~~Confidential~~

Helsinki, 06 May 2022

Addressees
Registrant of JS_931-371-5 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
30/07/2021

Registered substance subject to this decision ("the Substance")
Substance name: Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-18alkyl derivs.
EC number: 931-371-5

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 following deadlines:

- information listed under A.1., A.2., B.1., C.1. and C.2. by ***13 November 2023***; and
- information listed under C.3. and D.1.-D.2. by ***13 February 2025***.

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

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

1. Long-term toxicity testing on aquatic invertebrates also requested below (triggered by Annex VII, Section 9.1.1., column 2)

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

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

1. Long-term toxicity testing on fish also requested below (triggered by Annex VIII, Section 9.1.3., column 2)

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

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.; test method: OECD TG 210)

3. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216)

D. Information required from all the Registrants subject to Annex X of REACH

1. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test

method: OECD TG 222 or 220)

2. Long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.; test method: OECD TG 208 with at least six species tested or ISO 22030)

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

- Appendix entitled "Reasons common to several requests";
- Appendices entitled "Reasons to request information required under Annexes VII to X 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 to X to REACH, for registration at more than 1000 tpa.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

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

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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

The studies relating to biodegradation 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 Mike Rasenberg, 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. Triggering of long-term aquatic invertebrates and fish toxicity testing

Similar considerations are relevant for the application of the following information requirements, which are therefore addressed here, before addressing endpoint-specific issues in the relevant Appendix:

1. Long-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1., column 2)
2. Long-term toxicity testing on fish (Annex VIII, Section 9.1.3., column 2)

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

You have provided information which indicates that the Substance includes constituents that are poorly water soluble. In the provided OECD TG 105 study you conclude following: "*The mean water solubility of the test substance at 20.0 degrees Centigrade was 3.63 ± 0.15 mg/L […] As shown in Figure 10 (attached), the overall water solubility of the test substance, based upon use of C14-C18 salicylates dissociated from the test substance in water as a surrogate response for the test substance, was due to the relatively large contribution from the earliest eluting (C14 salicylate) component. Water solubility based on the C16 or C18 peaks appeared to be approximately a factor of ten or greater below the values reported.*" This indicates that the constituents with 16 and 18 carbons in the alkyl chain have water solubility below 1 mg/l, ie. are poorly water soluble.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates and fish must be provided.

2. Assessment of information provided on effects on terrestrial organisms

The same deficiencies apply to all the information requirements on toxicity to terrestrial organisms.

- Toxicity testing on soil micro-organisms is an information requirement under Annex IX to REACH (Section 9.4.2.);
- Long-term toxicity testing on soil invertebrates and plants are an information requirements under Annex X to REACH (Sections 9.4.4. and 9.4.6. respectively).

You have provided the following a justification to omit toxicity to terrestrial organisms studies: "*Current practice and risk management measures in use mean that direct or indirect exposure of the soil to test substance is unlikely and, in accordance with Regulation (EC) 1907/2006, in the absence of hazard and exposure justification and a chemical safety assessment it is unnecessary to investigate*" toxicity to terrestrial organisms.

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

a) Rejection of adaptation

According to Annexes IX and X, Section 9.4., Column 2 toxicity testing on terrestrial organisms does not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.

In the registration dossier you have identified a number of various industrial, professional and consumer uses with environmental release categories (ERCs) assigned which indicate potential releases to and/or exposure of the soil compartment. For instance, there are identified uses of the Substance in lubricants and greases used by consumers and professional users with ERC 9b (widespread use of functional fluid (outdoor)) assigned to them. Default worst-case release factor of [redacted] to soil applies to the ERC 9b (ECHA Guidance R.16 (Table R.16-7)), i.e. this indicates the potential of direct soil exposure. Furthermore, default worst-case release factor of [redacted] to water (before waste water treatment plant) applies to the ERC 9b which considering that based on information provided in the dossier the Substance contains poorly soluble in water and highly adsorptive constituents, indirect exposure (e.g. via application of the sewage sludge from municipal waste water treatment plants to the soil) cannot be ruled out.

Moreover, there is no exposure assessment and risk characterisation provided in the chemical safety report which would support your justification that direct/indirect exposure of the soil is unlikely.

