and very close to each other.*"

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which assumes that different compounds have the same type of effects. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

ECHA notes the following deficiencies with regards to the prediction of toxicological properties.

Missing supporting information

According to the ECHA Guidance[5] "*it is important to provide supporting information to strengthen the rationale for the read-across approach. Thus, in addition to the property/endpoint being read-across, it is also useful to show that additional properties, relevant to the endpoint, are also (qualitatively or quantitatively) similar between the source and target chemicals*".

In order to support your claim that your Substance and source substance(s) have similar properties for the endpoints under consideration in the read-across approach, you refer to their genotoxicity and repeated dose toxicity properties.

Whilst this data set suggests that the substances may have similar properties for genotoxicity and repeated dose toxicity, these studies do not inform on the sexual function, fertility and developmental properties of the target and source substances. Therefore, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substance(s) to support your read-across hypothesis.

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

Therefore the information requirement is not fulfilled.

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

Study design

Oral route is the "default" route for the detection of reproductive hazard, except for gases[5]. Therefore, 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[6] administration of the Substance.

2. Simulation testing on ultimate degradation in surface water

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII, Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - it is not readily biodegradable (*i.e.* <60% degradation in an OECD 301 B), and
  - it shows <70% degradation within 28 days in an inherent biodegradation test OECD 302B;
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:

[5] ECHA Guidance R.6, Section R.6.2.2.1.f
[6] ECHA Guidance R.7a, Section R.7.6.2.3.2.

- for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid;

Your registration dossier provides the following:

- The Substance is not readily biodegradable based on a study on an analogue substance 939-368-0 (0% degradation after 29 days in OECD TG 301 B);
- The Substance is not inherently biodegradable based on a study on an analogue substance 939-368-0 (27% degradation after 28 days in OECD TG 302 B);
- The Substance is a surfactant and therefore high potential for bioaccumulation cannot be excluded based on available information;

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the bioaccumulation potential of the Substance (see Appendix B, Section 5 of this decision)

The information above indicates that the Substance is a potential PBT/vPvB substance. Furthermore, you conclude in your PBT assessment that *"As the substance was found to be not readily biodegradable, it is not possible to conclude on its persistency in the environment."*

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

The examination of the available information or adaptations, and your comments on the draft decisison as well as the selection of the requested test and the test design are addressed respectively in Section B.5.

3. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

As already explained under Section A.2, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have not provided information on the identity of transformation/degradation products for the Substance.

On this basis, the information requirement is not fulfilled.

The examination of the available information or adaptations, and your comments on the draft decisison as well as further information on the selection of the approach to generate this information are addressed in Section B.6.

4. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is required for the purpose of PBT/vPvB assessment (Annex I, Sections 0.6.1 and 4 to REACH).

Annex I, Section 4 requires that the CSA includes the PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) assessments.

In accordance with Annex XIII, Section 2.1., if the result of the screening tests or other information indicate that the substance may have PBT or vPvB properties, further testing on bioaccumulation as set out in Annex XIII, Section 3.2 is required.

As described above in Section A.2, screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties. The available screening information is not sufficient to conclude on the B/vB properties of the Substance, and therefore further testing is required.

The examination of the available information or adaptations, and your comments on the draft decisison as well as the selection of the requested test and the test design are addressed in Section B.7.

Appendix B: 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.

To be considered compliant with the endpoint, you need to submit a study performed according to the OECD TG 413, or a valid adaptation according to either the specific rules of Column 2, Annex IX, Section 8.6.2. or the general rules of Annex XI.

You did not submit any information for the endpoint 'Sub-chronic toxicity study (90 day)'. Hence the information requirement is not met for this endpoint.

In your comments to the draft decision you agree that information on the Sub-chronic toxicity must be submitted for an Annex IX of REACH and you propose to cover this information requirement according to Annex XI, Section 1.5, (grouping and read-across) of the REACH Regulation using data from substance EC: 939-368-0, as source substance. ECHA understands that you intend to use the 90-day repeated dose inhalation study, available for the source substance, together with the (28-day) inhalation studies, available for the Substance and the source substance, as bridging studies to support the read across.

