~~Confidential~~

Helsinki, 7 December 2020

Addressees
Registrants of JS_14852-17-6_[redacted] listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject of a decision
17/09/2019

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Ethylenediamine, salt with phosphoric acid
EC number: 238-914-9
CAS number: 14852-17-6

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

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), your originally proposed test using the Substance is rejected, according to Article 40(3)(d):

Extended one-generation reproductive toxicity study in rats, (EU B.56./OECD TG 443)

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 Christel Schilliger-Musset, Director of Hazard Assessment

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

Appendix A: Reasoning

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

Extended one-generation reproductive toxicity study (EOGRTS)

A registrant may propose an extended one-generation reproductive toxicity study (OECD TG 443) in case of serious concerns about the potential for adverse effects on fertility or development (Section 8.7.1., column 2, last paragraph, Annex VIII to REACH).

You have submitted a testing proposal for an extended one-generation reproductive toxicity study (EOGRTS) according to OECD TG 443: *"We want to upgrade the tonnage band for the substance and there is no data available for the proposed data requirement for the substance. Thus we intend to perform this study to meet the data requirements."*

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 understands that based on business reasons, you anticipated an update of the tonnage band.

The examination and decision on the testing proposals are based on the standard information requirements for the registered tonnage band, as specified in Articles 10(a)(vii) and 12(1)(c) and Annexes VII to X of the REACH Regulation. ECHA has used your testing proposal entry in IUCLID, only for this testing proposal examination. ECHA has not considered your contradicting waiver for this endpoint, reproductive toxicity in your submitted CSR.

According to Annex VIII, Section 8.7.1., the registrant may propose an EOGRT study in case of serious concerns about the potential for adverse effects on fertility or development.

ECHA notes that there are results of a short-term repeated dose toxicity study (28 days) (OECD TG 407) and a Reproduction/Developmental Toxicity Screening Test (OECD TG 421) available in the registration dossier that did not indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.

In the absence of any serious concern, you have not demonstrated that the trigger for an EOGRT study at Annex VIII was fulfilled.

You anticipated a change of tonnage band based on business forecast but the dossiers of registrants of this joint submission were still at the tonnage band corresponding to Annex VIII. The plan to change the tonnage band is insufficient to legally trigger an EOGRT study at Annex VIII.

In your comments to the draft decision, you indicated that you have updated the technical dossier to comply with the information requirements of Annex IX and thereby submitted a testing proposal for EOGRT study under that Annex.

Please note that, as already explained in the initial draft decision that you received (see Appendix B), as well as the notification letter accompanying the latter, for the purpose of the present decision-making process, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH. Thus, ECHA's evaluation of your testing proposal is based on the specific tonnage band at which your substance was registered at the time when the draft

decision was notified to you, i.e. a tonnage band corresponding to Annex VIII. A change of tonnage band via an upgrade of the technical dossier to the next Annex(es), after this point of time, has therefore no impact on the decision-making process of this draft decision.

ECHA concludes that at this stage there is no information gap for the information requirement of Annex VIII, Section 8.7.3. Therefore, under Article 40(3)(d) of REACH, the proposed EOGRTS (OECD TG 443) is rejected.

This rejection is without prejudice to the need to perform the test to fulfil the information requirements at higher tonnage levels.

Appendix B: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 17 September 2019.

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

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The decision making followed the procedure of Articles 50 of the REACH Regulation, as described below:

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

ECHA took into account your comments and did not amend the request(s).

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 C: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.