~~Confidential~~

Helsinki, 07 September 2021

Addressee
Registrant of Reaction mass of aluminium chloride, iron dichloride, magnesium chloride and manganese dichloride listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
21/11/2019

Registered substance subject to this decision ("the Substance")
Substance name: Reaction mass of aluminium chloride, iron dichloride, magnesium chloride and manganese dichloride
EC number: 701-325-7
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 ***14 September 2023***.

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. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: EU B.13/14. / OECD TG 471)

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

3. 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. In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.; test method: OECD TG 473) or In vitro micronucleus study (Annex VIII, Section 8.4.2.; test method: OECD TG 487)

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

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

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)

5. Long-term toxicity to terrestrial invertebrates also requested below (triggered by Annex IX, Section 9.4.1., column 2)

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

7. Long-term toxicity to terrestrial plants also requested below (triggered by Annex IX, Section 9.4.3., column 2)

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

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rat/rabbit)

2. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: OECD TG 222 or OECD TG 220 or OECD TG 232)

3. Long-term toxicity to terrestrial plants (X, Section 9.4.6., column 2; test method: OECD TG 208 with at least six species 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.

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:

- In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)
- In vitro cytogenicity study in mammalian cells or in vitro micronucleus study (Annex VIII, Section 8.4.2.)
- In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)
- Sub-chronic toxicity study (90-day), (Annex IX, Section 8.6.2.)
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)
- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.)

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.

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 R.6. and related documents[2,3].

A. Predictions for toxicological and ecotoxicological properties

You have not provided a read-across justification document in IUCLID Section 13 or your CSR. However, you have provided an explanation of the proposed approach for the prediction of ecotoxicological in the summary of Section 6 of your technical dossier and for toxicological properties in the summary of Section 7 of your technical dossier.

You read-across between the structurally similar substances,

- Iron (II) dichloride, EC number 231-843-4;
- Iron (III) trichloride, EC number 231-729-4;
- Aluminum (III) trichloride, EC number 215-477-2;
- Aluminium (III) citrate, CAS RN 31142-56-0;
- Aluminium (II) sulphate, EC number 233-135-0;
- Hydrogen chloride, EC number 231-595-7,

as source substances and the Substance as target substance.

You have provided the following reasoning for the prediction of ecotoxicological and toxicological properties: "*The test substance is a watery solution of metal chlorides and free hydrogenchloride. The toxicity of this mixture has therefore to be regarded as a summary of*

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

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

the toxicity of the different ingredients".

ECHA understands that your read-across adaptation is based on a constituent-based approach whereby the properties of the Substance are predicted from available information on the constituents of the Substance after correcting for the relative mass of these constituents in the Substance.

ECHA notes the following shortcoming with regards to predictions of ecotoxicological and toxicological properties:

A. *The proposed constituent-based approach is incomplete as it does not cover each relevant constituent and impurity of the Substance*

Hazard information can be obtained from tests conducted with the Substance or from the integration of information on the individual constituents of the Substance as part of a constituent-based approach (ECHA Guidance R.6.2.2.1.). Whenever a constituent-based approach is applied, the assessment must cover each relevant constituent, impurity and additive included in the composition of the Substance to ensure that a reliable conclusion on the presence or absence of hazardous properties can be made. In case certain constituents are considered not to be relevant for the hazard assessment, a justification must be provided.

Under Section 1.2. of your technical dossier, the Substance is described as:

Constituents:

- Iron (II) dichloride, EC number 231-843-4: [redacted] (w/w);
- Manganese (II) dichloride, EC number 231-869-6: [redacted] (w/w);
- Aluminum (III) chloride, basic, EC number 215-477-2: [redacted] (w/w);
- Magnesium (II) chloride, EC number 232-094-6: [redacted] (w/w);

Impurities:

- Vanadium (IV) dichloride oxide, EC number 233-517-7: [redacted](w/w);
- Titanium (IV) dichloride oxide, EC number 237-430-5: [redacted](w/w);
- Calcium (II) chloride, EC number 233-140-8: [redacted](w/w);
- Zirconium (IV) dichloride oxide, EC number 231-717-9: [redacted](w/w);
- Chromium (III) trichloride, EC number 233-038-3: [redacted](w/w);
- Insoluble material, unidentified: [redacted](w/w).

