~~Confidential~~

Helsinki, 03 June 2021

Addressees
Registrant of JOINT_ANS_IP as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
28 May 2018

Registered substance subject to this decision ("the Substance")
Substance name: Naphthalenesulfonic acid, bis (1-methylethyl)-, Me derivs., sodium salts
EC number: 272-715-8
CAS number: 68909-82-0

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 ***10 June 2024***.
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. 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)

2. If negative results are obtained in tests performed for the information requirement of Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2. then: In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490

3. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: OECD TG 203)

4. Simulation testing on ultimate degradation in surface water (triggered by Annex VIII, Section 9.2.; 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.

5. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: OECD TG 309)

6. Bioaccumulation in aquatic species (triggered by Annex I, sections 0.6.1. and 4.; Annex XIII, Section 2.1.; test method: OECD TG 305)

Reasons for the requests are explained in the following appendix/appendices:

- Appendix entitled "Reasons common to several requests";
- Appendix entitled "Reasons to request information required under Annex VIII 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.

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 read-across approach under Annex XI, Section 1.5.

You seek to adapt the information requirements for the following standard information requirements by grouping substances in the category and applying a read-across approach in accordance with Annex XI, Section 1.5:

- *In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)*
- *In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)*
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

ECHA has considered the scientific and regulatory validity of your grouping and read-across approach in general before assessing the specific standard information requirements in the following appendices.

Grouping of substances and read-across approach

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 (addressed under 'Scope of the grouping'). 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 (addressed under 'Assessment of prediction(s)').

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

A. Scope of the grouping

In your registration dossier you have formed a group (category) of Alkyl Naphthalene Sulfonates (ANS). You have provided a justification document [redacted] in IUCLID Section 13. In this document you have addressed chemical and structural considerations, toxicokinetics and toxicological properties of the substances. You have also provided a data matrix on physico-chemical and (eco)toxicological properties of the substances.

In the read-across justification document you list the substances below as members of the ANS category:

- Naphthalene sulfonic acid, reaction products with isobutanol,sodium salts (ANS DIB) (EC: 947-977-8)
- Reaction products of aromatic hydrocarbons, C10-13 with branched nonene, sulfonated, sodium salts (ANS N), EC: 800-660-7, CAS: 1258274-08-6, hereafter the "source substance"
- Naphthalenesulfonic acid, bis(1-methylethyl)-, Me derivs., sodium salts (ANS IP), EC: 272-715-8, CAS: 68909-82-0, hereafter the Substance
- Naphthalenesulfonic acid, butyl-, Me derivs., sodium salts (ANS B), EC: 272-716-3, CAS: 68909-83-1
- Naphthalenesulfonic acid, dibutyl-, Me derivs., sodium salts (ANS DB), EC: 272-717-9, CAS: 68909-84-2

You have provided the following reasoning for the grouping:

All members are produced following a similar production process (starting material [redacted]) "*leading to a* [redacted]. *The structural variation between the products is mainly related to the attached alkyl chains*".

Further you state that "*The main components consist of* [redacted]

ECHA understands that this is the applicability domain of the grouping and your predictions are assessed on this basis.

B. Predictions for (eco)toxicological properties

You have provided the following reasoning for the prediction of (eco)toxicological properties:

"*Read-across is based on structural similarity, physico-chemical properties, comparable mechanistic and endpoint specific profiling and a common MoA for all involved structures*".

You have supported your reasoning with a data matrix, presented in Appendix 3 of your category justification document.

You use the following assumptions to support the prediction of properties of the Substance from data for the source substances:

- "*All ANS have similar chemical structures that contain the same functional groups*" and that "*The only difference consists of some difference in length of the chains that are attached to the rings, with variation involving C3 (isopropyl), C4 (sec.butyl and butyl) and C9 (branched nonyl*)."
- You state that the substances have "*similar bioavailability and metabolic profile*"
- The substances show similar (eco)toxicological properties and you intend to use "*[...] the data from the substances showing the highest toxicity thus represents a worst case approach in the risk assessment of the other ANS".*

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 based on a worst-case approach.

For prediction of the toxicological properties you state that "*At most the results might indicate that toxicity increases with increasing alkyl and/or sulfonate substitution. (ANS B and ANS IP have on average around C7 of alkyl substitution and a 1.2 sulfonation ratio, whereas the ANS N ('high nonene') has an average around C4 alkylation, and 1.0 sulfonation ratio.)".*

Based on this hypothesis, you intend to predict the toxicological properties for the category members from information obtained from EC: 800-660-7 (ANS N; source substance)

For prediction of the ecotoxicological properties you state that "*Based on the available ecotoxicity data the high nonene is representing the worst-case in relation to ecotoxicity and fate for all other members in the category. Read across from the high nonene product to the*

other members for which certain ecotoxicity data is missing can be considered as a worst-case approach and for this reason justified".

