~~CONFIDENTIAL~~

European Chemicals Agency

Decision number: TPE-D-0000000850-79-05/F
Decision date: 2 July 2010

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

For [redacted] (EC Nr. 700-184-9), Registration Number: [redacted]

Addressee: [redacted]

I. Procedure

Pursuant to Article 40(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), the European Chemicals Agency (ECHA) has examined two testing proposals set out in the registration dossier for [redacted] *(EC Nr. 700-184-9)*, submitted by [redacted] (the "Registrant"), latest submission number [redacted], for ≥ 1000 tonnes per year.

[redacted] The resulting oligomers are subsequently hydrogenated to produce the final substance. The resulting oligomers undergo some structural rearrangement during the reaction to produce randomly branched oligomers, the final structures of which cannot be predicted from the starting materials. It is not possible to identify the exact branching, which is unknown and variable; only the sum of the carbon numbers in each oligomer remains constant and can be used to characterise the substance. The process is controlled to produce primarily dimers and trimers. The molecular formula provided by the Registrant is [redacted] The weight percentages are approximately [redacted] % for the dimer, [redacted] % for the trimer and [redacted] % for the tetramer.

In accordance with Article 12(1)(e) of the REACH Regulation, the Registrant submitted the following two testing proposals as part of the registration dossier to fulfil the information requirements set out in Annex X:

- testing proposal for developmental toxicity study in rats (OECD test guideline 414);
- testing proposal for two-generation reproductive toxicity study in rats (OECD test guideline 416)

The examination of testing proposals was initiated on 1 July 2009.

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ECHA held a public consultation for the testing proposals from 10 August 2009 until 24 September 2009. The following information that addresses the endpoint developmental toxicity was received:

1. U.S. EPA HPV Challenge Program Submission on Alkenes, C6-10, hydroformulation products, high-boiling
2. OECD SIDS Initial Assessment Report on Alfa Olefins; and
3. National Industrial Chemicals Notification and Assessment Scheme report on Gulftene C14 isomerised olefins

The following information that addresses the endpoint two-generation reproductive toxicity was received:

1. Initial Hazard Identification using QSAR assessments
2. Recommendations for the consideration of ECHA and the registrant
3. US EPA report on Alkenes, C6-C10, hydroformylation products, high boiling point;

On 17 December 2009, ECHA notified the Registrant of its draft decision and invited him pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 9 February 2010, ECHA received no comments on the draft decision from the Registrant.

On 25 February 2010, ECHA notified the Member State Competent Authorities of its draft decision and the information received from third parties and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

After receiving proposals for amendments from the Member State Competent Authorities, ECHA did not amend its draft decision and reasons to it and forwarded the proposals for amendments to the Registrant on 13 April 2010. The Registrant did not provide any comments on the proposals for amendments.

On 12 April 2010, the draft decision was referred to the Member State Committee.

After discussion in the Member State Committee meeting on 9-10 June 2010, a unanimous agreement of the Member State Committee on the draft decision was reached on 9 June 2010.

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 to initiate a compliance check on the present dossier at a later stage.

II. Testing required

ECHA has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of the REACH Regulation.

Pursuant to Article 40(3)(a) of the REACH Regulation, the registrant must carry out the following test:

- Developmental toxicity test in rats, oral route (method B.31 of Regulation (EC) No 440/2008; OECD test guideline 414)

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- Two-generation reproductive toxicity test in rats, oral route (method B.35 of Regulation (EC) No 440/2008; OECD test guideline 416)

Pursuant to Articles 40(4) and 22 of the REACH Regulation the Registrant must submit to ECHA by 3 years from the date of the decision an update of the registration containing the information required by this decision.