However, for all endpoints covered by your read-across approaches, you have provided information on only few main constituents of the Substance, specified in introduction to this Appendix.

Your constituent-based approaches cover only the properties of part of the constituents of the Substance. The source substances address the properties of Iron (II) dichloride and Aluminum (III) chloride which are two of the main constituent of your Substance. However, as indicated above, other constituents/impurities are listed in the composition of the Substance. You have neither addressed the impact of exposure to each of these constituents/impurities by providing hazard data on these constituents/impurities nor provided a justification that these constituents/impurities are irrelevant for the purpose of hazard identification. In the absence of this information, no reliable conclusions on the hazardous properties of the Substance as a whole can be derived. Therefore your adaptation is rejected.

ECHA acknowledges your intention to update the dossier read-across with a constituents-based approach for the substance, ensuring that all constituents (and

relevant impurities) will be assessed to fill all data requirements according to the tonnage band registered. In more detail, you indicate that iron (II) dichloride, manganese (II) dichloride, aluminum (III) chloride and magnesium (II) chloride will be listed in Section 1.10 as assessment entities (each identified as type "3. (group of) constituent in the registered substance"). In addition, you indicate that the impurities will be assessed too to understand whether their nature and concentrations require them to be added to the assessment entity list for further combined risk assessment.

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 selected analogue substances. Therefore, your adaptations do 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.

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

1. In vitro gene mutation study in bacteria

An *in vitro* gene mutation study in bacteria is an information requirement under Annex VII to REACH (Section 8.4.1.).

You have provided key studies in your dossier:

i. [redacted] (2004) with the following strains, TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 uvr A, with Iron (II) dichloride, EC 231-843-4
ii. [redacted] (2010) with the following strains, TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 uvr A, with Aluminum trichloride, EC 215-477-2
iii. [redacted] (1988) with the following strains, TA 1535, TA 1537, TA 98 and TA 100, with hydrogen chloride, EC 231-595-7
iv. [redacted] (1988) with the following strains, E. coli strains W3110 (pol A+) and P3078 (pol A-), with hydrogen chloride, EC 231-595-7

All these studies are perfomed on analogue substances which are constituents of the Substance. However, for the reasons explained in the Appendix on Reasons common to several requests, your constituent-based approach is rejected.

Therefore, the information requirement is not fulfilled.

Study design

To fulfil the information requirement for the Substance, the *in vitro* gene mutation study in bacteria (OECD TG 471) is considered suitable.

2. Short-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.).

You have omitted this information and you provided the following justification: "*The submission item is an aqueous solution constituted of four main metal kations, which are subject to intense speciation, transformation, precipitation and binding to particulate matter, sediments and soils. The risk should be assessed on the basis of the main constituent, which belongs to the iron category, but regarding particular relevant effects known from the other main constituents. Ecotoxicological effects should be related to the dry matter of the parent solution, which would result in the relative threshold concentration. As all relevant constituents are subject to individual registration and significant data are published the risk can be assessed on the basis of this component information and regarding their role and interaction in natural biotopes. Accordingly the hazard assessment can be based on a suchlike approach. Direct testing of the submission item is not required Environmental effects of metals are always dependent from a number of determinants, which vary largely in the single biotope. Accordingly direct testing of the submission item would always result in an artificial exposure and represent an artefact. Thus direct testing would be not insightful and is considered technically not feasible and/or not adequate. According to the exposure scenario no relevant release to the environment occurs".*

We have assessed this information and identified the following issues:

A. The legal basis for your adptations are unclear

A registrant may only adapt this information requirement based on the specific rules set out under column 2 of Section 9.1.1. or the general rules set out in Annex XI to REACH.

Your justification to omit this information does not explicitly refer to any legal grounds for adaptation under column 2 of Section 9.1.1. or Annex XI to REACH.

In your statement you claim that "*direct testing would be not insightful and is considered technically not feasible and/or not adequate"*.

ECHA understands that you do not claim that the study is technically not possible (Annex XI, section 2 of REACH) but rather claim that the study is not required because the constituents of the substance are each subject to registration and that data for this information requirement may already be available in the registration dossiers of those individual constituents.

This is not a valid adaptation under column 2 of Section 9.1.1. or Annex XI to REACH.

Therefore, you have not demonstrated that this information can be omitted.