ECHA notes that neither the source nor the supporting studies with the proposed source substance are reported in the technical dossier or in your comments. Therefore, ECHA cannot evaluate the adequacy and reliability of those studies. In addition, in your comments you also did not provide any new justification on your intended read-across approach for this endpoint. In the absence of such information, ECHA is not in a position yet to assess or conclude on the compliance of the read across adaptation. Therefore, the information requirement is not fulfilled. You remain responsible for complying with this decision by the set deadline.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the inhalation route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is solid, classified as irritating to the eyes and the information provided on the uses and human exposure indicate potential exposure to dust of inhalable size.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 413, in rats and with administration of the Substance by inhalation.

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 developmental toxicity study (OECD TG 414) in rats ([redacted] 1995) conducted with sodium diisobutylnaphtalene sulfonate (CAS No. 91078-64-7 referring to EC No. 293-346-9).

While you have not identified this information as a read-across approach, the test material used (hereafter referred to as the "source substance") and reported in the technical dossier corresponds to information obtained from a different substance than the substance subject to this decision. Therefore, the provided studies conducted with CAS No. 91078-64-7 will be evaluated as a read-across adaptation under Annex XI, Section 1.5 of REACH.

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You have not provided a read-across justification document.

You predict the properties of the Substance from the substance: Reaction product of naphthalene, butanol, sulfonated and neutralized by caustic soda; sodium diisobutylnaphtalene sulfonate, EC No. 293-346-9 (CAS No. 91078-64-7; i.e. the source substance).

ECHA notes the following decficiencies with regards to the prediction of toxicological properties.

Absence of read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).[7]

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

In your comments to the draft decision, you claim that the Substance is the same as the source substance EC: 293-346-9.

ECHA notes that the source substance (EC: 293-346-9) and your Substance (EC: 939-707-2) have been registered as two different substances (with two separate registrations). In order to be considered as "same" substances, there must be an agreement by the two registrants on the sameness of the substances. This is important, as there are certain regulatory consequences once the sameness of the substances is confirmed, including data sharing obligations and no duplication of animal testing. Currently, such an agreement has not been provided, therefore, ECHA does not consider that the source substance (EC: 293-346-9) is the same as your Substance. Consequently, the use of data for the source substance, in order to predict the relevant property of your Substance, requires a read-across justification, which is currently not provided.

[7] ECHA guidance Chapter R.6, Section R.6.2.6.1

Therefore the information requirement is not fulfilled.

Study design

Oral route is the "default" route for the detection of reproductive hazard, except for gases[8]. A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[9] 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.).

In your dossier you have provided a justification to omit the study. In support of your adaptation, you provided the following justification: *"Based on the Chemical risk assessment of the substance, there is no need to investigate biodegradation in a simulation tests, considering that for all the uses of the substance all the risks in the compartments of environment are controlled."*

In your comments you state that the Chemical Safety Assessment do not indicate the need to investigate further the effects on aquatic organisms, since the uses of the substance were demonstrated to be safe (RCR<1) and the substance is not PBT/vPvB.

We have assessed this information and identified the following issue:

In general, a registrant may adapt the standard testing regime in accordance with the specific rules set out in column 2 of Annexes VII to X (if applicable) or the general rules set out in Annex XI. For the present information requirement, column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to aquatic invertebrates under Column 1 (Decision of the Board of Appeal in case A-011-2018).
Your adaptation does not refer to any of the general adaptation possibilities under Annex XI. It is therefore unclear what adaptation possibility you refer to under Annex XI.

Your adaptation is therefore rejected.

In your comment to the draft decision you firstly disagree to perform the long-term toxicity test on aquatic invertebrates stating that the decision *Decision of the Board of Appeal in case A-011-2018* does not apply to the standard information requirement of Column 1, Section 9.1.5 (Long-term toxicity testing on aquatic invertebrates).

