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Helsinki, 03 May 2024

Addressee
Registrant of RS-MEA-EO as listed in the last Appendix of this decision

Date of submission for the jointly submitted dossier subject to this decision
20 September 2023

Registered substance subject to this decision ("the Substance")
Substance name: Oligomerisation products of ethylene oxide with reaction products of rape oil and ethanolamine
EC number: 932-164-2

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

DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

By the decision of 26 June 2020 (communication number CCH-D-2114514420-66-01/F, "the original decision") ECHA requested you to submit information by 3 January 2023 in an update of your registration dossier.

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration dossier specified in the header above, and concludes that:

Your registration still does not comply with the following information requirement(s):

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

Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, and specified as follows:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

You are therefore still required to provide this information requested in the original decision.

Reasons for the request(s) are explained in Appendix 1 "Reasons for the request(s).

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

The respective Member State competent authority (MSCA) and National enforcement authority (NEA) will be informed of this decision. They have the duty under Articles 125 and 126 of Regulation No 1907/2006 to ensure that the requests in the original decision are enforced and complied with and, to that end, inter alia, to carry out checks and impose effective, proportionate and dissuasive penalties[1].

Authorised[2] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the request(s)
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[1] See paragraph 143 of the judgment of the European Court of Justice of 21 January 2021 in Case C-471/18 P Germany v Esso Raffinage.
[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Reasons to request information required under Annex X of REACH

1. Extended one-generation reproductive toxicity study

1 You were requested to submit information derived with the Substance for Extended one-generation reproductive toxicity (EOGRT) study (EU B.56/ OECD TG 443) in Wistar rats, oral route with 10-week premating exposure, at dose levels that shall aim to induce some toxicity at the highest dose, including Cohorts 1A and 1B without extension to mate the Cohort 1B animals to produce the F2 generation.

1.1. Information provided

2 In response, you have adapted this information requirement by using Annex XI, Section 1.5. (grouping of substances and read-across approach) based on experimental data from the following substance:

(i) Two-generation reproduction toxicity study (1985) with the analogue substance Amides, rape-oil, N-(hydroxyethyl), ethoxylated (EC / 617-719-6).

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

4 You provided the following reasoning for the prediction of this information requirement:

"*This read-across is based on the hypothesis that Target and Source substances are well defined organic UVCBs and have near-identical mechanisms of toxic action (MechoA) and similar structural and compositional profiles and that consequently their physico-chemical, environmental fate and (eco)toxicological properties are also similar. This hypothesis is supported by a direct comparison of the compositions and properties of the substances*."

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

1.2. Assessment of the information provided

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

1.2.1. Read-across adaptation rejected

7 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.

8 Additional information on what is necessary when justifying a read-across approach can be found in the Guidance on IRs and CSA, Chapter R.6. and related documents (RAAF, 2017; RAAF UVCB, 2017).

1.2.1.1. Source study not adequate for the information requirement

9 Under Annex XI, Section 1.5., the study to be read across must have an adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), in this case, OECD TG 443. Therefore, the following specifications must be met:

a) the animals are dosed with the test chemical daily for 7 days a week;

b) the duration of exposure covers mating, gestation, lactation and exposure of the F1 generation starting in utero and continuing up to adulthood;

c) the highest dose level is based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths in P0 animals, or it follows the limit dose concept;

d) the route of administration is oral if the substance is a solid or liquid. A justification is provided in case of deviations (Annex X, Section 8.7.3.).

10 In study (i):

a) dosing of the substance was not performed daily but limited to three times per week only;

b) the animals were not exposed during mating;

c) the highest dose levels tested was 250 mg/kg bw/day, which is below the limit dose of the test guideline, and no adverse effect were observed, and no justification for the dose setting was provided;

d) the route of administration was dermal rather than oral despite the substance being a liquid with the justification that it was the principal route of human exposure. However, no information on exposure and uses of the test substance was provided.

11 The information provided does not give adequate and reliable coverage of the key parameters of by the OECD TG 443.

12 Therefore, the provided study is not reliable.

13 Based on the above, your adaptation is rejected.

1.2.2. Column 2, Section 8.7.3 adaptation rejected

14 ECHA has assessed the provided Two-generation reproduction toxicity study (1985) with the analogue substance Amides, rape-oil, N-(hydroxyethyl), ethoxylated (EC / 617-719-6) (study (i)) also under Annex X, Section 8.7.3, Column 2 and has identified the following issue(s).

15 Under Annex IX and X, Section 8.7.3, Column 2, two-generation reproductive toxicity studies (B.35, OECD TG 416) that were initiated before 13 March 2015 shall be considered appropriate to address this standard information requirement.

1.2.2.1. The available study is not reliable

16 The study is described as a two-generation reproduction toxicity study (OECD TG 416, 1985).

17 However, we have identified the following issues with the study:

a) Study not according to OECD TG 416:

- dosing of the substance was not performed on a 7-days-a-week basis, but limited to three times per week only;
- the animals were not exposed during mating;
- the highest dose levels tested was 250 mg/kg bw/day, which is below the limit dose of the test guideline, and no adverse effect were observed, and no justification for the dose setting was provided;

b) Study not conducted by the most appropriate route:

- The oral route of administration (diet, drinking water, or gavage) is preferred. If another route of administration is used, justification shall be provided, and appropriate modifications may be necessary;

  (i) the route of administration was dermal rather than oral only with the justification that it was the principal route of human exposure. However, no information on exposure and uses of the test substance was provided.

18 Therefore, the provided study is not reliable and the adaptation under Annex X, Section 8.7.3, Column 2 is rejected.

1.3. Conclusion

19 Therefore, the information you provided does not fulfil the information requirement and you are still required to provide an extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: OECD TG 443) in rats, oral route, and specified as follows:

- Ten weeks premating exposure duration for the parental (P0) generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity); and
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi-constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online: https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

In accordance with Article 42(1) of the REACH Regulation, the Agency examined the information submitted by you in consequence of decision of 26 June 2020 ("the original decision"). Agency considered that this information did not meet one or more of the requests contained in that decision. Therefore, a new decision-making process was initiated under Article 41 of the REACH Regulation.

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.

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

ECHA did not receive any comments within the commenting period.

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.

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Appendix 3: 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 at the time of the original ECHA decision
[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.

Appendix 4: Requirements to fulfil when conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. 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].

4. Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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:

- the variation in compositions reported by all members of the joint submission,
- 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 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

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

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 (https://echa.europa.eu/manuals).