EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002210-93-09/F Helsinki, 27 February 2014

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

For geraniol, CAS No 106-24-1 (EC No 203-377-1), 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 geraniol, CAS No 106-24-1 (EC No 203-377-1), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex IX, Section 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 ore more per year. This decision does not take into account any updates submitted after 31 October 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 29 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 28 June 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments. On basis of this information, only the deadline in Section II was amended. The Statement of Reasons (Section III) was modified to reflect the Registrant's comments.

On 31 October 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 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 method and the registered substance subject to the present decision:

- 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 **27 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 requirements.

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity study 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 dermal Reproduction/Developmental Toxicity Screening Test (OECD 421) with the registered substance and an oral Reproduction/Developmental Toxicity Screening Test (OECD 421) with the read-across substance reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E-) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z-) (neither EC nor CAS numbers given by the Registrant). However, OECD 421 studies do not provide the information required by Annex IX, Section 8.7.2. They lack, 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.

In his comments, the Registrant proposed to postpone ECHA's decision for the study request until a final decision on the testing proposal for a study according to OECD 416 or OECD 443 on the registered substance has been made by the European Commission and the data are available for further assessment. The Registrant sought to justify this strategy by stating that the design of the study which is under consideration by the Commission does allow to address both endpoints, i.e. pre-/post-natal developmental toxicity and adverse effcts on fertility. According to the Registrant, the data obtained would need to be assessed if they meet the criteria for classification concerning adverse effects on fertility and developmental toxicity and if they are adequate to support a robust risk assessment.

ECHA notes that while the one- and the two-generation reproductive toxicity study do address the post-natal development and fertility, neither of them can fully address the key parameters for pre-natal development. Furthermore, ECHA notes the arguments related to classification, but points out that the Registrant has not specified that he would expect the one- or the two-generation reproductive toxicity study to lead to the classification 'toxic for reproduction category 1A or 1B: May damage the unborn child (H360D)' and that he therefore expects that the results of the study would lead to the possibility to adapt the standard information requirement for pre-natal developmental toxicity. As the Registrant has not sufficiently justified the proposed testing strategy, ECHA does not accept delaying the pre-natal developmental toxicity study.

Furthermore, the Registrant comments that exposure considerations like the predominant exposure via the dermal route and the very low concentrations show that the needs of further studies are questionable. ECHA assumes that the Registrant refers to Annexes IX, 8.7., Column 2, third indent, that the study does not need to be conducted if "*the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.*" The Registrant has however not documented that the cumulative conditions of that adaptation possibility are fulfilled. While the registrant has provided some evidence of low toxicity, it has not been shown/documented that there is "no systemic absorption via relevant routes". On the contrary, according to IUCLID 7.1., the substance is bioavailable and metabolites have been identified for example in urine. The Registrant has neither demonstrated that the conditions of an exposure-based waiving pursuant to Annex XI, Section 3. are fulfilled.

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) 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.

2. Extension of the timeline

In his comments, the Registrant asked for an extension of the timeline for submitting the required information on pre-natal developmental toxicity. Upon ECHA's request to further demonstrate the need for extension, the Registrant provided a statement indicating that the [redacted] is booked for at least 12 months in advance and that further 12 months are required for performing the study, including dose and formulation rangefinding experiments. ECHA acknowledges the statement and has extended the timeline for submitting the requested information to 24 months.

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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