Sections 9.1.5. ('Long-term toxicity testing on invertebrates') and Section 9.1.6. ('Long-term toxicity testing on fish') correspond to standard information requirements falling under Section 9.1. ('Aquatic toxicity') of Annex IX. As a result the provisions of the second column of Annex IX, Section 9.1. apply to both these information requirements. Therefore, the Board of Appeal's interpretation of the second column of Annex IX section 9.1 in its decisions in cases A-010-2018 and A-011-2018 cannot be interpreted as being restricted only to Section 9.1.6. In fact, in its most recent decision in relation to this end-point the Board of Appeal further clarified that there is no explicit wording in column 2 of section 9.1. of Annex IX that could be interpreted as allowing the standard information required in column 1 of section 9.1

[8] ECHA Guidance R.7a, Section R.7.6.2.3.2.
[9] ECHA Guidance R.7a, Section R.7.6.2.3.2.

of Annex IX to be omitted (see paragraph 45 of the Board of Appeal decision of 19 January 2021 in Case A-010-2019).

Therefore, we consider that the second column of Annex IX, Section 9.1. apply also to the information requirement on long-term toxicity testing on aquatic invertebrates and your justification to adapt this information requirement is rejected.

Secondly, in your comments on the draft decision you disagree in general with the Board of Appeal decision A-011-2018, where it was decided that the Column 2 does not allow omitting the need to submit information on long-term toxicity to aquatic organisms under Column 1. You refer to on-going revision work of REACH Annexes VI-XI;

However, irrespective of the possible revision of the REACH Annexes, ECHA has to interpret the information requirements stipulated in the REACH Regulation as they currently are. Moreover, you have not have further substantiated your claim that you disagree with the decision of the Board of Appeal in case A-011-2018 which has been confirmed also in its recent decision in case A-010-2019, as explained above.

On this basis, the information requirement is not fulfilled.

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 provided a justification to omit the study. In support of your adaptation, you provided the following justification: "*Based on the Chemical risk assessment of the substance, there is no need to investigate biodegradation in a simulation tests, considering that for all the uses of the substance all the risks in the compartments of environment are controlled*".

In your comments you state that the Chemical Safety Assessment do not indicate the need to investigate further the effects on aquatic organisms, since the uses of the substance were demonstrated to be safe (RCR<1) and the substance is not PBT/vPvB.

We have assessed this information and identified the following issue:

In general, a registrant may adapt the standard testing regime in accordance with the specific rules set out in column 2 of Annexes VII to X (if applicable) or the general rules set out in Annex XI.
For the present information requirement, column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

Your adaptation does not refer to any of the general adaptation possibilities under Annex XI. It is therefore unclear what adaptation possibility you refer to under Annex XI.

Your adaptation is therefore rejected.

Furthermore, in your comments on the draft decision you provide similar justification as specified under request A.2 above, in which you disagree with the Board of Appeal decision A-011-2018 on the interpretation Column 2, Section 9.1 of Annex IX, without being aware of the on-going revision work of REACH Annexes.

As explained under section A.2 above, ECHA has to interpret the information requirements stipulated in the REACH Regulation as they currently are. Moreover, you have not have further substantiated your claim that you disagree with the decision of the Board of Appeal in case A-011-2018 which has been confirmed also in its recent decision in A-010-2019.

Finally, you refer to the fact that *"the Decision of the Board of Appeal in case A-011-2018 is not consistent with the inner spirit of the REACh Regulation as to promote the replacement, reduction or refinement of animal testing (REACH Article 13, Paragraph 1)".*

Article 13(1) specifies that information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met.

The Decision from the Board of Appeal in case A-011-2018 does not impact the provision set in Annex XI. Your arguments on replacement, reduction or refinement of animal testing do not refer to any of the general adaptation possibilities under Annex XI. Minimisation of vertebrate animal testing is not provided for as an adaptation possibility under the general rules for adaptation set out in Annex XI. It is therefore unclear what adaptation possibility you refer to under Annex XI.

On this basis, 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.).

5. Simulation testing on ultimate degradation in surface water

Simulation testing on ultimate degradation in surface water is an information requirement under Annex IX to REACH (Section 9.2.1.2.).

You have provided the following information:

i. an adaptation under Annex IX, Section 9.2., Column 2 with the following justification: *"Based on the Chemical risk assessment of the substance, there is no need to investigate biodegradation in a simulation tests, considering that for all the uses of the substance all the risks in the compartments of environment are controlled."*

We have assessed this information and identified the following issues:

Under Section 9.2., Column 2 of Annex IX to REACH, the study may be omitted if the chemical safety assessment (CSA) does not indicate the need for further biotic degradation testing. The CSA does indicate such need (Annex I, Section 4; Annex XIII, Section 2.1) if, for instance, the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4).