You intend to predict the aquatic toxicity properties of the Substance from information obtained from the source substance.

ECHA notes that with regards to prediction(s) of (eco)toxicological properties there are issues that are common to all information requirements under consideration, common to some information requirements and also issues that are specific for these information requirements individually. Altogether they result in a failure to meet the requirement of Annex XI, 1.5. The common issues are set out here, while the specific issues are set out under the information requirement(s) concerned in the Appendices below.

A. Characterisation of the group members/source substance(s)

Annex XI, Section 1.5 of the REACH Regulation provides that *"substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of chemical similarity may be considered as group."*

According to the ECHA Guidance, *"in identifying a category, it is important that all potential category members are described as comprehensively as possible"*, because the purity profile and composition can influence the overall toxicity/properties of the potential category members.[2] Therefore, qualitative and quantitative information on the compositions of the category members should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, the provided information for categories consisting of UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances needs to include qualitative compositional information of the individual constituents of the category members; as well as quantitative characterisation in the form of information on the concentration of the individual constituents of these substances; to the extent that this is measurable.[3]

Your read-across justification document contains, in Appendix 1, compositional information for the members of your category. Your category members are UVCBs consisting of [redacted] In addition, you have reported an [redacted] (ANS N; source substance) to [redacted] (ANS IP, the Substance).

Although you specified most of the components in the composition, the following deficiencies relating to the characterisation of the group members are detected:

- Constituents for which the exact substitution is not defined for instance, for *"group substances"* (e.g. C1-C11; C2-C14): you have not provided information on the distribution of the different alkyl chain substituents and/or on their chemical identity within the blocks (i.e. number and chemical identity of substitutes).
- You have not provided information on the chemical identity of the constituent reported as "[redacted]; source substance) to [redacted] (ANS IP, the Substance) and you did not discuss what would be its impact on the prediction.

[2] ECHA Guidance R.6, Section R.6.2.4.1
[3] ECHA Guidance R.6, Section R.6.2.5.5

Lacking the above information, ECHA cannot establish the similarities/differences of the substances and their impact for the prediction. Without such information, ECHA cannot conclude on the qualitative and quantitative similarity of the compositions of the different category members.

B. Read-across hypothesis

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled to apply grouping and read-across. 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 (read-across approach).

An endpoint-specific read-across hypothesis needs to be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis should be based on recognition of the structural similarities and differences between the substances[4]. It should explain why the differences in the chemical structures and compositions of the substances should not influence their toxicological/ ecotoxicological properties or should do so in a regular pattern.

As indicated above, your read-across hypothesis is based on the assumption that the source substances constitute a worst case for the prediction of the properties under consideration of the Substance. You define the worst case by comparing the structural differences/similarities between the substances based on average alkyl chain length for (eco)toxicological properties and also on degree of sulfonation for toxicological properties.

ECHA notes that when comparing the composition of the substances you did not explain how the average alkyl chain length and degree of sulfonation are determined for each substance e.g. which constituents are used for their calculation. Quantitative and qualitative differences in the compositions of substances, i.e. different combinations of constituents, can lead to the same averages. Average values as provided in your read-across hypothesis do not inform on the combination of constituents that you consider as the worst-case. Therefore you did not explain how the the differences in the chemical structures and compositions of the substances influence their properties according to your hypothesis.

Therefore ECHA considers that your read-across hypothesis does not constitute a reliable basis to predict the properties of the Substance.

Nevertheless, ECHA assessed and identified further deficiencies of your read-across approach under the relevant endpoint sections.

C. Adequacy of the source studies for the prediction of in vitro genotoxicity properties

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across must, among others:

- be adequate for the purpose of classification and labelling and/or risk assessment;
- have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3).

[4] ECHA *Guidance*, Chapter R.6

The *in vitro* ToxTracker studies, used to cover the requirements for *in vitro* cytogenicity (Appendix B, section 1) and *in vitro* gene mutation in mammalian cells (Appendix B., section 2) were not performed according to the testing specifications set out in the corresponding OECD TGs 473/487 and 476/490.

