EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114293043-54-01/F Helsinki, 19 March 2015

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 3,5,5-trimethylhexyl acetate, CAS No 58430-94-7 (EC No 261-245-9), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for 3,5,5-trimethylhexyl acetate, CAS No 58430-94-7 (EC No 261-245-9), submitted by [redacted] (Registrant).

- 90-day oral toxicity study (OECD 408);
- Developmental toxicity / teratogenicity study (OECD 414).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 30 October 2014, 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 decision does not imply that the information provided by the Registrant in his 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.

On 14 May 2013, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a third party consultation for the testing proposals from 18 February 2014 until 4 April 2014. ECHA did not receive information from third parties.

On 17 July 2014 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 19 August 2014 ECHA received comments from the Registrant on the draft decision.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 30 October 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.
As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

Note for consideration by the Registrant:

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **26 September 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Sub-chronic toxicity study (90-day)

a) Examination of the testing proposal

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

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. 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.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats via the oral route (EU B.26/OECD 408).

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation

The Registrant proposed testing by the oral route. In light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is most appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

In the comments to the draft decision the Registrant refers to a "*conflict between performing animal tests and the marketing ban stemming from the "Cosmetics Regulation" (Regulation EC 1223/2009)*" and states that the registered substance "*was developed for the use in perfume oils, which are predominantly used in cosmetic products*". Therefore, according to the Registrant, performing the studies requested by ECHA may result in a marketing ban. The Registrant claims that the ECHA draft decision would not sufficiently justify that carrying out the proposed animals studies is the "*last resort to complete the respective data packages*". In addition, the Registrant refers to legal uncertainties and requests ECHA to postpone the request to perform the studies until legal certainty is achieved regarding the consequences of conducting animal studies for REACH purposes of ingredients used in cosmetic products.

The European Commission, in cooperation with ECHA, has after ECHA issued the draft decision for the Registrant's comments, clarified that the testing and marketing bans in the Cosmetics Regulation do not apply to testing required under the REACH Regulation for environmental endpoints, exposure of workers and non-cosmetic uses of substances under REACH (see ECHA news alert of 27 October 2014 ECHA/NA/14/46 (http://echa.europa.eu/en/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation) and the ECHA factsheet on the Interface between REACH and Cosmetics regulations [http://echa.europa.eu/documents/10162/13628/reach_cosmetics_factsheet_en.pdf)). In particular, it was clarified that registrants of substances that are used for a number of purposes and not solely in cosmetics, are permitted to perform animal testing as a last resort for human health endpoints, i.e. this should not trigger a marketing ban under the Cosmetics Regulation, as explained by the European Commission in their communication on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics (COM(2013) 135 final) of 11 March 2013.

ECHA notes that the registered substance is not exclusively used in cosmetics: according to the Chemicals Safety Report provided in the registration dossier, the substance is used in industrial, professional and consumer washing and cleaning products, professional and consumer polishes and wax blends, consumer air care and biocide products, in addition to consumer (professional) cosmetic use. Therefore it can be concluded that the substance is used in cosmetic products, as stated by the Registrant, but not exclusively so.

ECHA notes that it is up to the Registrant to consider and include in his registration dossier all the available information on the substance, including adaptation possibilities pursuant to column two of REACH Annexes VII-X or pursuant to Annex XI REACH. Given that no

adaptation has been presented by the Registrant, he considers animal testing as the last resort.

In addition, the sub-chronic toxicity (90-day) and pre-natal developmental toxicity studies fall among those studies performed for the purposes of the REACH Regulation, i.e. for purposes other than the Cosmetic Regulation, and should thus not trigger the cosmetic marketing ban.

Given that there is clarity on the scope of the marketing ban under the Cosmetics Regulation and the interface with REACH; that animal testing is not banned for substances also used for purposes other than cosmetics; and that there is a data gap in the Registrant's registration dossier for the sub-chronic toxicity study (90 day) for the purposes of REACH, ECHA concludes that the study must be carried out and there is no reason to postpone the studies as proposed by the Registrant.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408).

2. Pre-natal developmental toxicity study

a) Examination of the testing proposal

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.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used and route for testing. 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.

In his comments to the draft decision the Registrant requests ECHA to postpone the request to perform the sub-chronic (90-day) and pre-natal developmental toxicity studies until legal certainty is achieved regarding the consequences of conducting animal studies for REACH purposes of ingredients used in cosmetic products. As explained in detail in section III.1.a. above, the scope of the marketing ban under the Cosmetics Regulation and the interface with REACH has now been clarified. As registrants of substances that are used for a number of purposes and not solely in cosmetics are permitted to perform animal testing as a last resort for human health endpoints and as there is a data gap in the Registrant's registration

dossier for the pre-natal developmental toxicity study for the purposes of REACH (), ECHA concludes that the study must be carried out and there is no reason to postpone the studies as proposed by the Registrant.

b) Outcome

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

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the proposed tests, the sample of substance used for the new studies 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 of the same substance to agree to the tests proposed (as applicable to their tonnage level) 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 studies 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 studies 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 studies 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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation