EUROPEAN CHEMICALS AGENCY

~~Confidential~~

Helsinki, 03 June 2021

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

Date of submission of the dossier subject to this decision
05 April 2019

Registered substance subject to this decision ("the Substance")
Substance name: Reaction products of aromatic hydrocarbons, C10-13 with branched nonene, sulfonated, sodium salts
EC number: 800-660-7
CAS number: 1258274-08-6

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***9 September 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. Simulation testing on ultimate degradation in surface water also requested below (triggered by Annex VIII, Section 9.2.)
2. Identification of degradation products also requested below (triggered by Annex VIII, Section 9.2.)
3. 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. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)
2. 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.
3. Identification of degradation products (Annex IX, 9.2.3.; test method: using an appropriate test method)
4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: OECD TG 305)
5. Long-term toxicity testing on terrestrial invertebrates (test method: OECD TG 222 or 220 or 232) or long-term toxicity testing on terrestrial plants (OECD 208 or ISO 22030) (triggered by Annex IX, Section 9.4.1., column 2)
6. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; nitrogen transformation test, test method: EU C.21/OECD TG 216 and carbon transformation test, test method: EU C.22/OECD TG 217)

Reasons for the requests are explained in the following appendices entitled "Reasons to request information required under Annexes VIII to IX of REACH", respectively.

Information required depends on your tonnage band

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

- the information specified in 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.

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

1. 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 OECD TG 301D), and
- it meets the criteria B/vB as set out in Annex XIII (i.e. BCF > 2 000/5 000);
- it meets the T criteria set in Annex XIII: NOEC or EC10 < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier provides the following :

The Substance is potentially P or vP since it is not readily biodegradable (29% 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 Appendix B.4 of this decision).
- it is not possible to conclude on the toxicity of the Substance (see Appendix B.1 of this decision).

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

In your comments to the draft decision, you stated 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 Persistent.

However, as you have not provided the OECD TG 302A study referred to in your comments neither in the registration dossier nor with your comments, ECHA cannot carry out an independent assessment of the reliability of the information obtained from this study and of the conclusions that you derived from this study.

Furthermore, the ready biodegradation tests or inherent biodegradability (such as OECD TG 302B) are only regarded as screening information on P/vP properties (Annex XIII, Section 3.1. ECHA guidance *R.11.4.1.1*). Only results obtained from higher tier tests (e.g. simulation studies or 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.).

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

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B.2.

2. 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 1 of this Appendix, 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 have provided the same observation as that provided for the request A.1. above.

As already explained above, the screening information indicate the need for further degradation investigation.

The examination of the available information or adaptations, as well as the selection of the requested test and the test design are addressed in Appendix B.3.

3. 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).

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 an OECD 301D);
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as for some groups of substances (e.g. surface active, 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.
- it meets the T criteria set in Annex XIII: NOEC or EC_{10} < 0.01 mg/L or classification as carc. 1A or 1B, muta. 1A or 1B, repro. 1A, 1B or 2, or STOT RE 1 or 2.

Your registration dossier provides the following:

- The Substance is not readily biodegradable (29% degradation after 28 days in OECD TG 301D);
- The Substance is a surfactant (surface tension= 30 mN/m) 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 toxicity of the Substance (see Appendix B.1 of this decision).

The information above indicates that 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.

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 Appendix B.4.

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

1. 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 the following information:

- a justification to omit the study which you consider to be based on Annex IX, Section 9.1, Column 2. In support of your adaptation, you provided the following justification: "*The CSA does not indicate the need for further testing of vertebrates. Moreover, the low bioaccumulative potential does not trigger the need for long-term testing. Therefore long-term toxicity testing with fish is waived*".

We have assessed this information and identified the following issue:

Annex IX, Section 9.1, Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. It must be understood as a trigger for providing further information on long-term toxicity to fish if the chemical safety assessment according to Annex I indicates the need (Decision of the Board of Appeal in case A-011-2018).

Your adaptation is therefore rejected.

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.).

