~~Confidential~~

Helsinki, 20 January 2022

Addressees
Registrants of JS 247-421-8 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
03/07/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Reaction products of monoethanolamine and boric acid (1:3)
EC number: 701-024-0
CAS number: NS

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***26 April 2024***.

The requested information must be generated using the Substance unless otherwise specified.

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

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) by oral route, in rats

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./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: EU C.47./OECD TG 210)

5. Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: EU C.21./OECD TG 216 and test method: EU C.22./ OECD TG 217)

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

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) by oral route, in a second species (rat or rabbit)

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

3. Long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.; test method: OECD TG 227 with at least six species tested)

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 IX of REACH" and "Reasons to request information required under Annexes X of REACH".

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 registrations at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registrations at more than 1000 tpa.

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

How to comply with your information requirements

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

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

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix on Reasons common to several requests

1. Deadline to submit the requested information in this decision

In your comments to the draft decision, you have requested an extension of the deadline to 27 months. You specify that "*Estimates from the preferred laboratories contacted to evaluate timings suggests lead times of several months based on their current workload and specific study types. As a result, the Consortium requests a total of 27 months to complete all studies required in the draft decision*". The documentary evidence from the CROs provided in the comments indicate that 24 months are required to conduct the requested studies, considering lead time as well as capacity and administrative issues. On this basis, ECHA has extended the initial 12-month deadline for the 90-day study with 12 months, resulting with a deadline of 24 months for all requested information.

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

This decision is based on the examination of the testing proposals you submitted.

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

A sub-chronic toxicity study (90 day) is an information requirement under Annex IX to REACH (Section 8.6.2.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Sub-chronic toxicity study (90 day) according to OECD TG 408 with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Repeated dose toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that a 90-day study is necessary.

1.2. Specification of the study design

You proposed testing in the rat. ECHA agrees with your proposal because the rat is the preferred species according to the OECD TG 408. Therefore, the study must be conducted in the rat.

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is appropriate to investigate systemic toxicity (ECHA Guidance R.7a, Section R.7.5.4.3.2.).

1.3. *Outcome*

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

You have proposed a tiered strategy with the developmental study (OECD TG 414) conducted prior the 90-day study (OECD TG 408). You propose that "*As part of this tiered strategy the developmental study (EU B.31/OECD TG414) will be conducted prior the 90-day study (OECD TG 408).*" and indicate the following reasons:

i. *"Results from one test may render a subsequent test unnecessary, as appropriate classification and labelling information and risk management measures may be able to be derived from these without other tests.*
ii. *Results from one test may help as range finders for subsequent tests and/or may help in refining the protocol.*
iii. *On the grounds of animal welfare […] Utilisation of a tiered testing strategy, in which additional tests are potentially avoided dependent on the results of preceding tests, is desirable and consistent with the aims and objectives of REACH*."

Regarding points i. and iii. above, ECHA points out that the information requirements of Annex IX, 8.6.2 and 8.7.2 for a sub-chronic toxicity study and a pre-natal developmental toxicity study, respectively, cannot be adapted based on the outcome of the other study.

Regarding point ii. and the use of the PNDT as a dose range finder for the sub-chronic toxicity study (90-day), ECHA observes that the PNDT study is conducted only in pregnant female animals following exposure to the test substance for approximately 14 days during gestation. Therefore, this study may not provide reliable information on the tolerability of the virgin females and males to the Substance.

In your comments to the draft decision, you have further refined your tiered testing strategy. In your refined strategy, you propose to provide extended dose range finding (DRF) studies (28-day) supported by OECD 414 studies conducted with the Substance and with the structurally similar substance (Reaction products of monoethanolamine and boric acid (1:1); EC 701-025-6) as supporting information. You indicate that depending on the findings in these studies, the 90-day study would be conducted with either one (worst case) or with both substances, the Substance and the structurally similar substance.

However, you have not provided any of the proposed supporting information, and the strategy relies on data which is yet to be generated. Therefore, no conclusion on the compliance of the proposed approach can be made.

2. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study (OECD 414) in one species is an information requirement under Annex IX to REACH (Section 8.7.2.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a PNDT study according to OECD TG 414 by the oral route with the Substance.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA agrees that a PNDT study in a first species is necessary.

1.2. Specification of the study design

You did not specify the species to be used for testing. You may select between the rat or the rabbit because both are preferred species under the OECD TG 414 (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

You proposed testing by the oral route. ECHA agrees with your proposal because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study as requested.

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.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) with the Substance.

Your registration dossier does not include any information on long-term toxicity on aquatic invertebrates.

ECHA agrees that an appropriate study on long-term toxicity on aquatic invertebrates is needed.

1.2. Test selection and study specifications

The proposed *Daphnia magna* reproduction test (test method: EU C.20/OECD TG 211) is appropriate to cover the information requirement for long-term toxicity on aquatic invertebrates (ECHA Guidance R.7.8.4.1.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study as requested.

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.).

Under Article 40(3)(c) of REACH, ECHA may require a registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. The information requirement on Aquatic toxicity at Annex IX covers both long-term toxicity on invertebrates (Section 9.1.5.) and on fish (Section 9.1.6.). However, you have provided a testing proposal for long-term testing on aquatic invertebrates only. In case of data gap for long-term toxicity testing on fish, it is necessary to request this information as an additional test to ensure compliance with the endpoint.

1.1. Information provided to fulfil the information requirement

You have omitted this information and you provided the following justification: "*According to 9.1 of REACH Annex IX: 'Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.' As the substance is used in fertilisers, a long-term Daphnia study is proposed. According to the integrated testing strategy, the Daphnia study will be conducted first. Based on the result, a long-term fish study may need to be conducted.*"

We have assessed this information and identified the following issue:

A registrant may only adapt this information requirement based on the general rules set out in Annex XI. It is noted that Column 2 of Annex IX, Section 9.1, cannot be used as a basis for omitting the need to submit information on long-term toxicity to fish under Column 1 (see for example, decision of the Board of Appeal in case A-011-2018).

