~~Confidential~~

Helsinki, 04 November 2020

Addressees
Registrant of [redacted] as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
16 September 2019

Registered substance subject to this decision ("the Substance")
Substance name: [redacted]
List number: [redacted]
CAS number: NS

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***11 November 2022***.

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. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: EU C.2./OECD TG 202)

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

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

3. Adsorption/ desorption screening (Annex VIII, Section 9.3.1.; test method: OECD TG 106)

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

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

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

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

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

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

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

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH, the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.

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".

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

- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)
- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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)').

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance[2] and related documents[3, 4].

A. Predictions of (eco)toxicological properties

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

You have provided the following read-across hypothesis common for the prediction of toxicological and ecotoxicological properties:

- *"The substances are structural analogues and have similar physiochemical properties and are therefore expected to have similar (eco)toxicity profiles"*
- The substances have similar environmental fate properties: on the basis of similar physico-chemical properties (water solubility, relative density, Log Kow and particle size), you state that it can *"be safely assumed that they behave very similar in the environment (low potential for adsorption and bioaccumulation) and have similar toxicokinetic properties"*;
- The substances have similar ecotoxicological properties: all three substances show very similar short-term toxicity to aquatic invertebrates and similar toxicity to algae. The two selected analogues show a similar (lack of) short-term toxicity to fish;
- The substances have similar toxicological properties: based on bridging data on acute oral toxicity, skin irritation, and skin sensitisation and on claimed similar physico-chemical and toxicokinetic properties, you conclude that the read-across for repeated dose toxicity and toxicity to reproduction is justified.

ECHA understands that you predict the properties of the Substance using a read-across

[2] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals. 2008 (May) ECHA, Helsinki. 134. pp. Available online: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

[3] 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)

[4] 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

hypothesis which assumes that different compounds have similar properties. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

You intend to predict the properties of the Substance from information obtained from the following source substances:

i. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)
   - Acetic acid, oxo-, sodium salt, reaction products with cresol and ethylenediamine, iron sodium salts (FeNa-EDDHMA, CAS 84539-53-7, EC 283-041-9); [redacted], 1997 (Key study)

ii. Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
   - Acetic acid, oxo-, sodium salt, reaction products with ethylenediamine and phenol, iron sodium salts (FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5); [redacted], 1998 (Oral route, Key study)

iii. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
   - Acetic acid, oxo-, sodium salt, reaction products with ethylenediamine and phenol, iron sodium salts (FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5); [redacted], 1978 (Key study)

iv. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.):
   - Acetic acid, oxo-, sodium salt, reaction products with ethylenediamine and phenol, iron sodium salts (FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5); [redacted], 2010 (Key study) and [redacted], 1978 (Supporting study)

v. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.):
   - Acetic acid, oxo-, sodium salt, reaction products with cresol and ethylenediamine, iron sodium salts (FeNa-EDDHMA, CAS 84539-53-7, EC 283-041-9); [redacted], 1995 (Key study)

ECHA notes the following shortcomings with regards to predictions of (eco)toxicological properties:

1. *Read-across hypothesis*

According to Annex XI, Section 1.5., two conditions must be fulfilled:
1- there must 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;
2- the relevant properties of a substance within the group can be predicted from data for reference substance(s) within the group (read-across approach).

Furthermore, a read-across hypothesis must be provided, establishing why a prediction for a toxicological or ecotoxicological property is reliable. This hypothesis must be based on recognition of the structural similarities and differences between the source substance(s) and your Substance[5]. It must explain why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

Your read-across hypothesis is that the similarity in chemical structure and in some of the physicochemical, ecotoxicological and toxicological properties between the source substance(s)

[5] Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals.

and your Substance is a sufficient basis for predicting the properties of your Substance for other endpoints.

Similarity in chemical structure and similarity of some of the physicochemical ecotoxicological and toxicological properties does not necessarily lead to predictable or similar human health and ecotoxicological properties in other endpoints. As described above, a well-founded hypothesis is needed to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source substance(s) and your Substance. You have not provided a well-founded hypothesis why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern.

2. *Read-across hypothesis contradicted by existing data*

Annex XI, Section 1.5. states 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*". ECHA Guidance R.6, Section R.6.2.2.1.f specifies 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 source substances. The observation of differences in the toxicological properties between the source substances and the Substance is a warning sign. An explanation for such a difference resulting in a contradiction between the similarities in properties claimed in the read-across hypothesis and the observation of different properties 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 target and source substances cause the same type of effects.