B. The absence or no significant exposure of the environment is not demonstated

Under Annex XI, Section 3, this information may be omitted based on the exposure scenario(s) developed in the Chemical Safety Report. The justification must be based on a rigorous exposure assessment in accordance with Annex I, Section 5 and must meet any one of the following criteria:

(a) It can be demonstrated that all the following conditions are met:
   i. the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5., and
   ii. a PNEC can be derived from available data, which:
      - must be relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes and therefore must be based on reliable information on the hazardous properties of the substance on at least three trophic levels;
      - must take into account the increased uncertainty resulting from the omission of the information requirement, in this case by selecting an appropriate assessment factor (AF) as described in ECHA Guidance R.10.3.
   iii. the ratio between the results of the exposure assessment (PECs) and the PNEC are always well below 1

(b) For substances that are not included in articles, it must be demonstrated for all relevant scenarios that strictly controlled conditions as set out in Article 18(4)(a) to (f) apply throughout the life cycle

In Section 3.5 of your registration dossier you report widespread use by professional workers (treatment of drinking water and process water, desulphurisation of biogas and soil remediation for which your assigned the environment release categories (ERC) 8b and 8e).

The requirements described above must be met for all uses throughout the life-cycle including waste stage (ECHA Guidance R.5). The uses reported by you for the Substance include 'widespread use by professional workers' (treatment of drinking water and process water, desulphurisation of biogas and soil remediation). These uses are, by definition, considered as widespread (ECHA Guidance R.12) and indicate a potential for significant release (ECHA Guidance R.16). Hence, you have not

demonstrated that environmental exposure throughout the life-cycle including waste stage of the Substance is absent or no significant. Furthermore, you have not demonstrated that the conditions set-out under Annex XI, Section 3.2.(b) are met.

Therefore, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

3. 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 omitted this information and you provided the same justification as already specified under Appendix A.2.

We have assessed this information and identified the following issues:

A. The legal basis for your adptations are unclear

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

B. The absence or no significant exposure of the environment is not demonstated

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

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

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

An *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study is an information requirement under Annex VIII to REACH (Section 8.4.2.).

You have provided key studies in your dossier:

i. [redacted] (2010) according to OECD TG 487 with Aluminum trichloride, EC 215-477-2;
ii. [redacted] (1989) similar to OECD 473 with hydrogen chloride, EC 231-595-7.

You also provided an *in vivo* mammalian somatic cell cytogenicity study was provided:

iii. [redacted] (2004) according to OECD 474 with Iron (II) chloride, EC 231-843-4

All these studies are perfomed on analogue substances which are constituents of the Substance. However, for the reasons explained in the Appendix on Reasons common to several requests, your constituent-based approach is rejected.

Study design

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

2. In vitro gene mutation study in mammalian cells

An *in vitro* gene mutation study in mammalian cells is an information requirement under Annex VIII to REACH (Section 8.4.3.) in case of a negative result in the *in vitro* gene mutation test in bacteria and the *in vitro* cytogenicity test.

Trigger

Your dossier contains studies on *in vitro* gene mutation in bacteria, and studies on in vitro cytogenicity in mammalian cells or *in vitro* micronucleus.

However all the studies provided are rejected for the reasons provided in sections A.1 and B.1.

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

Consequently, you are required to provide information for this endpoint, if the *in vitro* gene mutation study in bacteria and the *in vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study provide a negative result.

Study design

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

3. Short-term toxicity testing on fish

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

You have omitted this information and you provided the same justification as already specified under Appendix A.2.

We have assessed this information and identified the following issues:

A. The legal basis for your adptations are unclear

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

B. The absence or no significant exposure of the environment is not demonstated

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

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 an information requirement under Annex IX to REACH (Section 8.6.2.).

You have provided the following studies via the oral route:

i. [redacted] (2004): key study, according to OECD TG 422 with iron(2+) dichloride / 231-843-4;
ii. Sato (1992): key study, according to OECD 408 TG with Iron (III) trichloride / 231-729-4;
iii. [redacted] (2007): key study, according to OECD TG 422 with Aluminum trichloride / 215-477-2;
iv. ATSDR (2008): supporting study, citation from the DRAFT TOXICOLOGICAL PROFILE FOR MANGANESE, 2008, by the Agency for Toxic Substances and Disease Registry.

