EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000004921-74-02/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, esters with ethylene glycol, CAS No. 68512-65-2 (EC No. 270-986-7), 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 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, esters with ethylene glycol (CAS No. 68512-65-2; EC No. 270-986-7), submitted by [redacted] (Registrant). The dossier contains a document "*Testing strategy for a UVCB category comprising Rosin Esters*", which can be summarised as follows:

- Sub-chronic toxicity (90-days) studies (OECD Guideline 408, rat, oral route) to be performed on Resin acids and Rosin acids, esters with ethylene glycol (CAS No. 68512-65-2; *i.e.* the substance subject to the present decision); and Resin acids and Rosin acids, esters with triethylene glycol (CAS No. 8050-25-7); and an additional sub-chronic toxicity study will be conducted on Esters of rosin oligomers with pentaerythritol (CAS No. 65997-12-8) if this substance is absorbed and demonstrates potential to cause systemic toxicity in an OECD 422 study.

- Pre-natal developmental toxicity study (OECD Guideline 414, rat, oral route) to be performed on Resin acids and Rosin acids, methyl esters (CAS No. 68186-14-1); Resin acids and Rosin acids, esters with ethylene glycol (CAS No. 68512-65-2; i.e. the substance subject to the present decision); Resin acids and Rosin acids, esters with triethylene glycol (CAS No. 8050-25-7); Resin acids and Rosin acids, esters with glycerol (CAS No. 8050-31-5); and Resin acids and Rosin acids, esters with pentaerythriol (CAS No. 8050-26-8).

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. In order to follow the procedure outlined in Articles 50(1) and 51 of the REACH Regulation and to allow ECHA complete the necessary administrative practices for the Member States Competent Authorities' referral, ECHA took into consideration dossier updates pertinent to the decision received by the deadline of 7 January 2014 as agreed between ECHA and the Registrant.

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 11 June 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 for the substance mentioned above, in relation to sub-chronic and pre-natal developmental toxicity based on a read-across argumentation.

ECHA held a third party consultation for the testing proposals from 2 July until 16 August 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. That draft decision was based on submission number [redacted].

On 5 December 2013 ECHA received comments from the Registrant on the draft decision.

On 20 December 2013 the Registrant updated his registration dossier (submission number [redacted]). In the updated registration dossier the Registrant substantially changed the category and read-across approach. In particular, the substances proposed to be tested as well as the number of proposed tests for each of the endpoints were changed.

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II (testing required) was amended. The 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 the present 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, will 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 presumption 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) which may be subjected to hydrogenation or oligomerisation prior to esterification.

The Registrant hypothesises that there is a trend of toxicity within the category for the relevant endpoints; *i.e.* the toxicity decrease with increasing complexity of the ester formed. According to the Registrant, the structural variation within the category is caused by the fact that the starting material Rosin; Rosin, hydrogenated; or Rosin, oligomers is esterified. Depending on which alcohol that is used for the esterification the resulting ester will be "simple" (i.e. methanol ester), "linear" (i.e. mono-, di- or tri-ethyleneglycol esters), or "bulky" (i.e. glycerol or pentaerythritol esters). To confirm the trend the Registrant is proposing to test several substances which are members of the category; this includes the substance subject to this decision.

ECHA has considered, for the purpose of the read-across and grouping approach, each substance proposed to be tested in the light of this assumed trend and provided conclusions in respective 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 substance subject to this decision. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted oral sub-chronic toxicity studies (90-days; OECD Guideline 408) on the substances Resin acids and Rosin acids, hydrogenated, Me esters (CAS No. 8050-15-5); Resin acids and Rosin acids, esters with glycerol (CAS No. 8050-31-5); Resin acids and Rosin acids, hydrogenated, esters with glycerol (CAS No. 65997-13-9); and Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol (CAS No. 64365-17-9).

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 with the substances Resin acids and Rosin acids, esters with ethylene glycol (CAS No. 68512-65-2; *i.e.* substance subject to the present decision); and Resin acids and Rosin acids, esters with triethylene glycol (CAS No. 8050-25-7); an additional sub-chronic toxicity study will be conducted on Esters of rosin oligomers with pentaerythritol (CAS No. 65997-12-8) if this substance is absorbed and demonstrates potential to cause systemic toxicity in an OECD 422 study.

ECHA notes that one of the substances proposed to be tested is the substance subject to the present decision. Therefore, ECHA considers that for the purpose of this decision testing with the substance subject to the present decision is sufficient to fulfil the information requirements for sub-chronic toxicity (90-days).

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-days) in rats, oral route (test method: EU B.26/OECD 408) using the substance subject to the present 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 two oral reproduction/developmental toxicity screening studies (OECD Guideline 421 or 422) on the substances Resin acids and Rosin acids, esters with pentaerythritol (CAS No. 8050-26-8); and Resin acids and Rosin acids, hydrogenated, Me esters (CAS No. 8050-15-5). ECHA notes that in the OECD 422 study performed using Resin acids and Rosin acids, hydrogenated, Me esters developmental effects were observed.

In addition, the Registrant has submitted a testing proposal for pre-natal developmental toxicity studies (EU B.31/OECD 414), proposed to be carried out, in rats, via the oral route with the substances Resin acids and Rosin acids, methyl esters (CAS No. 68186-14-1); Resin acids and Rosin acids, esters with ethylene glycol (CAS No. 68512-65-2; *i.e.* the substance subject to the present decision); Resin acids and Rosin acids, esters with triethylene glycol (CAS No. 8050-25-7); Resin acids and Rosin acids, esters with glycerol (CAS No. 8050-31-5); and Resin acids and Rosin acids, esters with pentaerythriol (CAS No. 8050-26-8).

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.

ECHA notes that one of the substances proposed to be tested is the substance subject to the present decision. Therefore, ECHA considers that for the purpose of this decision testing with the substance subject to the present decision is sufficient to fulfil the information requirements for pre-natal developmental toxicity.

The Registrant proposed testing in rats 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 following additional study: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414) using the substance subject to the present 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 5 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.

Furthermore, 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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