In the comments to the draft decision, you propose to support the adaptation by an exposure and risk characterisation (assessment) and if revised "*CSA[2] result in apparent risk to the soil compartment, it is accepted that the required terrestrial toxicity (as listed above[3]) would then be conducted*".

Thus, it is not justified that the direct or indirect exposure of the soil is unlikely and therefore, your adaptation is rejected.

The information in your comments is not sufficient for ECHA to make an assessment because you have only provided the intention to perform exposure assessment and risk characterisation in order to support your adaptation. You remain responsible for complying with this decision by the set deadline.

3. Assessment of your read-across approach under Annex XI, Section 1.5.

You seek to adapt the following standard information requirements by applying (a) read-across approach(es) in accordance with Annex XI, Section 1.5:

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

ECHA has considered the scientific and regulatory validity of your read-across approach(es) 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. 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)').

[2] Chemical Safety Assessment

[3] *C 7. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216) D 1. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: OECD TG 222 or 220) D 2. Long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.; test method: OECD TG 208 with at least six species tested or ISO 22030)*

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[4,5].

A. Predictions for ecotoxicological properties

You have provided a read-across justification document in respective IUCLID sections 5.2.1 and 6.1.4.

You read-across between the structurally similar substances, Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1), EC No. 931-276-9, CAS No. 114959-46-5 as source substance and the Substance as target substance.

You have provided the following reasoning for the prediction of ecotoxicological properties: *"Comparison of overall physico-chemical (and toxicity) profiles for target and source chemicals indicates it is appropriate to apply read-across data from the structural analogue when considering potential for biodegradation/ long-term toxicity to aquatic invertebrate.".*

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

ECHA notes the following shortcoming with regards to predictions of fate and ecotoxicological properties.

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 must:

- 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);
- cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3) if exposure duration is a relevant parameter.

Specific reasons why the studies on the source substance do not meet these criteria are explained further below under the applicable information requirement in Appendix C, Section 1. Therefore, no reliable predictions can be made for these information requirements.

B. Conclusions on the read-across approach

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

4. Proposed read-across approach in the comments to the draft decision

In your general comments to the draft decision you propose all requested testing to be

[4] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[5] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

conducted with the analogue source substance Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1), EC No. 931-276-9 and the results to be read-across to the Substance.

ECHA considers that the proposed read-across approach could fulfil the information gaps. However, it is in your discretion to generate and provide reliable studies with the analogue source substance which would be adequate for the purpose of classification and labelling and/or risk assessment as well as generate and provide the necessary supporting information in order to justify your proposed read-across adaptation to fulfil the information requirements in accordance with the requirements of Section 1.5 of Annex XI to REACH.

Furthermore, it should be noted that the molecular weight of the counter-ion (non-common transformation product) of the source substance(s) should be considered:

- for the selection of the maximum test concentration/dose, in order to ensure that the test concentration/dose of the common anion relevant for the (target) Substance (i.e. expected to be present when maximum concentration/dose of the (target) Substance as required by the test guideline would be present in the test solution) has been reached in the test with the source substance; and
- for the estimation of effect concentration/level for the (target) Substance.

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

1. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided following information on short-term toxicity of aquatic invertebrates:

1) Key study, OECD TG 202.
2) Supporting study with analogue substance Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1), CAS No. 114959-46-5.

We have assessed this information and identified the following issue:

As explained in Section 1 of the Appendix common to several requests, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

The examination of the information provided on long-term toxicity on aquatic invertebrates, comments to the draft decision as well as the selection of the requested test and the test design are addressed under Appendix C, Section 1.

2. Growth inhibition study aquatic plants

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

You have provided the following information:

1) Key study, OECD TG 201.

We have assessed this information and identified the following issues:

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

- the concentrations of the test material are measured at least at the beginning and end of the test:
  1) at the highest, and
  2) at the lowest test concentration, and
  3) at a concentration around the expected EC_{50}.