You have also provided studies performed via the inhalation route:

v. [redacted] (1973): key study, similar to OECD 413 (90d inhalation study) with dialuminium chloride pentahydroxide / 234-933-1;
vi. Steinhagen (1978): supporting study with aluminium chlorhydrate;
vii. [redacted] (1984): key study, similar to OECD 413 with hydrogen chloride / 231-595-7;
viii. [redacted] (1984): supporting study, with hydrogen chloride / 231-595-7;
ix. [redacted] (2009): supporting study, [redacted]

All these studies are perfomed on analogue substances which are constituents of the Substance. However, your constituent-based approach is rejected for the reasons explained in the Appendix on Reasons common to several requests.

Based on the above, the information you provided do not fulfil the information requirement.

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 the Substance is a liquid of very low vapour pressure (10^-6 Pa at 20°C) and no uses with spray application are reported that could potentially lead to aerosols of inhalable size.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of 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 an information requirement under Annex IX to REACH (Section 8.7.2.).

You have provided the following key studies:

i. [redacted](2004) according to OECD TG 422 with iron(2+) dichloride, EC 231-843-4;
ii. [redacted](2010) similar to OECD 426 and OECD 452 with aluminium citrate, CAS 31142-56-0.

You have also provided the following supporting study:

iii. [redacted] (1976) no guideline followed developmental toxicity study with hydrogen chloride, EC 231-595-7.

All these studies are perfomed on analogue substances which are constituents of the Substance. However, your constituent-based approach is rejected for the reasons explained in the Appendix on Reasons common to several requests.

Based on the above, the information you provided do not fulfil the information requirement.

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 administration of the Substance (ECHA Guidance R.7.6.2.3.2.).

3. Long-term toxicity testing on aquatic invertebrates

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

You have provided the following information:

i. the following justification to omit the study: "*According to the exposure scenario no relevant release to the environment occurs".*
ii. the same justification as already specified under Appendix A.2.

ECHA notes that the information included in your waiver under point i. above is already included in the waiver under point ii.

We have assessed this information and identified the following issues:

A. The legal basis for your adptations are unclear

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

B. The absence or no significant exposure of the environment is not demonstated

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

On this basis, the information requirement is not fulfilled.

4. Long-term toxicity testing on fish

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

You have provided the following information:

i. an adaptation under Annex XI, Section 1.5. ('Grouping of substances and read-across approach') with the following supporting information:
    a. a study similar to OECD TG 210 on *Pimephales promelas* using iron trichloride with EC number 231-729-4 ([redacted], 1985);
    b. A non guideline 60d study on *Salvelinus fontinalis* using aluminium sulphate with EC number 233-135-0 (Cleveland *et al.*, 1989).

You have also provided the following information:

ii. the following justification to omit the study: "*According to the exposure scenario no*

relevant release to the environment occurs".

iii. the same justification as already specified under Appendix A.2.

ECHA notes that the information included in your waiver under point ii. above is already included in the waiver under point iii.

We have assessed this information and identified the following issues:

A. *Your read-across approach is rejected*

The studies under (i) above are perfomed on analogue substances which are constituents of the Substance. However, your constituent-based approach is rejected for the reasons explained in the Appendix on Reasons common to several requests.

B. *The legal basis for your adptations are unclear*

For the reasons already explained under Appendix A.2. above, your adaptation is rejected.

C. *The absence or no significant exposure of the environment is not demonstated*

For the reasons already explained under Appendix A.2. above, your adaptation is 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.).

5. Long-term toxicity on terrestial invertebrates

Short-term toxicity to terrestrial invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1.). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

The substance is a mixture of inorganic salts and therefore it is considered very persistent. Furthermore, as the constituents are ionisable the Substance is considered to have a high potential to adsorb to soil. Therefore, information on long-term toxicity to terrestrial invertebrates as specified under Annex X, Section 9.4.4. must be provided.

However, you have not provided any long-term toxicity to terrestrial invertebrates. Therefore this information requirement is not fulfilled.

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 D.2.

