EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000004415-77-03/F Helsinki, 14 August 2014

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

For Resin acids and Rosin acids, fumarated, esters with glycerol, CAS No 97489-11-7 (EC No 307-051-0), 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)(d) thereof for Resin acids and Rosin acids, fumarated, esters with glycerol (CAS No 97489-11-7; EC No 307-051-0), submitted by [redacted] (Registrant). The dossier contains a document "Testing strategy for a UVCB category comprising Rosin Adduct Esters", which can be summarised as follows:

- Sub-chronic toxicity studies (OECD Guideline 408, rat, oral route) to be performed on the substance subject to the present decision; Resin acids and Rosin acids, fumarated, esters with pentaerythritol (CAS No. 94581-15-4); and Resin acids and Rosin acids, maleated, esters with pentaerythritol (CAS No. 94581-17-6).

- Pre-natal developmental toxicity study (OECD Guideline 414, rat, oral route) on the substance subject to the present decision.

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 6 March 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 17 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.

ECHA held a third party consultation for the testing proposal from 19 July 2013 until 2 September 2013. ECHA did not receive information from third parties.

On 6 November 2013 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 9 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision. In the comments the Registrant requested an extension of the deadline for providing the requested infromation.

ECHA considered the Registrant's comments. On basis of the comments, the deadline in Section II was amended and Statement of Reasons (Section III) was changed accordingly.

On 22 April 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

The Registrant has requested to carry out the required tests using the registered substance as part of a read-across and grouping approach, in accordance with Annex XI, 1.5.

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 substance subject to this decision:

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

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

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, shall result in a notification to the Enforcement Authorities of the Member States.

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.

3. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **21 August 2017** an update of the registration dossier containing the information required by this decision. 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 substance subject to the present decision.

The Registrant has requested to carry out the required tests using the registered substance as part of a read-across and grouping approach, in accordance with Annex XI, 1.5.

According to the Registrant, the substance subject to this decision can be grouped with other substances in a category for the purpose of read-across. The grouping is based on the premise that all substances that are members of the category are structurally related, i.e. all the substances are UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials) derived from the UVCB starting material Rosin (CAS No. 8050-09-7; EC No. 232-475-7), and are chemically modified in a similar manner.

In ECHA's understanding, the Registrant's read-across hypothesis is that if the substance selected for higher tier testing fully covers the structural diversity within the category, this will enable accurate predictions of the toxicological properties within the category. Furthermore, the hypothesis assumes that all substances within the category will exhibit similar toxicity; because the Registrant assumes that the same fraction of the substances will be absorbed. In particular, the Registrant assumes that there will be no difference in toxicity between the substance subject to this decision and the other substances of the category.

According to the Registrant, the structural variation within the category is caused by the fact that the starting material Rosin is reacted with either maleic anhydride, maleic acid or fumaric acid and esterified with "polyols such as glycerol or pentaerythritol". There are two types of structural diversity within the category: The first structural diversity depends on the reagent used in the "Adduct reaction", i.e. the relative proportions of maleopimaric acid anhydride and either (cis-)maleopimaric tricarboxylic acid or fumaropimaric tricarboxylic acid (the latter being the trans-isomer of (cis-)maleopimaric tricarboxylic acid) will vary between the "fumarated" and "maleated" adduct esters. The second structural diversity depends on which polyol is used for esterification, i.e. the relative proportion of mono-, di-, tri-, tetra-, and poly-esters as well as the amount of non–reacted resin acids may vary between the category members.

ECHA has considered, for the purpose of the read-across and grouping approach, each substance proposed to be tested in the light of the Registrant's assumption of no difference in toxicity and provided conclusions in respective draft decisions on the substances that are members of the category.

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

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.

ECHA notes that the Registrant has submitted an oral combined repeated dose toxicity and reproduction/developmental toxicity screening study (OECD Guideline 422) on the analogue substance Resin acids and rosin acids, fumarated, esters with pentaerythritol (CAS No. 94581-15-4) and on the substance Rosin, fumarated (CAS No. 65997-04-8). In addition, the Registrant has submitted a testing proposal for sub-chronic toxicity studies (90-days; EU B.26/OECD 408), proposed to be carried out, in rats, via the oral route, on three substances one of which is the substance subject to the present decision.

While OECD 422 Guideline studies provide some information on sub-acute toxicity, they do not meet the information requirement for sub-chronic toxicity (90-days) according to section 8.6.2 of Annexes IX.

ECHA notes that one of the substances proposed to be tested is the substance subject to the present decision and therefore testing with that substance is considered sufficient to fulfil the information requirements for sub-chronic toxicity.

The Registrant proposed testing by the oral route. In the 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 appropriate.

b) Outcome

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

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 an oral combined repeated dose toxicity and reproduction/developmental toxicity screening study (OECD Guideline 422) on the analogue substance Resin acids and rosin acids, fumarated, esters with pentaerythritol (CAS No. 94581-15-4); and a developmental toxicity screening test (OECD Guideline 421) on the substance Rosin (CAS No. 8050-09-07); a combined repeated dose toxicity and reproduction/developmental toxicity screening test (OECD Guideline 422) on the substance Rosin, fumarated (CAS No. 65997-04-8); and a developmental toxicity screening test (OECD Guideline 421) on the substance Resin acids and rosin acid, esters with pentaerythritol (CAS No. 8050-26-08). In addition, the Registrant has submitted a testing proposal, for a pre-natal developmental toxicity study (EU B.31/OECD 414), proposed to be carried out, in rats, via the oral route with the substance subject to the present decision.

While ECHA considers OECD Guideline 421/422 studies useful to screen substances for potential to cause reproduction/developmental toxicity; the tests are not sufficient to meet the information requirement for pre-natal developmental toxicity according to Section 8.7.2 of Annexes IX and X.

The Registrant proposed testing in rats. He proposed testing by the oral route. 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) Outcome

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

3. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the deadline to provide the requested information was 24 months from the date of adoption of the decision. In his comments on the draft decision of 9 December 2013 the Registrant requested an extension of the timeline to 48 months.

The Registrant put forward several arguments. Firstly, he highlights the complexity of the testing strategy, which requires sequential testing for several endpoints and substances, and thereafter reassessment of the read-across and category approach in view of the results. Secondly, in order to minimise variability and facilitate interpretation of data for the category the Registrant intends to perform the tests in the same testing facility.

Considering the complexity of the overall testing strategy, the number of tests to be performed, need for sequential testing; ECHA considers that there are justified reasons to extend the deadline for providing requested information by 12 months. Therefore, the deadline is extended to 36 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.

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

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. 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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