  For strongly adsorbing test substances, additional samplings for analysis at 24 hour intervals is required.
- analytical monitoring of exposure concentrations must be conducted. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided. The justification must explain why a lower detection limit could not be achieved, i.e. the test solution cannot be analytically measured after the separation of non-dissolved test material (*i.e.* the dissolved concentration is below the limit of detection). It must explain which analytical methods were considered and (not) applied, and justify that there is no adequate analytical method available.
- demonstration that the stock solution preparation method:
  1) is of adequate quality (*e.g.* water solubility limit is reached when targeted), and
  2) allows to produce reproducible stock solutions (*i.e.* acceptable variation between preparations);

Your registration dossier provides the key study showing that no analytical monitoring of exposure concentrations throughout duration of the study was conducted.

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

Furthermore, you note that, as stated in the IUCLID registration dossier, "*prior to the toxicity tests, efforts were made to develop an analytical method using solvent partitioning followed by measurement of UV absorbance, or rotary evaporation and UV absorbance but they were not able to determine test material in a Water Accommodated Fraction.* "

The information in your comments and in the IUCLID dossier does not explain why other analytical methods (e.g. full-scan GC or HPLC indicated in OECD GD 23) could not be employed for analytical monitoring of exposure concentrations. Furthermore, while it is stated in the IUCLID registration dossier that "*The time to equilibration was not demonstrated because the results of the equilibration study (see Appendix D, attached) showed that, even after approximately 96 h stirring, the net Total Organic Carbon (TOC) concentration was less than the limit of determination and the born concentration had not reached equilibrium.*", there is neither Appendix D attached in the dossier nor justification provided which other solution preparation methods were considered and tested.

Thus, the Substance is difficult to test (it is multi-constituent; has constituents which are poorly soluble in water; based on information in the registration dossier there are constituents with Log Kow >5 and constituents with log Koc >4 as well as based on the information on chemical structure of constituents they are expected to be present in ionised forms at environmental pHs between 4 and 9, i.e. they are highly adsorptive; and constituents have potential to bioaccumulate in aquatic organisms as BCFs of constituents are above 1000) and there are critical methodological deficiencies resulting in the rejection of the study results.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

The request in the comments to the draft decision to extend deadline to submit the information requested is addressed under Appendix G below.

Study design

As explained in this section above the Substance is difficult to test. OECD TG 201 specifies that, for difficult to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 201. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solution.

For multi-constituents, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test

(e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

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

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided the following information on short-term toxicity of fish:

1) Key study, OECD TG 203.

We have assessed this information and identified the following issue:

As explained in Section 1 of the Appendix common to several requests, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

The examination of the information provided on long-term toxicity on fish, comments to the draft decision as well as the selection of the requested test and the test design are addressed under Appendix C, Section 2.

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

1. Long-term toxicity testing on aquatic invertebrates

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

You have provided an adaptation under Annex XI, Section 1.5 (grouping and read-across) supported by the following information:

1) Experimental study, OECD TG 211 with analogue substance Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1), CAS No. 114959-46-5 which "*was stopped after 14 days due to poor fecundity in the 1000 mg/L treatment group, which rendered the data unacceptable.*"

We have assessed this information and identified the following issues:

Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case OECD TG 211, and meet the requirements of OECD GD 23 if the substance is difficult to test. Therefore, the following specifications must be met:

- the concentrations of the test material leading to no observed effect (NOECs) on the following parameters are estimated:

1) the reproductive output of *Daphnia* sp. expressed as the total number of living offspring produced at the end of the test, and
2) the survival of the parent animals during the test, and
3) the time to production of the first brood.

Your registration dossier provides experimental OECD TG 211 study from 2006-2008 showing the following:

- only one exposure concentration of 1000 mg/l (nominal) was used for testing;
- your conclusion that "*The study was stopped after 14 days due to poor fecundity in the 1000 mg/L treatment group, which rendered the data unacceptable.*".

Thus, ECHA observes that due to the observed effects at the only tested exposure concentration no NOEC for reproduction could be estimated for the experimental study 1 provided as well as no NOECs reported for other two parameters. Thus, the key parameters of OECD TG 211 are not covered and therefore, results of this study cannot be read-across.

Thus, as explained in Section 4 of the Appendix common to several requests, your grouping and read-across approach is rejected.