Therefore, the studies are not adequate for the purpose of classification and labelling and/or risk assessment. The specific reasons, and the reflections on your comments to the draft decision on the adequacy of the ToxTracker studies, are explained further below under the reasons given for the relevant information requests in Appendix B. section 1. And Appendix B. section 2.

D. Read-across hypothesis contradicted by existing data for the prediction of short-term toxicity on fish

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and (eco)toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. The ECHA Guidance[5] indicates that "*it is important to provide supporting information to strengthen the rationale for the read-across*". The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the category members. The observation of differences in the toxicological properties between the category members would contradict the hypothesis that the properties of the Substance can be predicted from the data on the source substance(s). An explanation why such differences do not affect the read-across hypothesis needs to be provided and supported by scientific evidence.

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar category members cause the same type of effect(s) and that the source substance constitutes a worst-case for the prediction of the property under consideration of the Substance.

For algae toxicity data you have provided in your dossier the following studies:

- A key study (according to OECD 201; [redacted] 2012), performed on the source substance and for which you have reported an ErC10 = 71.5 mg/L.
- A key study (according to OECD 201; [redacted], 2017), performed on the Substance and for which you have reported an ErC10 = 14.8 mg/L.

The results obtained from the algae study on the Substance indicate a differences with the results obtained from the source substance. While the data of the source substance (considered as the worst case) showed an ErC10 of 71.5 mg/L, the data of Substance showed a lower value of ErC10 = 14.8 mg/L. These results indicate differences in the (eco)toxicological properties of the substances, specifically that the Substance is more toxic than source substance. This contradicts your read-across hypothesis that the structurally similar category members cause the same type of effect(s) and that the source substance constitutes a worst case. You have not provided an explanation supported by scientific evidence on why this contradiction does not affect the predictions.

C. Conclusion on the grouping of substances and read-across approach

As explained above, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. In your comments to the draft decision you recognise the

[5] ECHA Chapter R.6, Section R.6.2.2.1.f

deficiencies and you intend "*to improve the read-across support documentation, addressing the shortcomings mentioned in the draft decision*".

ECHA acknowledges your intention, however in your comments you did not provide any new information to address the identified deficiencies. 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, your adaptation is rejected.

Further specific considerations related to the read-across adaptations are addressed under the individual information requirements.

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

1. In vitro cytogenicity study in mammalian cells or In vitro micronucleus study

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is a standard information requirement in Annex VIII to REACH.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. You have provided:

(i) *In vitro* MN assay (supporting study, according to OECD TG 487, GLP) performed with the source substance giving negative results.
(ii) ToxTracker mechanistic studies performed with the Substance (key study) and with the source substance (supporting study).

As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

In addition ECHA has assessed the provided information and has identified the following deficiencies:

Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should be adequate for the purpose of classification and labelling and/or risk assessment and should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). The key parameters of the OECD TG 473/478 include, among others:

- Detection and quantification of the frequency of cells with structural chromosomal aberration(s) or the frequency of micronuclei in cultured mammalian cells

The ToxTracker mechanistic studies (ii) do not provide such information. Therefore, those studies (ii) performed with the Substance and with the source substance do not have adequate and reliable coverage of the key parameters foreseen to be investigated in the OECD TG 473/478 and are not adequate, on their own, for the purpose of classification and labelling and/or risk assessment.

In your comments to the draft decision you agree that the current information for mutagenicity in the dossier *"[...] is not sufficient to adequately cover the requested endpoints".* In order to address the data gaps, identified by ECHA you express your intention *"to improve the read across support documentation"* by including results from *in vitro* gene mutation study in bacteria for all category members *and "to perform both in vitro micronucleus (MN) test and in vitro mutation in mouse lymphoma (MLA) on some of the substances in the category".* In addition you intend to perform ToxTrackerACE on all substances in the category *"in order to cover the respective endpoints both by read-across and with ToxTrackerACE".*

In your comments to the draft decision you disagree with ECHA's conclusion that the ToxTracker mechanistic studies do not provide adequate information on the required endpoint. You argue that the *"ToxTrackerACE, is an in vitro mammalian cell based assay, that is shown to be capable to identify cytogenic and mutagenic activity by substances at an even better level of predictivity than the commonly applied in vitro micronucleus (MN) test and in*

vitro mutation in mouse lymphoma (MLA)". You further refer to the ECVAM strategy (2013) to avoid and reduce animal use in genotoxicity testing and to the conclusion from Kirkland et al (2007) of "*low specificity of the in vitro mammalian cell tests*". You also state that you intend to perform ToxTracker studies on all substances in the category "*in order to cover the respective endpoints both by read-across and with ToxTrackerACE*".