2. 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 not provided any adaptation regarding the simulation testing in surface water, but a general statement: "*Based on the available studies on biodegradation* [of the Substance] *only part of the isomers present in the substance are degraded in sediment i.e. water soluble methylnaphthalenesulphonate, and dimethylnaphthalenesulphonate. Nonyl methylnaphthalenesulphonate and nonyldimethylnaphthalenesulphonate will be recalcitrant in sediment. Further testing in sediment is not expected to deliver more information. For sediment therefore the default half-life value of 30000 days is used for the sediment based on the log Koc of 3.5 until better data become available*".

We have assessed this information and identified the following issue:

To adapt this information requirement, the conditions set-out in either Annex IX, Section 9.2.1.2, Column 2 or the general adaptations set in Annex XI have to be fulfilled.

You have not specified which of the above adaptations you intend to use. The arguments you provided do not fulfil any conditions set in those provisions, therefore they do not constitute a valid adaptation.In your comments to the draft decision you further point out that *based on the results of screening studies"it can be concluded that ANS-N will eventually also be classified as Persistent according to Annex XIII of REACH. Thus, as the ANS-N is persistent or*

very persistent there is no need to further investigate the degradation. 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.

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). 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 criteria already listed in Appendix A.1.
As already explained under Appendix A.1, the results from screening tests do not allow to conclude on the P/vP properties of the Substance and the available information indicates that the Substance is a potential PBT/vPvB substance. Therefore, you have not demonstrated that the CSA does not indicate the need for further biotic degradation testing and your adaption is rejected.

Furthermore, 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 you 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.

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.).

3. Identification of degradation products

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

You have not provided any information on the identity of transformation/degradation products for the Substance in your dossier nor in your comments to the draft decision.

Therefore, this information requirement is not met.

In your comments to the draft decision you have provided an adaptation under Annex IX, Section 9.2., Column 2 with the same justification as that provided in Appendix B.2., above. This adaptation is rejected for the same reasons as indicated under Appendix B.2 above.

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 B.2. 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 (Appendix B.2.) 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).

4. 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 an adaptation under Annex IX, Section 9.3.2., Column 2 with the following justification: *"The log Kow of -3.3 suggests that the substance has a very low bioaccumulation potential".*

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).

You consider that the log Kow of -3.3 indicates that the substance has a very low bioaccumulation potential.

However, the Substance is a surfactant with a surface tension of 30mN/m and 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.

On this basis, the information requirement is not fulfilled.

ECHA understands that you agree to generate further information on the bioaccumulation properties of the Substance in your comments to the draft decision.

Since the Substance is a complex mixture of many constituents, you indicate your intention to conduct bioaccumulation testing following the advice given in ECHA Guidance R.11, Section R.11.4.2.2. In this context you propose to perform an initial profiling of the Substance composition before initiating the bioaccumulation testing. You indicate that you will first perform a bioaccumulation study using the whole Substance (i.e. applying a "whole substance" assessment approach) to be able to select the most relevant fractions of the product. Second, you will consider further bioaccumulation testing on constituents that you will select based on the relevance and representativeness for the overall B assessment of the Substance. You specify that further testing will depend on the results of the initial test and the possibilities to synthesise the different constituents/fractions. However, considering the complexity of the Substance, you expect that the isolation or synthesis of pure relevant constituent(s) may not be technically feasible. On this basis, you state that the "block profiling" or "whole substance" would be the most appropriate assessment approaches.

ECHA agrees that for the assessment of the PBT/vP properties of a UVCB substance the criteria given in ECHA guidance R.11.4.2.2.2 should be followed to select appropriate assessment approach(es). ECHA acknowledges your intention to generate data on the bioaccumulation properties of the Substance and its constituents, using either the "fraction/block profiling" or the "whole substance" approaches. ECHA notes that the approach(es) you will choose must

be clearly justified, as outlined in ECHA Guidance R.11, Section R.11.4.2.2. Issues related to feasibility and/or proportionality of efforts may play a role in the choice of the assessment approach in addition to the technical elements listed under each approach. These must also be duly described, where appropriate.

As indicated in your comments, this strategy relies essentially on data which is yet to be generated, no 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).

