EUROPEAN CHEMICALS AGENCY

Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: TPE-D-2114350590-55-01/F
Substance name: 2-(2-ethoxyethoxy)-2-methylpropane
EC number: 257-196-8
CAS number: 51422-54-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 22.09.2016
Registered tonnage band: [redacted]

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your testing proposal is accepted and you are requested to carry out:

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **21 March 2018**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

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, shall 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.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[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

The decision of ECHA is based on the examination of the testing proposal(s) submitted by you.

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species**

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31./OECD TG 414.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that 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 considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

You did not specify the species to be used for testing. According to the test method EU B.31/OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with the rat or rabbit as a first species.

You did not specify the route for testing. ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: EU B.31./OECD TG 414).

Notes for your consideration

For the selection of the appropriate species you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015), Chapter R.7a, section R.7.6.2.3.2.

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 24 months. You sought to justify this request by referring to a need to perform dose-range finding studies in non-pregnant and pregnant animals. You also indicated that a revision of the exposure assessment might be required if the study shows adverse findings requiring a change to the DNEL. ECHA considers that, whilst the standard timeline foresees the conduct of dose-range finding studies and updating of the CSR, in this particular case there is a need to perform an oral dose-range finding study in non-pregnant animals which justifies an extension of the standard deadline for providing information from a pre-natal developmental toxicity study. However ECHA considers that these specific circumstances do not justify a 12-month extension of the timeline set in the decision as you requested. Therefore ECHA agrees to extend the deadline for providing the requested information from 12 to 15 months. ECHA considers that this timeline also foresees time for a revision of the chemical safety assessment to take into account the new hazard information.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal(s) for examination pursuant to Article 40(1) on 4 December 2015.

ECHA held a third party consultation for the testing proposal(s) from 3 February 2016 until 21 March 2016. ECHA did not receive information from third parties.

You updated your registration dossier on 18 April 2016, dossier submission CP613126-41, and removed the testing proposal for a 90-day repeated dose toxicity study.

You were notified that the draft decision does not take into account any updates after **4 July 2016**, 30 calendar days after the end of the commenting period. You updated your registration with submission number JJ625891-31 on 01 July 2016. In your update the tonnage band was changed from the previous 100-1000 tonnes band to 10-100 tonnes per annum. On 22 September 2016 you notified ECHA that this tonnage downgrade was an administrative error and corrected your registration, reverting back to the tonnage band of 100-1000 tonnes per annum, with submission number HJ641111-55. Exceptionally therefore, and given the specific circumstances of this case, ECHA has taken into account the update of 22 September 2016 in this decision.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision on **27 April 2016** and invited you to provide comments. That draft decision was based on the registration dossier with submission number CP613126-41.

On 23 May 2016, ECHA received your comments agreeing to the draft decision and requesting an extension of the deadline to provide the information from 12 months to 24 months. You updated your registration with submission number HJ641111-55 on 22 September 2016.

The ECHA Secretariat considered your comments and update submitted on 22 September 2016 with submission number HJ641111-55 and amended the deadline.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.