ECHA acknowledges your intention to improve your read across approach, however in your comments you did not provide any new information or justification. In the absence of such information, no assessment or conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

With regard to your intention to perform ToxTracker studies on all substances in the category, ECHA points out that it is at your discretion to generate such data. Further, ECHA points out that ToxTracker test is not yet a validated OECD study. Therefore ECHA reiterates that it cannot be used, on its own, to cover the standard information requirements for this endpoint.

Therefore, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, both *in vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method OECD TG 473) and *in vitro* micronucleus study (Annex VIII, Section 8.4.2., test method OECD TG 487) are considered suitable.

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is a standard information requirement in Annex VIII to REACH in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Triggering of the information requirement

Your dossier contains a negative result for *in vitro* gene mutation study in bacteria with the Substance (Annex VII, Section 8.4.1.) and inadequate data for an *in vitro* cytogenicity study in mammalian cells with the source substance (Annex VII, Section 8.4.2.) which is rejected for the reasons provided in Appendix B, Section 1.

The results of the requests for information in B.1. will determine whether the present requirement for an *in vitro* mammalian cell gene mutation study in accordance with Annex VIII, Section 8.4.3 is triggered.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. You have provided

(i) *In vitro* gene mutation study in mammalian cells (supporting study, according to OECD TG 476, GLP), performed with source substance giving negative results.
(ii) ToxTracker mechanistic studies performed with the Substance (key study) and with the source substance (supporting study).

As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.

In addition ECHA has assessed the provided information and has identified the following deficiencies:

Adequacy and reliability of source studies

According to Annex XI, Section 1.5., if the grouping concept is applied then in all cases the results to be read across should be adequate for the purpose of classification and labelling and/or risk assessment and should have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). The key parameters of the OECD TG 476/490 include, among others:

- Detection and quantification of gene mutations (point mutations, frame-shift mutations, small deletions, etc.) including data on the frequency of mutant colonies in cultured mammalian cells

The ToxTracker mechanistic studies (ii) do not provide such information. Therefore, those studies (ii) performed with the Substance and the source substance do not have adequate and reliable coverage of the key parameters foreseen to be investigated in the TG 476/490 and are not adequate, on their own, for the purpose of classification and labelling and/or risk assessment.

In your comments to the draft decision you agree that the current information for mutagenicity in the dossier *"[...] is not sufficient to adequately cover the requested endpoints"*. In order to address the data gaps, identified by ECHA you express your intention *"to improve the read across support documentation"* by including results from *in vitro* gene mutation study in bacteria for all category members *and "to perform both in vitro micronucleus (MN) test and in vitro mutation in mouse lymphoma (MLA) on some of the substances in the category"*. In addition you intend to perform ToxTrackerACE on all substances in the category *"in order to cover the respective endpoints both by read-across and with ToxTrackerACE"*.

ECHA acknowledges your intention to improve your read across approach, however in your comments you did not provide any new information or justification. In the absence of such information, no assessment or conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

In your comments to the draft decision you also disagree with ECHA's conclusion that the ToxTracker mechanistic studies do not provide adequate information on the required endpoint. However, as also explained in Appendix A. section 1 above, ECHA reiterates that the ToxTracker study cannot be used, on its own, to cover the standard information requirements for this endpoint.

The information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, both the *in vitro* mammalian cell gene mutation tests using the hprt and xprt genes (OECD TG 476) and the thymidine kinase gene (OECD TG 490) are considered suitable.

3. Short-term toxicity testing on fish

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

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5. You have provided the following study record on the analogue substance:

- Short term study on fish (key study, according to OECD TG 203) with the source substance.

As explained in the Appendix on Reasons common to several requests, your adaptation in accordance with Annex XI, Section 1.5. is rejected.
Therefore, the information requirement is not fulfilled.

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

4. 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).

You have not provided any studies but a claim in your dossier that further degradation studies are not considered necessary since "*The risk assessment of the substance shows no concern for the sediment compartment.*"Also in your comments to the draft decision you mention that the Simulation testing on ultimate degradation in surface water is not required under Annex VIII, Section 9.2.

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 OECD TG 301D),

Your registration dossier provides the following:

- The Substance is potentially P or vP since it is not readily biodegradable (0% degradation after 28 days in OECD TG 301D);

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 in this Appendix, Section 6 of this decision), and

The information above indicates that the Substance is a potential PBT/vPvB substance.