In your dossier you have provided:

- *In vitro* mutagenicity studies for the Substance and the source substance FeNa-EDDHA (CAS 84539-55-9, EC 283-044-5). While the selected source substance was negative in equivalent *in vitro* studies, the Substance show positive results in an OECD TG 490 and an OECD TG 487 study;
- A reference to studies, in your read-across justification, indicating that the Substance and the source substances may have different properties with regard to skin sensitisation.

You have not provided an explanation for these differences, including supporting scientific evidence, to demonstrate that they will not impact the reliability of your predictions.

The available set of data on the target and source substances indicates differences in their toxicological properties. This contradicts your read-across hypothesis whereby the structurally similar target and source substances cause the same type of effects. Therefore you have not demonstrated and justified that the properties of the source substances and of the Substance are likely to be similar despite the observation of these differences.

3. *Missing supporting information*

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"[6]. 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 source substance(s).

[6] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

As indicated above, your read-across hypothesis is based on the assumption that the structurally similar substances cause the same type of effect(s). In this context, relevant, reliable and adequate information allowing to compare the properties of the Substance and of the source substance(s) is necessary to confirm that both substance cause the same type of effects. Such information can be obtained, for example, from bridging studies of comparable design and duration for the Substance and of the source substance(s).

We have identified the following issues related to your prediction of ecotoxicological properties:

- As explained under request A1 and A.2, you have not provided reliable studies on the Substance on short-term toxicity to aquatic invertebrates and growth inhibition to algae. You also have not provided robust study summaries for the studies referred to in your read-across justification and therefore the reliability of these studies cannot be assessed.
- While you claim in your read-across justification that short-term toxicity studies on fish are available for the source substances FeNa-EDDHMA (CAS 84539-53-7, EC 283-041-9) and FeNa-EDDHA (CAS 84539-55-9, EC 283-044-5), both studies reported in your dossier were conducted on FeNa-EDDHA.
- For long-term toxicity to invertebrates, you have provided a single source study with FeNa-EDDHMA and your dossier does not include reliable short-term bridging studies.

Furthermore, for toxicological endpoints, your dossier or your read-across justification does not include any reference to relevant bridging studies allowing to compare the properties of the Substance and the selected sources substances for the endpoints covered by your read-across adaptation (*i.e.* repeated-dose toxicity, toxicity to reproduction and developmental toxicity).

Based on the above, the data set reported in the technical dossier does not include relevant, reliable and adequate information for the Substance and of the source substances to support your read-across hypothesis.

In the absence of such information, you have not established that the Substance and of the source substances are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

4. Characterisation of the source substances

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 structural similarity may be considered as group.*"

According to the ECHA Guidance, "*the purity and impurity profiles of the substance and the structural analogue need to be assessed*", and "*the extent to which differences in the purity and impurities are likely to influence the overall toxicity needs to be addressed, and where technically possible, excluded*". The purity profile and composition can influence the overall toxicity/properties of the Substance and of the source substance(s).[7] Therefore, qualitative and quantitative information on the compositions of the Substance and of the source substance(s) should be provided to allow assessment whether the attempted predictions are compromised by the composition and/or impurities.

Furthermore, whenever the Substance and/or the source substances are UVCB (Unknown or Variable composition, Complex reaction products or of Biological materials) substances qualitative compositional information of the individual constituents of the category members needs to be provided; as well as quantitative characterisation in the form of information on the

[7] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.3.1

concentration of the individual constituents of these substances; to the extent that this is measurable.[8]

Your read-across justification document and the robust study summaries for the source substances do not contain any compositional information. The selected source substances are UVCBs. You have not provided quantitative information on the main constituent, on unreacted organic sodium salts and condensation products. No information on the presence of relevant impurities is reported.

Without this information, no qualitative or quantitative comparative assessment of the compositions of the Substance and of the source substances can be completed. Therefore, ECHA considers that it is not possible to assess whether the attempted predictions are compromised by the composition of the source substance.

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.

[8] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.5.5

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

1. Short-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH.

You have provided a study according to OECD TG 202 ([redacted], 2018) with the Substance.

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 202 or the EU Method C.2 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The concentration of the test substance is measured at least at the highest and lowest test concentration, at the beginning and end of the test;
- The results can only be based on nominal or measured initial concentration if the concentration of the test substance has been satisfactorily maintained within 20 % of the nominal or measured initial concentration throughout the test.

In the study by [redacted] (2018), you specified that no analytical monitoring was conducted.

In the absence of analytical monitoring of exposure, you have not demonstrated that exposure was satisfactorily maintained throughout the test and that effect values can be expressed based on nominal concentrations. Hence the requirements of OECD TG 202 are not met.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

2. Growth inhibition study aquatic plants

Growth inhibition study in aquatic plants is an information requirement under Annex VII to REACH.

You have provided a study according to OECD TG 201 ([redacted], 2018) with the Substance.