As described above in Section A.2, screening information provided in your dossier indicates that the Substance may have PBT/vPvB properties.

Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing and your adaption is rejected.

In your comments on the draft decision, you do not agree to perform the requested study. Instead, you indicate to cover this information requirement according to Annex XI, Section 1.5, (grouping and read-across) of the REACH Regulation.

To conclude on the PBT/vPvB properties of the Substance, you propose to predict its degradation properties from a source study that has yet to be conducted on the source substance (EC 939-368-0) using the following stepwise approach:

1. to conduct an enhanced biodegradability test extended to 60 days;
2. to generate bioaccumulation data on the Substance if the enhanced biodegradability test will show that the Substance is mineralized by less than 60% in 60 days;
3. to investigate the degradation properties of the Substance in a surface water simulation test according to OECD 309 (including the identification of the degradation products) if the Substance is concluded B or vB.

With regard the bioaccumulation testing strategy, the comments are addressed under Section 7 of this Appendix.

We have assessed the comment with regards to simulation testing requested and identified the following issue:

A. *Regarding your adaptation Annex XI, Section 1.5, (grouping and read-across)* as explained in the Appendix on Reasons common to several requests. ECHA cannot take a position on the compliance of your approach. You remain responsible for complying with this decision by the set deadline.

B. *With regard to the stepwise approach:*

1. *Enhanced Biodegrdation Screening Tests:* Prolongation of the test duration of ready biodegradability testing should only be considered if some initial, slow but steady, biodegradation was observed but did not reach a plateau by the end of the ready biodegradability test, i.e. after 28 days. However a late acceleration of biodegradation is likely to reflect an adaptation of the microorganisms and in that case the prolongation of the test duration should not be regarded as adequate for the P/vP assessment (ECHA guidance R.7.9.4.1.).

   In your comments, you acknowledge that during the standard ready biodegradability test no biodegradation was observed with the Substance (0% after 28 days).

   This information indicates that the extension of the test duration would result in an adaptation of the micro-organisms and therefore this information is not adequate to conclude on the P/vP properties for the Substance

   Furthermore, Identification of the PBT/vPvB-properties must take account of relevant constituents of a substance and relevant transformation and/or degradation products (Annex XIII of REACH). Ready biodegradability tests are intended for pure substances and are generally not applicable for complex compositions containing different types of constituents, like UVCB. For an UVCB substance, observed biodegradation may indeed represent the biodegradation of only some constituents (ECHA Guidance R.7.9.4.1.).

   The Substance is a UVCB and you propose to perform a prolonged ready biodegradation study on the Substance to conclude that that the Substance is not P/vP.

   Based on the enhanced biodegradation test it cannot be excluded that some constituents or relevant transformation/degradation product may be P/vP, even if

the study would show that the Substance mineralizes more than 60%. Therefore, on its own this information is not adequate to conclude on the PBT/vPvB properties of the Substance.

Based on the above, ECHA disagrees with your proposal to perform an enhanced biodegradability test to decide if further testing is needed.

2. *With regard to the bioaccumulation testing proposal: see Section 7 of this Appendix*

3. *With regard to the performance of the simulation test as the last step*

When for several PBT properties further information is needed, the assessment should normally focus on clarifying the potential for persistence first. When it is clear that the P criterion is fulfilled, a stepwise approach should be followed to elucidate whether the B criterion is fulfilled, eventually followed by toxicity testing to clarify the T criterion (ECHA Guidance R.11.4.1).

In a third step, you propose to investigate the degradation of substance only as a very last resort.

As already explained above, the information available in the dossier Substance have already indicated the PBT/vPvB potential of the Substance, therefore your proposal to perform the persistency testing last is not in line with ECHA Guidance on PBT assessment.

On this basis, the information requirement is not fulfilled.

Study design

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

You must perform the test, by following the pelagic test option with natural surface water containing approximately 15 mg dw/L of suspended solids (acceptable concentration between 10 and 20 mg dw/L) (ECHA Guidance R.11.4.1.1.3.).