In the comments to the draft decision, you propose to adapt this information requirement by conducting sediment toxicity testing.

You have, however, provided no legal basis for such adaptation.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

In the comments to the draft decision, you agree to perform the requested study. The request in the comments to the draft decision to extend deadline to submit the information requested is addressed under Appendix G below.

Study design

OECD TG 211 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A, Section 2.

2. Long-term toxicity testing on fish

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

You have provided the following a justification to omit the long-term toxicity study on fish: "*The test material has low water solubility, also a closely related chemical analogue was not found to cause toxicity when provided to fish at significant levels during a dietary bioaccumulation study. Additionally, longer term testing in mammalian systems did not produce any signs of toxicity in this analogue. An investigation of long-term toxicity in fish or other vertebrates is therefore considered unnecessary on the grounds of animal welfare.*"

We have assessed this information and identified the following issues:

A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, does not allow omitting the need to submit information on long-term toxicity to fish under Column 1 (Decision of the Board of Appeal in case A-011-2018).

Your justification to omit this information does not refer to any legal ground for adaptation under Annex XI to REACH.

Therefore, you have not demonstrated that this information can be omitted. Minimisation of vertebrate animal testing is not on its own a legal ground for adaptation under the general rules of Annex XI.

In the comments to the draft decision, you propose to adapt this standard information requirement. You note that "*between the lack of acute effects on fish, the BCF study results (including toxicity and elimination) and the fact that the substance will not remain in the aquatic compartment for any length of time (but will adsorb), it is highly unlikely there could be any potential for chronic toxicity to fish from either direct exposure or internal bioconcentration.*" Furthermore, in the comments you note the issue of vertebrate animals testing and welfare.

None of the arguments provided in your comments refers to adaptation possibilities under Annex XI. Therefore, the arguments provided in your comments are not appropriate to adapt the information requirement. Furthermore, as noted above, minimisation of vertebrate animal testing is not on its own a legal ground for adaptation.

Furthermore, in the comments to the draft decision, you propose to adapt this information requirement by conducting sediment toxicity testing.

You have, however, provided no legal basis for such adaptation.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

Study design

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix A, Section 2.

3. Effects on soil micro-organisms

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

You have adapted this information requirement according to Annex IX, Section 9.4., Column 2 with the following justification: "*Current practice and risk management measures in use mean that direct or indirect exposure of the soil to test substance is unlikely and, in accordance with Regulation (EC) 1907/2006, in the absence of hazard and exposure justification and a chemical safety assessment it is unnecessary to investigate toxicity to soil micro-organisms.*"

We have assessed this information and identified the following issues:

As explained in Section 2 of the Appendix common to several requests, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

The request in the comments to the draft decision to extend deadline to submit the information requested is addressed under Appendix G below and the intention to perform exposure assessment and risk characterisation in order to support your adaptation is addressed under Appendix on Reasons common to several requests, Section 2.

Study design

According to ECHA Guidance R.7c, Section R.7.11.3.1., the nitrogen transformation test EU C.21./OECD TG 216)is considered sufficient for most non-agrochemicals.

Appendix D: Reasons to request information required under Annex X of REACH

1. Long-term toxicity testing on terrestrial invertebrates

Long-term toxicity testing on invertebrates is an information requirement under Annex X to REACH (Section 9.4.4.).

You have adapted this information requirement according to Annex X, Section 9.4., Column 2 with the following justification: "*Current practice and risk management measures in use mean that direct or indirect exposure of the soil to test substance is unlikely and, in accordance with Regulation (EC) 1907/2006, in the absence of hazard and exposure justification and a chemical safety assessment it is unnecessary to investigate short-term toxicity to invertebrates in soil.*"

We have assessed this information and identified the following issues:

As explained in Section 2 of the Appendix common to several requests, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

The request in the comments to the draft decision to extend deadline to submit the information requested is addressed under Appendix G below and the intention to perform exposure assessment and risk characterisation in order to support your adaptation is addressed under Appendix on Reasons common to several requests, Section 2.

Study design

The earthworm reproduction test (OECD TG 222), Enchytraeid reproduction test (OECD TG 220), and Collembolan reproduction test (OECD TG 232) are each considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on terrestrial invertebrates.