We have assessed this information and identified the following issue:

To fulfil the information requirement, a study must comply with the OECD TG 201 or the EU Method C.3 (Article 13(3) of REACH). Therefore, the following requirements must be met:

- The concentration of the test substance is 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}.
- The results can be based on nominal or measured initial concentration only if the concentration of the test substance has been maintained within 20 % of the nominal or measured initial concentration throughout the test;

In the study by [redacted] (2018), you specified that no analytical monitoring was conducted.

In the absence of analytical monitoring of exposure, you have not demonstrated that exposure

was satisfactorily maintained throughout the test and that effect values can be expressed based on nominal concentrations. Hence the requirements of ECD TG 201 are not met.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

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

1. Screening for reproductive/developmental toxicity

Screening for reproductive/developmental toxicity study is a standard information requirement under Annex VIII to REACH, if there is no evidence from analogue substances, QSAR or *in vitro* methods that the Substance may be a developmental toxicant. There is no information available in your dossier indicating that your Substance may be a developmental toxicant.

You have provided:

i. an adaptation according to Annex XI, Section 1.5. In support of your adaptation you have provided a one generation reproduction toxicity study (OECD TG 415) with FeNa-EDDHMA, CAS 84539-53-7, EC 283-041-9 ([redacted], 1997);
ii. an adaptation which claims that "*there is no or no significant human exposure*". We understand that you consider the requirements of Annex XI, Section 3 (Exposure-based adaptation) to be fulfilled.

We have assessed this information and identified the following issues:

A. For the reasons explained under the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5 is rejected.

B. Section 3.1 of Annex XI explains that testing for this endpoint may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report, if the conditions described in Section 3.2 of Annex XI are met. The adaptation of the information requirement must be supported by adequate justification and documentation. It must be based on a thorough and rigorous exposure assessment in accordance with Section 5 of Annex I and must demonstrate that any of the following criteria are met:

- Under section 3.2(a) of Annex XI, the justification must fulfil all the following conditions:
  (i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5.;
  (ii) a suitable DNEL or a PNEC can be derived from results of available test data for the Substance taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;
  (iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC.

- Under section 3.2(b) of Annex XI, the justification must fulfil the following conditions:
  (i) where the substance is not incorporated in an article, strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply throughout the life cycle;
  (ii) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contsained by technical means and it can be demonstrated that:
    - the substance is not released during its life cycle, and
    - negligible workers or general public or environmental exposure occurs under normal or reasonably foreseeable conditions, and

- strictly controlled conditions as set out in Article 18(4)(a) to (f) must apply during all manufacturing and production stages including the waste management of the substance during these stages.

For the reasons explained under issue A. above, your dossier does not include any reliable information on reproductive toxicity. Therefore it is not possible to derive a suitable DNEL for the Substance. Therefore, the requirements of section 3.2(a) of Annex XI are no met.
Furthermore, in Section 3.5 of your IUCLID dossier, you report that the Subtsance is used in formulations of fertilizer products. Among others, you listed widespread uses by professionals including spreading and incorporation to soil (open fields). Therefore, strictly controlled conditions as set out in Article 18(4)(a) to (f) do not apply throughout the life cycle of the Substance and the requirements of section 3.2(b) of Annex XI are not met.

Based on the above your adaptation according to Annex XI, Section 3 is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you explain that you intend to adapt this iformation requirement under Section 8.7.1, column 2 , fourth indent of Annex VIII using the data of the Pre-natal developmental toxicity study requested under C.2.

2. Short-term toxicity testing on fish

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

You have adapted this information requirement according to Annex XI, Section 1.5. In support of your adaptation you have provided:
- a key short-term toxicity study to fish (OECD TG 201) with FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5 ([redacted], 2010);
- a supporting short-term toxicity study to fish (no guideline followed) with FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5 ([redacted], 1978).

For the reasons explained under the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5 is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

3. Adsorption/desorption screening

Adsorption/desorption screening is an information requirement under Annex VIII to REACH.

You have adapted this information requirement according to Annex VIII, Section 9.3.1, Column 2 with the following justification: "*the substance has a low octanol water partition coefficient* [Log Kow ≤ -1.53] *and the adsorption potential of this substance is related to this parameter*".

We have assessed this information and identified the following issue:

Annex VIII, Section 9.3.1., column 2 specifies that a study does not need to be conducted if the substance can be expected to have a low potential for adsorption (*e.g.* the log K_{ow} is low). To adapt this information requirement based on low Log K_{ow}, lipophilicity must be the sole

characteristic driving the adsorption potential of a substance. However, for some groups of substances (e.g. ionisable substances, surfactants) other mechanisms than lipophilicity may drive adsorption.