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 309.

As specified in ECHA Guidance R.7.9.4.1., the organic carbon (OC) concentration in surface water simulation tests is typically 2 to 3 orders of magnitude higher than the test substance concentration and the formation of non-extractable residues (NERs) may be significant in surface water tests. Therefore, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents. By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be

regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 309; ECHA Guidance R.11.4.1.).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the persistence of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

6. Identification of degradation products

Identification of degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

You have provided no information on the identity of transformation/degradation products for the Substance.

Therefore, this information requirement is not met.

This information is required for the purpose of the PBT/vPvB assessment (Annex I, Section 4) and the risk assessment (Annex I, Section 6) of the Substance.

In your comments to the draft decision, you do not agree to generate further data on the identification of degradation products. Instead, you indicate to cover this information requirement according to Annex XI, Section 1.5, (grouping and read-across) of the REACH Regulation, and therefore you will investigate the degradation products only if the P/vP and B/vB properties are confirmed through the stepwise approach proposed in this Appendix, Section 4 above.

ECHA acknowledge you intention to predict further data on the persistency properties of the Subsatnce from the source study that will be performed on the source substance (EC 939-368-0). However as explained in Section 5 and 7 of this Appendix, and in the Appendix on Reasons common to several requests, ECHA disagrees with your stepwise proposal and cannot take a position on the compliance of your approach.

On this basis, the information requirement is not fulfilled.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation study requested in Section B.5 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested study according to OECD TG 309 (Section B.5) must be conducted at 12°C and at a test concentration < 100 µg/L. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline, *e.g.* 20°C) and at higher application rate (*i.e.* > 100 µg/L).

7. Bioaccumulation in aquatic species

Bioaccumulation in aquatic species is a standard information requirement under Annex IX to REACH (Section 9.3.2.).

You have provided the following information:

i. an adaptation under Annex IX, Section 9.3.2., Column 2 with the following justification: the Substance has low potential for bioaccumulation.

We have assessed this information and identified the following issue:

Under Section 9.3.2., Column 2, first indent of Annex IX to REACH, the study may be omitted if the substance has a low potential for bioaccumulation and/or a low potential to cross biological membranes. A low log Kow (*i.e.* log Kow < 3) may be used to support low potential for bioaccumulation if the partitioning of to lipids is the sole mechanism driving the bioaccumulation potential of a substance. For some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes). For this reason log Kow is not considered a valid descriptor of the bioaccumulation potential for such substances (ECHA Guidance R.7c, Appendix R.7.10-3).

Your registration dossier provides an adaptation stating that the log Kow is < 3 and the Substance is not bioaccumulative.

The Substance is a surfactant (surface tension 52.2 mN/m (OECD TG 115)) and thus, based on high surface activity, it may react with cell membranes.

Therefore, log Kow is not a valid descriptor of the bioaccumulation potential of the Subtance and your adaptation is rejected.

In your comments on the draft decision, you do not agree to perform the requested study. Instead, you indicate to cover this information requirement according to Annex XI, Section 1.5, (grouping and read-across) of the REACH Regulation.

To conclude on the PBT/vPvB properties of the Substance, you propose to predict its degradation properties from a source study that has yet to be conducted on the source substance using the following stepwise approach:
You propose to predict the bioaccumulation property of the Substance from a source study that has yet to be conducted on the source substance (EC 939-368-0) using the following approach:

1- To confirm the P/vP properties of the Substance based on enhanced ready biodegradability test (i.e. only if the results show that the Substance is mineralized by less than 60% in 60 days).
2- To generate information on bioaccumulation potential, you do not intend to conduct the requested study but to provide an adaptation under Annex XI, section 1.2 (Weight

of Evidence) with the following supporting sources of information:
- An *in vivo* measured BCF test: *Hyalella Azteca* bioconcentration test
- An In silico predicted BCF

We have assessed the above comment and identified the following issue:

A. Regarding your adaptation Annex XI, Section 1.5, (grouping and read-across)
As explained in the Appendix on Reasons common to several requests. ECHA cannot take a position on the compliance of your approach. You remain responsible for complying with this decision by the set deadline.