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

In your comments to the draft decision you further point out that based on the results of screening tests, "*it is concluded that ANS-IP is vP (and P) according to Annex XIII of REACH based on the fact that it is inherently biodegradable, not fulfilling specific criteria. Because ANS-IP is considered to be very persistent there is no need to further investigate the degradation Annex IX, Section 9.2.1., Column 2. As it is expected that B-testing will anyway be needed a reverse order of testing may be appropriate as it is expected that this will not*

*lead to more vertebrate testing."*However, for the following reasons ECHA does not agree with your suggestions.

With regard to the Enhanced Biodegradation Screening Tests

Results obtained from screening tests (e.g.: ready biodegradation, tests on inherent biodegradability such as OECD TG 302B) are only regarded as screening information on P/vP properties (Annex XIII, Section 3.1.). Results obtained from higher tier tests (e.g. simulation studies or other information, such as from field studies or monitoring studies) are regarded as assessment information to conclude on P/vP properties (Annex XIII, Section 3.2.).

In your comments to the draft decision, you state that based on the results obtained from ready biodegradability tests and from the SCAS test with the Substance (OECD TG 302A), the Substance may be considered as vP (and P).
The studies that you are referring to are screening studies and do not fall in any of the information set out in Annex XIII, Section 3.2. that would allow to conclude on P/vP. As explained above, the results from screening tests do not allow to conclude that the Substance meets the P/vP criteria.

While the OECD TG 302A study referred to in your comments is not available in the registration dossier, the ready biodegradability study in your dossier shows that the Substance is potentially P/vP as already explained above.

The Substance may have PBT/vPvB properties and you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing. Therefore your adaption is rejected.

With regard to the reverse order of testing proposed

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 your comment, you propose to reverse the order of testing and start to investigate first the bioaccumulation properties of the Substance.

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 bioaccumulation testing first is not in line with ECHA Guidance on PBT assessment.

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.).

5. 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 4 of this Appendix, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have neither provided information on the identity of transformation/degradation products for the Substance in your dossier nor in your comments to the draft decision.

In your comment to the draft decision you have provided the same justification as that provided in Appendix A.4., above. For the same reasons, this adaptation is rejected.

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 Appendix A.4. 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 (Appendix A.4.) 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).

6. 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).

You have provided an adaptation under Annex IX, Section 9.3.2., Column 2 with the following justification: the Substance has low potential for bioaccumulation based on Log Kow below 3.

We have assessed this information and identified the following issue:

Triggering for the test

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species (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 OECD TG 301D).

As indicated under the requests in Appendix A, section 4 the Substance is a potential PBT/vPvB substance.

Therefore, the chemical safety assessment (CSA) indicates the need for further investigation on bioaccumulation in aquatic species.

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 without further explanation.

The Substance is a surfactant (surface tension 50 mN/m), thus it may interact with cell membranes based on chemical structure).

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

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

You propose to predict the bioaccumulation property of the Substance from a source study that has yet to be conducted on the source substance ANS-N (EC No. 800-660-7, CAS No. 1258274-08-6), which has been requested by ECHA in a separate compliance check decision.

You indicate that many constituents present in the source substance (ANS-N) are also present in the Substance. Therefore, you intend to use the BCF results that will be obtained for the constituents of source substance (ANS-N) to assess the bioaccumulation potential of the Substance. With regard to the constituents of the Substance that are not overlapping with the source substance (ANS-N), you intend to predict the bioaccumulation potential using the measured BCFs from the study with the source substance (ANS-N) in combination with *in-silico* methods.

As your strategy relies on a read-across approach and on other information (e.g. *in silico* predictions) that has not yet been fully described nor justified, as well as on data that has not been generated yet, no assessment or conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

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).

Appendix B: 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[6].

B. Test material

The Test Material used to generate the new data must be selected taking into account the following:

a) the boundary composition(s) of the Substance,
b) 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.

1. *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 identify all the constituents as far as possible as well as their concentration (OECD GLP (ENV/MC/CHEM(98)16) and EU Tests Methods Regulation (EU) 440/2008 (Note, Annex). 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[7].

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

Appendix C: 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 D: 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 amended 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 requested studies. You consider that an extension to 36 months is needed to perform consecutive bioaccumulation tests with the source substance considering the complexity of the Substance (UVCB) to be evaluated.
>
> ECHA took this information into account and granted 9 months extension to the original deadline. Therefore, the deadline is set to 36 months.

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 E: List of references - ECHA Guidance[8] 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)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[9]

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[10]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] 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 F: Addressees of this decision and their corresponding information requirements

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.