5. Long-term toxicity on terrestial invertebrates or Long-term toxicity on terrestrial plants

Effects on terrestrial organisms is an information requirement under Annex IX to REACH (Section 9.4.1.). Long-term toxicity testing must be considered (Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent. A substance is considered to be very persistent in soil if it has a half-life >180 days or, in absence of specific soil data, if it is not readily biodegradable (ECHA Guidance R.7.11.5.3. page 149).

According to the provided information, the Substance is considered to be very persistent in soil (as it is not readily biodegradable, 29% according to OECD 301 D). Therefore, long-term testing is triggered.

You have provided an adaptation under Annex IX, Section 9.4., Column 2 with the following justification: *"According to column 2 of REACH (Regulation 1907/2006/EC) Annex IX, the equilibrium partitioning method may be applied to assess the hazard to soil organisms if actual toxicity data is not available".*

ECHA has assessed this information and identified the following issue:

Under Section 9.4., Column 2 of Annex IX to REACH, in the absence of data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity which rely on the assignment of the Substance to a "soil hazard category" in order to decide what confirmatory toxicity tests must be conducted.

You have conducted an initial screening assessment based on a $PNEC_{screen}$ estimated using the EPM and a quantitative exposure assessment for the soil compartment (PEC_{soil}). This screening assessment does not indicate risks to the soil compartment. You have not provided any confirmatory test (No short or long term toxicity test(s) on terrestrial organisms) to support the outcome of the screening assessment.

Based on the information from your registration dossier, the Substance falls into the hazard category 3 (HC 3) since the Substance is very persistent in soil (as it is not readily biodegradable, as explained above) and the aquatic toxicity data does not screen for being very toxic to aquatic organisms. For this type of substances, ECHA Guidance specifies that a confirmatory long-term terrestrial toxicity test (either on terrestrial invertebrates or on plants) and toxicity testing on soil micro-organisms must be provided to confirm the outcome of the screening assessment.

As you have not provided any confirmatory long-term toxicity test to terrestrial organisms to support the outcome of the screening assessment, you have not demonstrated that toxicity to terrestrial organisms can be safely excluded. Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

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

Study design

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are considered adequate to fulfil the information requirement on long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties.

OECD TG 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Testing must be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD TG 208 guideline.

In the absence of indication of selective toxicity between invertebrates and plants, testing on invertebrates is preferred (ECHA Guidance R.7.11.5.3.).

6. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

Effects on soil micro-organisms is an information requirement under Annex IX to REACH (Section 9.4.2.).

You have provided an adaptation under Annex IX, Section 9.4., Column 2 with the following justification: *"According to column 2 of REACH (Regulation 1907/2006/EC) Annex IX, the equilibrium partitioning method may be applied to assess the hazard to soil organisms if actual toxicity data is not available".*

ECHA has assessed this information and identified the following issue:

Under Section 9.4., Column 2 of Annex IX to REACH, in the absence of data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for soil toxicity which rely on the assignment of the Substance to a "soil hazard category" in order to decide what confirmatory toxicity tests must be conducted.

As already explained in Appendix B.5, the Substance falls into the hazard category 3 (HC 3) and a confirmatory long-term terrestrial toxicity test (either on terrestrial invertebrates or on plants) and toxicity testing on soil micro-organisms must be provided to confirm the outcome of the screening assessment.

As you have not provided any confirmatory toxicity study on soil micro-organisms to support the outcome of the screening assessment, you have not demonstrated that toxicity to terrestrial organisms can be safely excluded. Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

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

Study design

According to ECHA R.7.11.3.1, the nitrogen transformation test (EU C.21/OECD TG 216) is suitable for most non-agrochemicals. However, for agrochemicals the carbon transformation test (EU C.22/OECD TG 217) must also be conducted. Considering that the Substance is used as a fertiliser co-formulant in plant protection products, both tests OECD TG 216 and 217 are required.

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[2].

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[3]

[2] https://echa.europa.eu/practical-guides
[3] 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 amended the requests and 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 the extension of the deadline to 36 months is needed to perform consecutive bioaccumulation tests 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 F: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[5]

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[6]

[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[6] 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 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.