III. Statement of reasons

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

a) Developmental toxicity test

ECHA has examined the scientific information submitted by third parties:

1. U.S. EPA HPV Challenge Program Submission on Alkenes, C6-10, hydroformulation products, high-boiling; Modified One-generation Test, OECD 422, Developmental Toxicity Test, OECD TG 414.
   The substances covered in the report are UVCB derived from hydroformylation of C6-C10 alkenes. The substances are different from the registered substance due to lower molecular weight and different carbon chain length, presence of hydroxyl groups, and higher number of double bonds.

2. OECD SIDS Initial Assessment Report on Alfa Olefins; Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, OECD TG 422.
   The substances covered in the report are alkenes (1-hexene, 1-octene, 1-decene, 1-dodecene, and 1-tetradecene). The substances are different from the registered substance due to lower molecular weight and different carbon chain length, absence of branched structures, and higher number of double bonds.

3. National Industrial Chemicals Notification and Assessment Scheme report on Gulftene C14 isomerised olefins; Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, OECD TG 422.
   The substance covered in the report is 1-tetradecene. Information on this substance is also included in the OECD SIDS Initial Assessment Report on Alpha Olefins. The substance is different from the registered substance due to lower molecular weight and different carbon chain length, absence of branched structures, and higher number of double bonds.

The information submitted by the third parties has been generated using substances that are different from the registered substance. Such information may be used if the physicochemical, toxicological and ecotoxicological properties are likely to be similar to the registered substance (read-across approach). However, in the present case ECHA concludes that the structural differences between the registered substance and the substances for which the third parties submitted the information are significant and that it is unlikely that read-across can be applied.

The test for developmental toxicity, OECD test guideline 414, proposed by the Registrant is thus necessary to fulfil the information requirement pursuant to point 8.7.2 of Annex X to the REACH Regulation.

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Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Developmental toxicity in rats, oral route (method B.31 of Regulation (EC) No 440/2008; OECD test guideline 414).

b) Two-generation reproductive toxicity test

ECHA has examined the scientific information submitted by third parties:

1. Initial Hazard Identification using QSAR assessments
   The information provided is a general statement of the potential use of QSAR in chemical safety assessments. It does not provide information on the registered substance or on similar substances.

2. Recommendations for the consideration of ECHA and the registrant
   The information consists of general comments and questions regarding the testing strategy for reproductive toxicity. It does not provide information on the registered substance or on similar substances.

3. U.S. EPA HPV Challenge Program Submission on Alkenes, C6-10, hydroformulation products, high-boiling; Modified One-generation Test, OECD 422, Developmental Toxicity Test, OECD TG 414.
   The substances covered in the report are UVCB derived from hydroformylation of C6-C10 alkenes. The substances are different from the registered substance due to lower molecular weight and different carbon chain length, presence of hydroxyl groups, as well as higher number of double bonds. The report refers to a screening study (OECD test guideline 422) but does not include a reference to a two-generation reproductive toxicity study which is generally required at this tonnage level.

The information submitted by the third parties has been generated using substances that are different from the registered substance. Such information may be used if the physicochemical, toxicological and ecotoxicological properties are likely to be similar to the registered substance (read-across approach). However, in the present case ECHA concludes that the structural differences between the registered substance and the substances for which the third parties submitted the information are significant and that it is unlikely that read-across can be applied.

The test for two-generation reproductive toxicity, OECD test guideline 416, proposed by the Registrant is thus necessary to fulfil the information requirement pursuant to point 8.7.3 of Annex X to the REACH Regulation.

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is thus requested to carry out the following test: Two-generation reproductive toxicity in rats, oral route (method B.35 of Regulation (EC) No 440/2008; OECD test guideline 416).

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

ECHA always reminds registrants of the requirements of Article 13(4) of the REACH Regulation that reads:

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"Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."

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 1907/2008 adapted to the technical progress by Commission Regulation (EC) No 761/2009 and use the applicable test methods to generate the information on the endpoints indicated above.

National authorities monitoring good laboratory practice (GLP) maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 at the Board of Appeal website 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.

Done at Helsinki

[redacted]

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