However ECHA notes that when log Kow >5 and log Koc >4, as in this case for some constituents of the Substance, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

ECHA is not in a position to determine the most appropriate test protocol between OECD TG 222 and OECD TG 220, since such determination is dependent upon species sensitivity and substance properties.

2. Long-term toxicity testing on terrestrial plants

Long-term toxicity testing on plants is an information requirement under Annex X to REACH (Section 9.4.6.).

You have adapted this information requirement according to Annex X, Section 9.4., Column 2 with the following justification: "*Current practice and risk management measures in use mean that direct or indirect exposure of the soil to test substance is unlikely and, in accordance with Regulation (EC) 1907/2006, in the absence of hazard and exposure justification and a chemical safety assessment it is unnecessary to investigate short-term toxicity to plants.*"

We have assessed this information and identified the following issues:

As explained in Section 2 of the Appendix common to several requests, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

In the comments on the draft decision, you proposed a new read-across adaptation which is addressed under under Appendix on Reasons common to several requests, Section 4.

The request in the comments to the draft decision to extend deadline to submit the information requested is addressed under Appendix G below and the intention to perform exposure assessment and risk characterisation in order to support your adaptation is addressed under Appendix on Reasons common to several requests, Section 2.

Study design

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 shall 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. You should consider if testing on additional species is required to cover the information requirement.

Terrestrial plants, growth test (OECD TG 208 with at least six species) and Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) are each considered capable of generating information appropriate for the fulfilment of the information requirement for long-term toxicity testing on terrestrial plants.

Appendix E: 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

1. Selection of the Test material(s)

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

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

This information is needed to assess whether the Test Material is relevant for the Substance.

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

A. 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 G: Procedure

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 03 February 2021.

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

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

ECHA has removed requests for ready biodegradability (Annex VII), simulation testing in surface water, soil and sediment, and identification of degradation products (all at Annexes VIII and IX).

In your comments on the draft decision, you requested an extension of the deadline to provide information on growth inhibition study aquatic plants and long-term toxicity testing on aquatic invertebrates from 12 to 18 months from the date of adoption of the decision. This request is substantiated by reference to physico-chemical properties of the Substance which makes it difficult to test for the aquatic toxicity, including establishment of the best analytical method and development of an approach for the application of the Substance into the test solution. You noted that supporting evidence from the potential test laboratory was not gathered because draft decision has been sent during the summer holiday period/the short commenting period/multiple draft decisions sent to the same lead registrant at the same time.

ECHA notes that the 30 days commenting period is set in the Article 50(1) of REACH Regulation. Furthermore, it is not possible to accommodate various holiday periods in different countries and companies while there is general practice to avoid sending multiple decisions at once to the same registrant(s) unless registered substances have common grouping and read-across applied.

ECHA acknowledges the difficulties in conducting the aquatic toxicity tests including the development of analytical method and approach of application of the Substance into the test solution.

On this basis, ECHA has granted the request and extended the deadline to 18 months. This also applies to the long-term toxicity testing on fish.

Furthermore, you requested an extension of the deadline to provide information on toxicity to terrestrial organisms from 30 to 36 months from the date of adoption of the decision. You justify this request by the need to revise CSA, including generation of exposure assessment and risk characterisation, before initiating requested testing on terrestrial orgaisms and challenges with development of analytical method.

ECHA notes that initial deadline of 30 months included extra 6 months (in order to align it with deadline given for simulation tests) comparing to the normal deadline which would be given for the terrestrial toxicity testing requests expected to be performed after aquatic toxicity testing, i.e. extra 6 months granted for aquatic toxicity testing do not have impact on the deadline for terrestrial toxicity testing. Furthermore, time for the revision of CSA after generation of information on aquatic toxicity are already included in the deadline of 18 months given for aquatic toxicity tests. However, ECHA acknowledges potential difficulties in

conducting the terrestrial toxicity tests due to physico-chemical properties and nature of the Substance.

On this basis, ECHA has partially granted the request and extended the deadline to 33 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 H: 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)[10]

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[11]

[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] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[11] 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 I: 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.