~~Confidential~~

Helsinki, 27 April 2023

Addressees
Registrants of [redacted] as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15/10/2019

Registered substance subject to this decision ("the Substance")
Substance name: 2-(2-methoxyethoxy)ethanol
EC/List number: 203-906-6

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

DECISION ON TESTING PROPOSAL(S)

Under on Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposal(s) listed below are rejected:

Testing proposal(s)

1. Pre-natal developmental toxicity study (OECD TG 414) in rat using the Substance.

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

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.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements

[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 1: Reasons for the decision

Contents

Testing proposal(s)

1. Pre-natal developmental toxicity study

1 A pre-natal developmental toxicity (PNDT) study (OECD TG 414) in one species is a standard information requirement under Annex IX, Section 8.7.2. to REACH. The pre-natal developmental toxicity (PNDT) study (OECD TG 414) in a second species is a standard information requirement under Annex X to REACH.

1.1. Information provided

2 Your dossier contains 4 oral-gavage prenatal developmental toxicity studies (3 in rats, 1 in mice) and one dermal study in rabbits. Severe developmental effects were reported reduced foetal viability in rats, mice and rabbits; increased visceral malformations in rats).

3 You have identified the need to perform a new PNDT study in rat and you have submitted a testing proposal for a PNDT study according to OECD TG 414 with the Substance, in the rat, by the oral route.

4 You have provided the following justification for performing the PNDT in rat:

5 "*Developmental toxicity has been investigated in three rat studies, one study with mice and one with rabbits. These studies were performed in the 1980's. All are published studies in the literature. This testing proposal only considers rodent data, so the rabbit study is not further considered. See separate attachment for details on existing rodent data. The registrants accept that the rodent studies, whilst reliable, have shortcomings because of inadequate number of animals to provide the statistical power required for an interpretation of the findings below 1000mg/kgbw/day. Since it would be poor science to extrapolate from effects seen at high doses well above 1000mg/kg to assess hazard to humans at more relevant doses at or below 1000mg/kgbw/day, a new study is needed with the number of animals specified in the current guideline and limited to a top dose of 1000mg/kgbw/day. Such a new study would enable an appropriate assessment for developmental effects at relevant doses to be derived with confidence*".

6 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.

1.2. Consideration of the need for testing

7 According to Annex IX/X, Section 8.7., Column 2, third paragraph, the study does not need to be conducted if the substance meets the criteria for classification as toxic for reproduction category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment.

8 The Substance meets the criteria for classification as Repro 1B (H360D) according to Regulation (EC) 1272/2008, based on RAC Opinion of 8 October 2020[2] and confirmed by Commision Delegated Regulation (EU) 2022/692[3]

[2] https://echa.europa.eu/documents/10162/93ff4085-a9c3-dc08-e7b4-a30d83760e4a
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0692&from=EN

9 This information is sufficient to enable the registrants to perform a robust risk assessment.

10 Based on this, there is no need for the study to be performed.

1.3. Outcome

11 Under Article 40(3)(d) of REACH, the proposed test is rejected.

12 In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the adequacy of the proposed test material nor the adequacy of the proposed test in relation to the information requirements were performed.

13 Notes for your consideration

14 As provided in Annex IX/X, Section 8.7., Column 2, third paragraph, you are invited to consider adapting the information requirement on the basis of the available information.

15 This decision does not prevent ECHA from initiating compliance checks at a later stage, to verify the compliance of your registration dossier.

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 (2012).
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

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 27 September 2019.

ECHA held a third party consultation for the testing proposal(s) from 21 October 2019 until 5 December 2019. 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.

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.

Appendix 3: Addressee(s) of this decision

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