EUROPEAN CHEMICALS AGENCY

Helsinki, 17 March 2017

Addressee: [redacted]

Decision number: CCH-D-2114356215-53-01/F
Substance name: 2-PHENYLETHANOL
EC number: 200-456-2
CAS number: 60-12-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28.04.2016
Registered tonnage band: 100-1000T

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on:

1. **Composition (Annex VI, Section 2.3.) of the registered substance;**
   - **Concentration values**

2. **Spectral data (Annex VI, Section 2.3.5.) of the registered substance;**
   - **Nuclear magnetic resonance or mass spectrum**

3. **Surface tension (Annex VII, Section 7.6.; test method: EU A.5./OECD TG 115) with the registered substance;**

4. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

You are required to submit the requested information in an updated registration dossier by **26 March 2018**. You shall also update the chemical safety report, where relevant.

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.

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Appendix 1: Reasons

1. Composition of the substance (Annex VI, Section 2.3.)

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Annex VI, section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, and as further outlined in chapter 4.2 of the "Guidance for identification and naming of substances under REACH and CLP" (Version: 1.4, June 2016) – referred to as the "SID Guidance" thereinafter, you shall note that, for well-defined substances, the following applies:

- Each main constituent shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.

In the present dossier, you reported 2-phenylethanol as one main constituent with typical concentration and minimum concentration of [redacted] % (w/w). You did not report the maximum concentration value in the composition.

Due to the missing maximum concentration values, the compositional information has not been provided to the required level of detail. You are accordingly requested to correct the information provided on the composition of the registered substance by including a maximum value for the concentration of your main constituent so that a concentration range can be established.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" (version: 1.0, April 2016) on the ECHA website.

2. Spectral data (Annex VI, Section 2.3.5.); Nuclear magnetic resonance or mass spectrum

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Spectral data are a formal information requirement of Annex VI Section 2.3.5. A nuclear magnetic resonance (NMR) spectrum is not available in the registration dossier.

ECHA regards this required information scientifically relevant for the registered substance because NMR spectroscopic analyses such as ^{1}H-NMR or ^{13}C-NMR allow for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflects the relative abundance of individual atoms.

You are therefore requested to submit an NMR spectrum, such as ^{1}H-NMR or ^{13}C-NMR. As an alternative to an NMR spectrum, mass spectra (MS) generated as part of mass spectroscopic analysis for the elucidation of the structure of the constituents in the substance can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

3. Surface tension (Annex VII, Section 7.6.)

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Surface tension" is a standard information requirement as laid down in Annex VII, Section 7.6 of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You sought to adapt the information requirement arguing "*In accordance with column 2 of REACH Annex VII, the surface tension study does not need to be conducted as, based on the structure of the substance, surface activity is not expected or predicted and surface tension is not a desired property of the material.*"

ECHA notes that the chemical structure of the registered substance contains both a hydrophobic moiety (i.e. aromatic ring) and a hydrophilic moiety (i.e. alcohol) which is indicative of surface active properties. Therefore, your adaptation argument cannot be followed. ECHA reminds you that if a substance decreases the surface tension of water, this may impact on the properties of the solutions and other physicochemical measurements.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Surface tension (test method EU A.5).

4. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a second species

Pursuant to Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same Regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Annex IX, Section 8.7.2., column 2 provides that the decision on the need to perform a pre-natal developmental toxicity study on a second species at a tonnage level of 100 to 1000 tonnes per year should be based on the outcome of the first test and all other relevant and available data. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet these information requirements.

The technical dossier contains four pre-natal developmental toxicity studies with rats by the oral (d) and by the dermal route (a-c):

a) [redacted], 1988: non-guideline pre-natal developmental toxicity study in rats, dermal route, to investigate the occurrence of cervical ribs, flagged as supporting study, NOAEL maternal 0.7 ml/kg bw/day, NOAEL dev 0.07 ml/kg bw/day;
b) [redacted], 1986: non-guideline pre-natal developmental toxicity study in rats, dermal route, flagged as key study, NOAEL maternal 0.43 ml/kg bw/day, NOAEL dev 0.14 ml/kg bw/day;
c) [redacted], 2010: non-guideline pre- and post-natal developmental toxicity study in rats, dermal route, flagged as key study, NOAEL maternal 430 mg/kg bw/day, NOAEL dev 140 mg/kg bw/day;
d) [redacted], 1983: non-guideline developmental toxicity study in rats, oral route, flagged as supporting study, NOAEL maternal 43 mg/kg bw/d, NOAEL dev <4.3 mg/kg bw/day.

ECHA observes that all of the above mentioned studies are non-guideline studies, for which reporting in IUCLID is limited. For example, no tables with results were provided. However, despite the limited available information, ECHA notes that in all provided dermal and oral studies, developmental toxicity was observed at doses that did not lead to maternal toxicity.

More specifically, in the studies with dermal administration of the test compound (a-c) delays in ossification and increased incidence of cervical ribs were observed at maternal non toxic doses but were indicated to be "*resolved*" by lactation day 21 (c). However, for the study with oral administration of the test compound (d), "*teratogenicity, embryolethality and developmental toxicity*" were reported at the maternal non-toxic dose of 4.3 mg/kg bw/day. No NOAEL for developmental toxicity following oral administration could be derived.

Therefore, the results of these studies show developmental toxic effects, which need to be clarified by a pre-natal developmental toxicity study in a second species. In particular, the results of the oral toxicity study are of concern as the oral route is the preferred route for hazard identificaction (ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) R.7a, chapter R.7.6.2.3.2.) Furthermore, as addressed by the Guidance, "*performance of a prenatal developmental toxicity study in a second species may be justified if developmental effects that are not sufficient to meet classification criteria to Category 1B reproductive toxicant (...) were observed in the prenatal developmental toxicity study with the first species.*" The available data for the registered substance subject to this decision does not allow to conclude on a respective classification.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The tests in the first species were carried out with rats. According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbits as a second species.

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 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD TG 414) in a second species (rabbit) by the oral route.

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Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 7 October 2016.

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 and invited you to provide comments.

ECHA did not receive any comments by the end of 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 took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present 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 your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) must be suitable to assess these grades. Finally 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.