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

In the comments to the draft decision, you explain that it is considered justified to fulfil this standard information requirement by relying on the existing algal growth inhibition study together with the requested chronic daphnia study (request A.3). You finally consider that "*this approach will also avoid the need for additional vertebrate animal testing in fish*". However, as explained above the Column 1 info requirement cannot be adapted based on the Column 2 referring to the Chemical Safety Assessment and the justification to omit this information provided in the comments does not refer to any legal ground for adaptation under Annex XI to REACH.

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

On this basis, the information requirement is not fulfilled.

1.2. Test selection and study specifications

The Fish, Early-Life Stage Toxicity Test (test method: OECD TG 210) is appropriate to cover the information requirement for long-term toxicity on fish (ECHA Guidance R.7.8.4.1.).

1.3. Outcome

Under Article 40(3)(c) of REACH, you are requested to carry out the additional test with the Substance, as specified above.

5. Effects on soil micro-organisms

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

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) and Carbon Transformation Test (EU C.22/OECD TG 217).

Your registration dossier does not include any information on effects on soil microorganisms.

ECHA agrees that appropriate studies on effects on soil microorganisms are needed.

1.2. Test selection and study specifications

The proposed Soil Microorganisms: Nitrogen Transformation Test (EU C.21/OECD TG 216) and Carbon Transformation Test (EU C.22/OECD TG 217) are appropriate to cover the information requirement on effects on soil microorganisms for the substance that has agrochemical uses with direct application to soil (ECHA Guidance R.7.11.3.1.). Your substance is used as fertilizer that can be applied directly into soil. The proposed test is therefore considered appropriate.

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the tests with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study as requested.

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

This decision is based on the examination of the testing proposals you submitted

1. Pre-natal developmental toxicity study

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

1.1. Information provided to fulfil the information requirement

In the registration dossier, you have provided

i. a justification for data waiving stating that "*Testing Proposal for a developmental toxicity study in a second species will be considered after completion of the study on the first species.*"

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

To be considered compliant, you need to submit a study performed according to the OECD TG 414, or a valid adaptation according to either the specific rules of Column 2, Annex X, Section 8.7 or the general rules of Annex XI.

You have not provided any experimental information for the developmental toxicity on the second species or demonstrated that the results of test in the first species or any other relevant available information enable adaptations in accordance with Section 8.7 of Annex X or Annex XI.

Therefore, the information requirement is not fulfilled.

1.2. Test selection and study specifications

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 A.2 in this decision).

The study shall be performed with oral[2] administration of the Substance because this route of administration is the most appropriate to investigate reproductive toxicity (ECHA Guidance R.7a, Section R.7.6.2.3.2.).

1.3. Outcome

Under Article 40(3)(c) of the REACH Regulation, you are requested to conduct additional test with the Substance, as specified above.

In your comments to the draft decision, you propose to conduct the requested study sequentially to the first PNDT study (request A.2). The deadline set in this decision allows you to perform this study after the first PNDT study. You may consider adapting the information requirement based on Annex X, section 8.7., column 2 or Annex XI.

2. Long-term toxicity testing on terrestrial invertebrates

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

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

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for an earthworm long-term toxicity test (test method: OECD TG 222).

Your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.

ECHA agrees that an appropriate study on long-term toxicity terrestrial to invertebrates is needed.

1.2. Test selection and study specifications

The proposed earthworm long-term toxicity test (test method: OECD TG 222) is appropriate to cover the information requirement for long-term toxicity to terrestrial invertebrates (ECHA Guidance R.7.11.3.1.).

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study as requested.

3. Long-term toxicity to terrestrial plants

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

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Terrestrial Plant Test: Vegetative Vigour Test (test method: OECD TG 227).

Your registration dossier does not include any information on long-term toxicity to terrestrial plants.

ECHA agrees that an appropriate study on long-term toxicity to terrestrial plants is needed.

1.2. Test selection and study specifications

The proposed Vegetative Vigour Test (test method: OECD TG 227) is appropriate to cover the information requirement for long-term toxicity to plants for the substance that causes plant exposure via deposition on the leaves and above-ground portions of plants (ECHA Guidance R.7.11.3.1.). Your substance is used as fertilizer that can be applied via direct spraying. The proposed test is therefore considered appropriate.

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with the Substance, as specified above.

In your comments to the draft decision, you agree to conduct the study as requested.

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

A. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[3].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

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

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) the impact of each constituent/ impurity on the test results for the endpoint to be assessed. For example, if a constituent/ impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier

a) You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[4].

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

Appendix D: 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 synthetize its relevant constituents and/or fractions.

Appendix E: Procedure

Your testing proposal to fulfil 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 is because the results from the 90-day study are first needed for determining the design of the EOGRTS. The EOGRTS may be addressed in a separate evaluation decision once the information from the Sub-chronic toxicity study (90-day) requested in the present decision is provided. In your comments to the draft decision, you agree that the results from the 90-day study are first needed.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 3 July 2019, following the necessary clarification of the identity of your substance.

ECHA held a third party consultation for the testing proposal(s) from 27 January 2020 until 12 March 2020. ECHA did not receive information from third parties.

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

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

ECHA took into account your comments and amended the deadline as explained in Appendix on Reasons common to several 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 F: List of references - ECHA Guidance[5] 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)[6]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

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

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

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix G: Addressees of this decision and 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) Data requirements to be fulfilled
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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.