B. With regard to testing strategy

1- Bioaccumulation in aquatic species is a standard information requirement at Annex IX, Section 9.3.2. In general, a registrant may adapt the standard testing regime in accordance with the specific rules set out in column 2 of Annexes VII to X (if applicable) or the general rules set out in Annex XI. For the present information requirement, Column 2 stipulates that the study need not be conducted if the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes, or direct and indirect exposure of the aquatic compartment is unlikely.

As the second step in your proposed testing strategy presented in the comments on the draft decision, you propose to investigate bioaccumulation potential in case the substance is mineralized by less than 60% in the enhanced ready biodegradability test. Your proposed strategy does not refer to any of the general adaptation possibilities under Annex XI.

Degradation of the Substance is not an adaptation possibility under the specific or general rules for adaptation set out in Annex IX section 9.3.2 and in Annex XI. Therefore, a ready biodegradation study cannot be used to adapt this information requirement.

2- In the absence of the above information and of a documentation of the proposed weight of evidence, ECHA cannot currently take a position of the validity of the proposed approach. However, ECHA emphasizes that, as specified under Annex IX, Section 9.3.2, Column 1 and in conjunction with Article 13(3), bioaccumulation in fish is the preferred test to investigate the bioaccumulation properties of a substance. If weight of evidence approach is applied, it must also fulfil the requirements of Annex XI Section 1.2.ECHA will assess its compliance in the follow-up to the dossier evaluation.

On this basis, the information requirement is not fulfilled.

Study design

Bioaccumulation in fish: aqueous and dietary exposure (Method EU C.13 / OECD TG 305) is the preferred test to investigate bioaccumulation (ECHA Guidance R.7.10.3.1.). Exposure via the aqueous route (OECD TG 305-I) must be conducted unless it can be demonstrated that:
- a stable and fully dissolved concentration of the test substance in water cannot be maintained within ± 20% of the mean measured value, and/or
- the highest achievable concentration is less than an order of magnitude above the limit of quantification (LoQ) of a sensitive analytical method.

This test set-up is preferred as it allows for a direct comparison with the B and vB criteria of Annex XIII of REACH.

You may only conduct the study using the dietary exposure route (OECD 305-III) if you justify and document that testing through aquatic exposure is not technically possible as indicated above. You must then estimate the corresponding BCF value from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

Under Annex XIII, you must assess the PBT/vPvB properties of the relevant constituents of the Substance. Therefore, the bioaccumulation of each relevant constituent present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable must be assessed. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

Appendix C: 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[10].

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:
   a) the variation in compositions reported by all members of the joint submission,
   b) the boundary composition(s) of the Substance,
   c) 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*
   a) 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.
   b) 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[11].

[10] https://echa.europa.eu/practical-guides
[11] https://echa.europa.eu/manuals

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

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

In particular, you are advised to first conclude whether the Substance fulfils the Annex XIII criteria for P and vP, and then continue with the assessment for bioaccumulation. When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

B. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (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.

Appendix E: 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 17 December 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA took into account your comments and did not amend the requests or the deadline.

> In the draft decision communicated to you, the time indicated to provide the requested information was 27 months from the date of adoption of the decision. In your comments on the draft decision, you requested ECHA to extend the standard granted time to a total of 36 months to allow time to perform the bioaccumulation test, using an alternative method (i.e. *Hyalella azteca* Bioconcentration test, HYBIT) as a part of Weight of Evidence instead of the OECD TG 305 requested in the draft decision. You considered that the extension of 36 months is needed because the test guideline is supposed to be released only in Q1 2022 (According to the Work Plan for the Test Guidelines Programme provided as a reference in you comment).
>
> ECHA sets deadlines to provide the studies requested in a decision. You have not provided any justification that would explain why the deadline set in this decision would not allow you to perform the requested bioaccumulation study. Therefore ECHA considers that the deadline set allows you to perform the requested studies to meet the information requirements addressed in this decision.
>
> On this basis, ECHA has not modified the deadline to provide the information.

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 F: List of references - ECHA Guidance[12] 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)[13]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[13]

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[14]

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

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

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 G: 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]

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.