6. Effects on soil micro-organisms

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

You have provided the following information:

i. an adaptation under Annex 9.4, column 2, 1st paragraph with the following justification: "[…] *the studies* […] *do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. According to the exposure scenario no release to soils is expected. Iron, manganese, and aluminium are present in significant amounts in soils. As the natural background concentrations of aluminium oxide in soils and sediments range in a comparable order of magnitude as the aluminium percentage of total metal molarity in the submission item, i.e. ca. 10% d.w. (*[redacted] *2010) it seems superfluous to discuss its impact. The iron and aluminium compounds may represent about 20% mass of the soil dry weight. Nonetheless natural aluminium is present almost in the oxide form the aluminium 3+ ions and in the solid particles dominate aluminium oxide, this difference is not relevant as the different aluminium species are in uninterrupted equilibration and the transformation in water-sediment systems and moist soils goes on readily. Moreover all three metals are involved in intense readily transformation to different species and any additional release would probably not result in an increase of bioavailable species but contribute to the anyhow large soil sinks/reservoirs.*";
ii. an adaptation under Annex 9.4, column 2, 2nd paragraph with the following justification: "*In accordance with REACH regulation (EC No 1907/2006 as published 29.5.2007 in the Official Journal of the European Union, page L 136/115) Annex IX, column 2, the studies as required in section 9.4.3 (i.e. Short-term toxicity to plants) can in the absence of toxicity data for soil organisms be replaced by estimations according to the equilibrium partitioning method (EPM) in order to assess the hazard to soil organisms. Nonetheless some data exist, which do not indicate a significant hazard caused by iron, the EPM was applied on the basis of the manganese effects. The calculated PNECadd is insignificant compared to the large natural background concentrations in soils. According to REACH regulation (EC No 1907/2006 as published 29.5.2007 in the Official Journal of the European Union, page L 136/118) Annex X, column 2 (section 9.4) long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. As this is obviously not the case, no testing is proposed.*".

We have assessed this information and identified the following issues:

A. The absence of direct or indirect exposure of the soil compartment is not demonstrated

Under Annex 9.4, column 2, 1st paragraph, the study may be omitted if direct and indirect exposure of soil compartment is unlikely. ECHA Guidance R.7.11.2.1. explains that this is the case if:

- there is no exposure of the soil, or
- the exposure is so low that no refinement of the PEC_{local} or $PEC_{regional}$, or $PNEC_{soil}$ organisms is required.

The ECHA Guidance further clarifies that it is assumed that soil exposure occurs unless it can be shown that

- there is no sludge application to land from exposed STPs, and
- that aerial deposition is negligible, and
- the relevance of other exposure pathways such as irrigation and/or contact with contaminated waste is unlikely.

Under Section 9.2.2.4. of your CSR, you state that "*Emission of the substance into the soil occurs during in situ soil remediation. However, in this specific case the goal of the identified use is to remove adverse organic pollutants from the soil. The amounts of metals added to the soil with the solution are less than or in the range of the natural background levels and, thus, no adverse effects to soil organisms are anticipated with*

the use of the substance in the in situ soil remediation". However, you have not provided a quantitative exposure assessment for the soil compartment.

In addition, you have not derived a PNEC for the soil compartment. Instead, you provided the following justification: "*According to the exposure scenario no soil exposure is expected. Iron, manganese and aluminium are naturally present in high concentrations of 21, 0.55, and 30 g/kg soil d.w. respectively. No PNECadd is derived as no NOECs were established for soil organisms. Calculating nonetheless according to the EPM on the basis of the manganese aquatic freshwater PNEC of 114 µg/L, the log Kp sed 3.19 L/kg, and a Henry constant of 0 would result in a PNECadd of 3.55 mg Mn/kg soil d.w. while the natural background concentration in soils is 550 mg Mn/kg soil dw*".

For the reasons explained under Appendix A.2., you have not demonstrated the absence or no significant exposure in all scenarios of the manufacture and all identified uses referred to in Annex VI, Section 3.5. In addition, as explained above, you acknowledge that exposure of the soil compartment may occur, for instance, when the Substance is used for soil remediation.

You have provided some justification that exposure to the soil compartment is expected to be insignificant considering the natural background levels in iron, aluminium and managanese in most soil. However, your justification does not take into account the various impurities present in significant amounts in the composition of the Substance. Furthermore, you have not provided a quantitative exposure assessment allowing to derive a PEC_{local} or $PEC_{regional}$ in your technical dossier. You also have failed to provide a PNECsoil either using the results substance-specific terrestrial toxicity data or extrapolated from reliable aquatic toxicity data. In the absence of this information, you have not demonstrated that the exposure is so low that no refinement of the PEC_{local} or $PEC_{regional}$, or $PNEC_{soil}$ organisms is required.

