EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002118-79-09/F Helsinki, 6 November 2013

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

For Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene, List No. 700-308-1, 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 40(1) of the REACH Regulation, ECHA has examined a testing proposal set out in the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene, List No 700-308-1, submitted by [redacted] (Registrant).

- Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test (test method: OECD 208) in radish

This decision is based on the registration dossier 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 after 14 June 2012, 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.

The examination of the testing proposal was initiated upon the date when receipt of the complete registration dossier was confirmed on 7 September 2011.

On 2 December 2011 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 2 January 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 14 June 2012 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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided to amend the draft decision.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

The Registrant did not provide any comments on the proposed amendment.

After discussion in the Member State Committee meeting on 19-21 September 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC was reached on 20 September 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This testing proposal decision is interlinked with a compliance check decision for the same substance (communication number CCH-D-0000002118-79-10/F) for the information requirement of toxicity to terrestrial plants (Annexes IX and X).

II. Testing required

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

- Short-term toxicity to plants in radish (Annex IX, 9.4.3., test method: OECD 208).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **6 August 2013** an update of the registration dossier containing the information required by this decision.

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.

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

Short-term toxicity to plants study is part of the information requirements as laid down in Annex IX, section 9.4.3. of the REACH Regulation. There is information currently available for this endpoint for one of the components of the registered substance (1-decene dimer, hydrogenated), where for radish a 35% reduction in growth relative to controls was observed at the test concentration of 945 mg per kg of soil.

The Registrant justified the testing proposal stating that further follow-up investigations would be needed in radish, in order to confirm and validate effects observed in limit studies (only one soil treatment concentration and a control were evaluated). As a concern the growth effects reported in radish were indicated that may occur due to possible physical effects (e.g., occlusion at the high soil concentration tested 1000 mg/kg nominal loading 945 mg/kg measured). There would be a need to confirm the results of observed growth effects in radish from the initial study as reproducible using a definitive study test design involving different soil concentration exposures (to evaluate a dose response). The results will be used to determine if a no observed adverse effect concentration (NOAEC) can be established and to carry out a definitive predicted no effect concentration (PNEC) assessment related to terrestrial compartments which is not possible with currently available data. The proposed terrestrial plant toxicity study forms part of the technical registration dossier and the chemical safety report (CSR).

ECHA agrees to the justification provided by the Registrant and in particular to the fact that it is necessary to perform the test to derive a PNEC. Moreover the currently available data is not sufficiently covering the information requirement for short-term toxicity on plants as stipulated by Annex IX, 9.4.3. of the REACH Regulation.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Short-term toxicity to plants in radish (test method: OECD 208) using the registered substance, Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene.

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 meets 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 has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study to be assessed.

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V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Jukka Malm
Director of Regulatory Affairs