Decision number: CCH-D-0000003713-76-05/F Helsinki, 28 February 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-ethanol, CAS No 52722-86-8 (EC No 258-132-1), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-ethanol, CAS No 52722-86-8 (EC No 258-132-1), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 8.6.2. and 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 5 September 2013, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 25 April 2013.

On 24 May 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 3 June 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision with reference to section II b) and disagreeing to ECHA's draft decision with reference to section II a).

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 5 September 2013 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision.

On 11 October 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and did not amend the draft decision.

On 21 October 2013 ECHA referred the draft decision to the Member State Committee.

By 11 November 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 25 November 2013 in a written procedure launched on 14 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a)/(b), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX, of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

a) Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408); and
b) Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **28 February 2016**.

Data from a second pre-natal developmental toxicity study on another species is a standard information requirement according to Annex X, 8.7.2. of the REACH Regulation. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement.

(a) Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, section 8.6.2. 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.

The Registrant has proposed to adapt the information requirement of sub-chronic toxicity. In the justification of this proposed adaptation the Registrant claims that "in a 28-day study in rats, there were basically no findings apparent except for local irritation/inflammation of the gastro-intestinal tract. It is concluded that due to the absence of any organ toxicity as well as good tolerability of the treatment up to a dose of 1000 mg/kg/day, prolonged treatment is not expected to induce any relevant findings. It is foreseen however worsening of the irritation reaction on the site of contact at high doses. Therefore, the usefulness of performing a subchronic toxicity study is considered doubtful in terms of both additional value in understanding the hazard potential of the substance and in terms of animal welfare." and that performing a sub-chronic toxicity study is "scientifically unjustified". However, ECHA notes that neither column 2 of Section 8.6.2. nor general rules for adaptation in Annex XI include the possibility to adapt this standard information requirement on the basis of the argument made by the Registrant.

ECHA stresses that in accordance with the first indent of column 2 of Section 8.6.2. of Annex IX, the availability of a reliable short-term toxicity study (argument raised by the Registrant above) makes the sub-chronic toxicity study only unnecessary if the 28 day study showed severe toxicity effects (further conditions for that adaptation apply). The absence of toxicity in the 28-day study does not allow for an adaptation of the standard information requirement of Annex IX, 8.6.2. Therefore, since the Registrant has not justified the proposed adaptation, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

In his comments, the Registrant brought forward the same arguments on low toxicity as in the technical dossier, adding further details on the outcome of the 28-day study (effects found in the high dose group, but not considered as adverse by the Registrant). Furthermore, the Registrant provided in his comments toxicokinetic considerations in support of omission of the sub-chronic toxicity study. According to this information the test article is absorbed and metabolically degraded after oral administration, but may not bioaccumulate. As a third reason for not agreeing with ECHA's draft decision the Registrant notes that the test material is only used in an industrial setting and the general population is not exposed at any time and that the test article use is to produce polymers, which occurs under strictly controlled conditions by highly trained industrial workers, therefore limiting the risk of exposure.

It is ECHA's understanding that the Registrant now in his comments may refer to the fourth indent of column 2 of Section 8.6.2. of Annex IX, according to which the sub-chronic toxicity study does not need to be conducted if "the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit-test', particularly if such a pattern is coupled with limited human exposure."

The Registrant has, however, not demonstrated that the cumulative conditions of that adaptation possibility are fulfilled. Moreover, the registered substance is soluble and is absorbed after oral administration, so that one of the conditions of the adaptation in question is not fulfilled.

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

In light of the physico-chemical properties of the substance (powder with not inhalable mean particle size, not irritating to skin) and the information provided on the uses and human exposure (only industrial use), ECHA considers that testing by the oral route is appropriate. According to the test method the rat is the preferred rodent species. ECHA considers this species as being appropriate.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, the Registrant is requested to submit information on sub-chronic toxicity (90-day) in rats, oral route (test method EU B.26/OECD 408) derived with the registered substance subject to the present decision.

(b) Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant provided information with which he sought to fulfil this standard information requirement. The provided information stems from a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) with the read-across substance 2,2,6,6-Tetramethylpiperidin-4-ol (EC 219-291-2, CAS 2403-88-5). This study does not provide the information required by Annex IX, Section 8.7.2. It lacks, amongst others, sound data on pre- and post-implantation losses, external, soft tissue and skeletal malformations, types and incidences of individual anomalies. As the information provided is insufficient even for the proposed read-across substance, ECHA did not need to assess whether the conditions for applying the group concept (condition for a read-across argument) have been justified by the Registrant.

The technical dossier neither contained a testing proposal nor an adaptation in accordance with column 2 of Annex IX, Section 8.7.2. or with the general rules of Annex XI for this standard information requirement.

As explained above, the information available 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.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1)(a) and 41(3) of the REACH Regulation, the Registrant is requested to submit information on Pre-natal developmental toxicity on rats or rabbits, oral route (test method EU B.31/OECD 414) on the registered substance.

When considering the need for a testing proposal for a prenatal developmental toxicity study in a second species (Annex X, 8.7.2.), the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species (Annex IX, 8.7.2.) and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.
In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given 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 substance tested in the new study 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study 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 study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/regulations/appeals.
The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Leena Ylä-Mononen
Director of Evaluation