ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002961-72-05/F Helsinki, 18 March 2013

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

For Distillate (Shale Oil) light fraction EC No 923-592-0, 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)(e) thereof for Distillate (Shale Oil) light fraction (EC No 923-592-0), by [redacted] (Registrant),

- Viscosity of Liquids (OECD 114)
- Developmental toxicity / teratogenicity study in rats (OECD 414)

This decision is based on the registration dossier as submitted with latest submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 2 November 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 to initiate a compliance check on the registration at a later stage.

On 27 December 2010, 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. The registration dossier contained additional testing proposals for: 90 day oral toxicity study and Two-generation reproduction toxicity study on the read-across substance Distillates (Shale Oil) middle fraction, CAS No 68308-34-9 (EC No 269-646-0).

ECHA held a third party consultation for the testing proposals from 17 November 2011 until 2 January 2012. ECHA did receive information from third parties (see section III below).

On 19 July 2012 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 10 August 2012 the Registrant updated his registration dossier, withdrawing two of the four originally submitted testing proposals and amending the proposal for a pre-natal developmental toxicity study to a study to be performed on the registered substance instead of an analogue substance.

On 13 August ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received and the registration update, and amended the decision accordingly.

On 2 November 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 proposals for amendment to the draft decision.

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

ECHA reviewed the proposals for amendment received and decided not to amend the draft decision.

On 17 December 2012 ECHA referred the draft decision to the Member State Committee.

On 27 December 2012, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 5-7 February 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 6 February 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

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 methods and the registered substance subject to the present decision:

- Viscosity of Liquids (Annex IX, 7.17.; OECD Guideline 114)
- Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex X, 8.7.2.; test method: EU B.31/OECD 414).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **18 June 2014** an update of the registration dossier containing the information required by this decision.

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, subject to the Annex IX, 8.7.2 column 2 requirements. If the Registrant considers that testing is necessary to fulfil this information requirement taking into account the outcome of the pre-natal developmental toxicity study on a first species and all other relevant and available data, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species.

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

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

1. Viscosity of Liquids (Annex IX, 7.17.)

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. The proposed test (Viscosity) is a standard information requirement as laid down in Annex IX, section 7.17 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 test material shall be the registered substance Distillate (Shale Oil) light fraction.

2. Pre-natal developmental toxicity study in rats, oral route (Annex X, 8.7.2.)

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. 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 test material shall be the registered substance Distillates (shale oil), light fraction

In his comments on ECHA's draft decision, the Registrant modified significantly the testing programme and indicated agreement with the request to study the pre-natal developmental toxicity with the registered substance.

The Registrant did not specify the route to be used 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.

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.

One third party submitted information stating that in the context of toxicology testing programs for the United States authorities, inhalation teratology studies in rats were conducted on three separate raw shale oils (R01, R03, R04), and reports submitted to US EPA (TSCATS studies are referenced and a file is attached). In view of ECHA, the identity of the test material in these studies is not clearly elucidated; furthermore, the attached report mentioned by the third party uses as test substance Shale Oils R04 identified with a CAS number of 8002-05-9, which differs from the generic CAS number for shale oils 68308-34-9.

Therefore, after having taken into account the information provided, ECHA concludes that it is not sufficient for demonstrating that the information requirements of Annex X, 8.7.2 and Annex XI, Section 1.2 of the REACH Regulation are met. The proposed weight-of-evidence approach is not sufficient to assume that the proposed raw shale oil retorts considerations and data provided are able to fulfil the data requirements.

Although ECHA recognises that the information as provided by the third party might be scientifically valid, it is not sufficient to fulfil the standard information requirement in section 8.7.2., Annex IX and is therefore not sufficient to allow ECHA to reject the testing proposal. Nevertheless, ECHA acknowledges that the Registrant may itself supplement under its own responsibility the argumentation and information provided by the third party in order to make use of adaptation possibilities. This would require that the Registrant documents, using several independent sources of information, that there is sufficient weight of evidence leading to the conclusion that a substance has or has not particular dangerous properties, according to the criteria laid down in Annex XI section 1.2 of the REACH Regulation.

As the read-across claims in the dossier have been removed, there is no reason to address third party comments in relation to this.

c) Outcome

Based on the information provided by the Registrant in the dossier, although the substance has been self-classified as Carc. 1B, and risk management measures described, an explicit conclusion on genotoxic potential has not been drawn and, therefore, the Annex X, 8.7 column 2 adaptation is currently not fulfilled.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the following study: Pre-natal developmental toxicity study in rats, oral route (test method: EU B.31/OECD 414) using the registered substance Distillate (Shale Oil) light fraction

3. Deadline of the decision

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 24 months from the date of the adoption of the decision. During the commenting period the Registrant updated the registration dossier withdrawing two of the four originally submitted testing proposals. The time frame for the completion of a pre-natal developmental toxicity study and the update of the registration dossier with the new information is normally of 12 months from the date of the final decision.

However, the Registrant has duly communicated the reasons of a potential delay and shown a formal commitment with a clear and reasonable deadline for submitting the missing information, within 15 months from the date of the adoption of the decision. ECHA acknowledges the reasons above and therefore the deadline will be extended to a total of 15 months.

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

The tested material for these studies should be the registered substance; however, it must be pointed out that any possible subfraction of the registered substance will be outside the scope of this registration.
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 registered to enable the relevance of the study/studies to be assessed.

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).

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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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