You have justified the low potential for adsorption because the partition coefficient value (log K_{ow}) was determined to be -1.53 at pH 8.7-8.8 based on OECD TG 107. You have also provided a testing proposal for dissociation constant. Furthermore, in your read-across justification you explain that the Substance is a chelating agent complexed with iron to keep iron in solution to make it available for plant uptake. Therefore, it can be assumed that the Substance is ionized at environmentally relevant pH.

While anionic substances may be expected to have lower tendency to sorb compared to cationic substances, ionic binding to positively charged soil constituents (e.g. hydrous oxides of aluminium and iron) cannot be excluded. Therefore log Kow is not a valid descriptor for assessing the adsorption potential of the Substance and your adaptation is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

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

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

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

You have adapted this information requirement according to Annex XI, Section 1.5. In support of your adaptation you have provided:

- a key sub-chronic toxicity, oral route in rats (OECD TG 408) with FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5 ([redacted], 1998);
- a supporting short-term repeated dose toxicity, oral route in rats (OECD TG 407) with FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5 ([redacted], 1996).

For the reasons explained under the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5 is rejected.

Therefore, the information requirement is not fulfilled.

Study design

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because although the substance is used in fertiliser formulations with non-industrial spraying (PROC 11), no oral repeated dose toxicity study is currently available to evaluate systemic toxicity following oral administration of the Substance.

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

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

2. Pre-natal developmental toxicity study in one species

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

You have adapted this information requirement according to Annex XI, Section 1.5. In support of your adaptation you have provided a key developmental toxicity study (OECD TG 414) with FeNa-EDDHA, CAS 84539-55-9, EC 283-044-5 ([redacted], 1995).

For the reasons explained under the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5 is rejected.

Therefore, the information requirement is not fulfilled.

Study design

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral[9] administration of the Substance.

In your comments on the draft decision, you agreed to conduct the requested study on the

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

Substance.

3. Long-term toxicity testing on aquatic invertebrates

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

You have adapted this information requirement according to Annex XI, Section 1.5. In support of your adaptation you have provided a key long-term toxicity study to aquatic invertebrates (OECD TG 211) with FeNa-EDDHMA, CAS 84539-53-7, EC 283-041-9 ([redacted], 1995).

For the reasons explained under the Appendix on Reasons common to several requests, your adaptation according to Annex XI, Section 1.5 is rejected.

Therefore, the information requirement is not fulfilled.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

4. Long-term toxicity testing on fish

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

You have adapted this information requirement according to Annex IX, Section 9.1., column 2 based on the following justification: "*Acute toxicity studies with three different trophic levels (algae, daphnia and fish) revealing EC50 values over 100 mg/L, show that the substance is non-toxic to aqueous species. In an available long-term toxicity study with daphnia for the structural analogue substance Fe-EDDHMA-Na, the results of the acute tests are confirmed with an NOAEL of 320 mg/L. Therefore, no further testing of long-term fish toxicity is needed*".

We have assessed this information and identified the following issue:

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

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

You have not derived PNECs as you consider that "*no hazard* [was] *identified*". In your Chemical Safety Report (CSR), you state that "*Exposure assessment and risk characterisation are not required for the environment as no hazard has been identified for the environment*".

As explained under request A.1, A.2, B.2, and C.3, your dossier does not include any reliable information on ecotoxicological properties of the substance towards aquatic organisms. Therefore, no reliable PNECs can be derived for the Substance. Furthermore,

your CSR does not include an exposure assessment in relation to the uses of the Substance.

Without this information your Chemical Safety Assessment does not demonstrate that the risks of the Substance are adequately controlled. As a consequence, your adaptation is rejected as it does not meet the specific rules for adaptation of Annex IX, Section 9.1., Column 2.

Therefore these information requirements are not fulfilled.

According to the integrated testing strategy (ITS) (ECHA Guidance R7b,Section R.7.8.5 including Figure R.7.8-4), the *Daphnia* study is to be conducted first. If based on the results of that study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), the long-term fish study may not need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

In your comments on the draft decision, you agreed to conduct the requested study on the Substance.

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

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[10].

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:

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.

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.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[11].

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

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

A. Testing strategy for aquatic toxicity testing

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

B. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituens 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 synthetize its relevant constituents and/or fractions.

Appendix F: Procedure

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

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

The compliance check was initiated on 16 January 2020.

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

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

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix G: List of references - ECHA Guidance[12] and other supporting documents

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

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

Read-across assessment framework (RAAF, March 2017)[13]

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

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

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

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

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

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

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

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

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

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

OECD Guidance documents[14]
Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

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

Guidance document on 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.

~~Confidential~~

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

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

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

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.