

Decision number: TPE-D-2114298535-36-01/F

Helsinki, 18 June 2015

DECISION ON TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006**For vinyl neononanoate, CAS No 54423-67-5 (EC No 259-160-7), 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 proposal submitted as part of the jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1) (d) thereof for vinyl neononanoate, CAS No 54423-67-5 (EC No 259-160-7, submitted by [REDACTED] (Registrant).

- Developmental toxicity / teratogenicity study (OECD 414), in rabbits, oral route.

This decision is based on the registration dossier as submitted with submission number [REDACTED], for the tonnage band of [REDACTED] tonnes per year. ECHA notes that the tonnage band for one member of the joint submission is [REDACTED] per year. This decision does not take into account any updates after 15 January 2015, 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.

ECHA received the updated registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 08 July 2014

ECHA held a third party consultation for the testing proposal from 21 March 2014 until 5 May 2014. ECHA received information from third parties (see section III below).

On 29 October 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.

By 5 December 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 15 January 2015 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 test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31/OECD 414) in 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 **27 June 2016** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance and scientific information submitted by third parties.

A. Tests required pursuant to Article 40(3)

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2)

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. 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 annum should be based on the outcome of the first test and all other relevant and available data.

The dossier contains a pre-natal developmental toxicity study in rats. The Registrant has identified a need to perform a pre-natal developmental toxicity study in a second species. Hence, the Registrant has submitted a testing proposal for a pre-natal developmental toxicity study in a second species (rabbits) according to EU B.31/OECD 414 with the following justification: "As per ECHA guidance a second O.E.C.D. test guideline 414, Prenatal Developmental Toxicity Study in the rabbit by the oral route of exposure is proposed. The Test Period will be established once the ECHA approves this Test Plan." ECHA agrees with the Registrant that based on the outcome of the first test and all other relevant available data already at the tonnage level of 100 to 1000 tonnes per year there is a need for the study on the second species at the tonnage level.

Furthermore, ECHA notes that the tonnage band for one member of the joint submission is [REDACTED] per year, and therefore pre-natal developmental toxicity studies on a second species are part of the standard information requirements for the substance registered by the joint submission (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation)

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 proposed testing in rabbits. He proposed testing by the oral route. The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is 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 rabbit.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party has indicated "the registrant proposed classification for developmental toxicity in Cat. 2 (H361: Suspected of damaging fertility or the unborn child) based on a rat study which showed embryo-/ fetotoxicity and distinct signs of clinical neurotoxicity in the dams.

Referring to REACH Guidance the available data are considered to be sufficient for classification and risk assessment. Consequently, the proposed study in a second species is not scientifically justified."

ECHA notes that it is the Registrant's responsibility to consider and justify in the registration dossier any need to perform a study at this tonnage band on a second species based on the outcome of the first test and all other relevant available data following REACH Annex IX, Section 8.7.2., column 2. ECHA further notes that the results of the available pre-natal developmental toxicity study indicate an alert for developmental toxicity at a maternal toxic dose.

The Registrant has self-classified the substance as toxic to reproduction category 2. The data might be insufficient for classification as toxic to reproduction category 1B. ECHA Guidance on information requirements and chemical safety assessment (version 2.4, February 2014), Chapter R.7a, Section R.7.6.6.3 recommends further testing in case of insufficient data or if alerts exist. Therefore, the study proposed by the Registrant is scientifically justified.

c) 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 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 study 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 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 test, 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 of the same substance to agree to the test 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 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 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.



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