Therefore, your adaptation under Annex 9.4, column 2, 1st paragraph is rejected.

B. The equilibrium partitioning method (EPM) cannot be used to adapt the information requirement on effects on soil micro-organisms

Under Annex 9.4, column 2, 2nd paragraph, the study may be omitted if the assessment of the hazard of the substance to soil organisms using the equilibrium partitioning method (EPM) indicates that testing is not needed. In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy for effects on terrestrial organisms which involves conducting a screening risk assessment based on a $PNEC_{screen}$ derived from aquatic toxicity data and $PNEC_{freshwater}$ using the EPM. However, the intrinsic properties of soil microbial communities are not addressed through the EPM (as the $PNEC_{freshwater}$ does not account for toxicity to micro-organsims) and therefore the potential adaptation possibility outlined in Annex IX, Section 9.4., Column 2, Second paragraph does not apply for the information requirement on Effects on soil micro-organisms.

Therefore, your adaptation under Annex 9.4, column 2, 1st paragraph is rejected.

On this basis, the information requirement is not fulfilled.

Study design

ECHA Guidance R.7.11.3.1. specifies that Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) and Soil Microorganisms: Carbon Transformation Test (EU C.22/OECD TG 217) are both considered suitable for assessing long-term adverse effects on soil microorganisms for most non-agrochemicals.

7. Long-term toxicity on terrestial plants

Short-term toxicity to terrestrial plants is an information requirement under Annex IX to REACH (Section 9.4.3). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

The substance is a mixture of inorganic salts and therefore it is considered very persistent. Furthermore, as the constituents are ionisable the Substance is considered to have a high potential to adsorb to soil. Therefore, information on long-term toxicity to terrestrial plants as specified under Annex X, Section 9.4.5. must be provided.

However, you have not provided any long-term toxicity to terrestrial plants. Therefore this information requirement is not fulfilled.

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 D.3.

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

1. Pre-natal developmental toxicity study in a second species

Pre-natal developmental toxicity (PNDT) studies (OECD TG 414) in two species is an information requirement under Annex X to REACH (Section 8.7.2.).

You have not provided information on a second species.

However, you have provided a statements claiming that the study is scientifically not necessary in the rabbit with FeCl2, HCl and MnCl2.

We have assessed this information and identified the following issue:

A registrant may only adapt this information requirement based on the specific rules set out under column 2 of Section 8.7 of Annex X or the general rules set out in Annex XI to REACH. However the statement does not relate to any of these possible adaptations.

In order to be compliant and enable concluding if the Substance is a developmental toxicant, information provided has to meet the requirements of OECD TG 414 in two species.

Based on the above, the information you provided do not fulfil the information requirement.

Study design

A PNDT study according to the OECD TG 414 study should be performed in the rabbit or rat as the preferred second species, depending on the species tested in the first PNDT study (request C2 in this decision). The study shall be performed with oral administration of the Substance 9ECHA Guidance R.7.6.2.3.2).

2. Long-term toxicity testing on terrestial invertebrates

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

You have provided the following information:

i. an adaptation under Annex 9.4, column 2, 1st paragraph with the same justification as already specified under Appendix C.6.;
ii. an adaptation under Annex 9.4, column 2, 2nd paragraph with the following justification: "[…] *the studies as required in section 9.4.3 (i.e. Short-term toxicity to plants) can in the absence of toxicity data for soil organisms be replaced by estimations according to the equilibrium partitioning method (EPM) in order to assess the hazard to soil organisms. Nonetheless some data exist, which do not indicate a significant hazard caused by iron, the EPM was applied on the basis of the manganese effects. The calculated PNECadd is insignificant compared to the large natural background concentrations in soils. According to REACH regulation (EC No 1907/2006 as published 29.5.2007 in the Official Journal of the European Union, page L 136/118) Annex X, column 2 (section 9.4) long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. As this is obviously not the case, no testing is proposed*".

We have assessed this information and identified the following issues:

A. *The absence of direct or indirect exposure of the soil compartment is not demonstrated*

For the reasons already explained under Appendix C.6. above, your technical dossier indicates that exposure to soil may occur. Further, your technical dossier does not include adequate and reliable information to demonstrate that the exposure is so low that no refinement of the PEC_{local} or $PEC_{regional}$, or $PNEC_{soil}$ organisms is required. Therefore, your adaptation under Annex 9.4, column 2, 1st paragraph is rejected.

B. *Missing information to support your adaptation under Annex 9.4, column 2, 2nd paragraph (EPM approach)*

Under Annex 9.4, column 2, 2nd paragraph, the study may be omitted if the assessment of the hazard of the substance to soil organisms using the equilibrium partitioning method (EPM) indicates that testing is not needed. In this context, ECHA Guidance R.7.11.6. describes an integrated testing strategy (ITS) for effects on terrestrial organisms which involves conducting a screening risk assessment based a $PNEC_{screen}$ derived from aquatic toxicity data using the EPM to decide on the information needed for the chemical safety assessment.

For the reasons explained under appendices A.2. to A.3., B4. and C.4. to C.5., your technical dossier does not include reliable information on aquatic toxicity. Therefore, no reliable $PNEC_{screen}$ can be derived. Furthermore, your CSR does not include a quantitative exposure assessment of the soil compartment for any of the uses described under Section 3 of your technical dossier. In the absence of this information no initial screening assessment using the EPM can be conducted and your adaptation under Annex 9.4, column 2, 2nd paragraph is rejected.

On this basis, the information requirement is not fulfilled.

Study design

ECHA Guidance R.7.11.3.1. specifies that the Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*) (OECD TG 222), the Enchytraeid Reproduction Test (OECD TG 220) and the Collembolan Reproduction Test in Soil (OECD TG 232) are considered suitable for assessing long-term adverse effects on terrestrial invertebrates.

3. Long-term toxicity testing on terrestial plants

Long-term toxicity to terrestrial plants is an information requirement under Annex X to REACH (Section 9.4.5).

You have provided the following information:

i. an adaptation under Annex 9.4, column 2, 1st paragraph with the same justification as already specified under Appendix C.6.;
ii. an adaptation under Annex 9.4, column 2, 2nd paragraph with the following justification: "*the studies as required in section 9.4.3 (i.e. Short-term toxicity to plants) can in the absence of toxicity data for soil organisms be replaced by estimations according to the equilibrium partitioning method (EPM) in order to assess the hazard to soil organisms. Nonetheless some data exist, which do not indicate a significant hazard caused by iron the EPM was applied on the basis of the manganese effects. The calculated PNECadd is insignificant compared to the large natural background concentrations in soils. Thus any additional testing is unlikely to reveal any new insights and accordingly no testing proposal is made. According to REACH regulation (EC No 1907/2006 as published 29.5.2007 in the Official Journal of the European Union, page L 136/118) Annex X,*

column 2 (section 9.4.6, i.e. Long-term toxicity testing on plants) long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. As this is obviously not the case, no testing is proposed".

We have assessed this information and identified the following issues:

A. *The absence of direct or indirect exposure of the soil compartment is not demonstrated*

For the reasons already explained under Appendix C.6. above, your technical dossier indicates that exposure to soil may occur. Further, your technical dossier does not include adequate and reliable information to demonstrate that the exposure is so low that no refinement of the PEClocal or PECregional, or PNECsoil organisms is required. Therefore, your adaptation under Annex 9.4, column 2, 1st paragraph is rejected.

B. *Missing information to support your adaptation under Annex 9.4, column 2, 2nd paragraph (EPM approach)*

For the reasons already explained under Appendix D.2. above, your technical dossier does not include adequate and reliable information to support that testing is not needed following the outcome of a screening level assessment using the EPM. Therefore, your adaptation under Annex 9.4, column 2, 2nd paragraph is rejected.

Study design

The Terrestrial Plant Test (test method: OECD TG 208) is appropriate to cover the information requirement for long-term toxicity on terrestrial plants.

The OECD TG 208 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.

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[4].

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[5].

[4] https://echa.europa.eu/practical-guides
[5] 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

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This may be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS. Similarly the information requirement for a Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.) is not addressed in this decision; as the EOGRTS will cover the same parameters.

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 06 March 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 H: List of references - ECHA Guidance[6] 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)[7]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[8]

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[9]

[6] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[7] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[8] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[9] 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.