EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000004358-69-06/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, magnesium salts, CAS No 68440-56-2 (EC No 270-461-2), 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 jointly submitted registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Resin acids and Rosin acids, magnesium salts, CAS No 68440-56-2 (EC No 270-461-2), submitted by [redacted] (Registrant).

- Sub-chronic toxicity studies (OECD Guideline 408, rat, oral route) to be performed on Rosin (CAS No. 8050-09-7), Rosin hydrogenated (CAS 65997-06-0) and Rosin, reaction products with formaldehyde (CAS 91081-53-7).
- Pre-natal developmental toxicity study (OECD Guideline 414, rat, oral route) to be performed on Rosin (CAS No. 8050-09-7).
- Two-generation reproduction toxicity study (OECD Guideline 416, rat, oral), or Extended one-generation reproductive toxicity study on Rosin, (CAS No. 8050-09-7).

The present decision relates solely to the examination of the testing proposal for Sub-chronic toxicity study (90–days) and Pre-natal development toxicity studies. The testing proposals for Two-generation reproductive toxicity study are addressed in a separate decision although the testing proposals were initially addressed together in the same draft decision.

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. In order to follow the procedure outlined in Articles 50(1) and 51 of the REACH Regulation and to allow ECHA to 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 1 October 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposal set out by the Registrant in the registration dossier for

the substance mentioned above in relation to pre-natal developmental toxicity based on a read-across argumentation.

ECHA held a third party consultation for the testing proposal from 6 March 2012 until 20 April 2012. ECHA did receive information from third parties (see section III. below).

The dossier was later updated by the Registrant with additional testing proposals for sub-chronic toxicity (90-days) and two-generation reproductive toxicity and with additional substances covered by the category.

On 26 April 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 updated registration dossier.

ECHA held a third party consultation for the testing proposal from 2 July 2013 until 16 August 2013. ECHA did not receive information from third parties.

On 23 October 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 25 November 2013 ECHA received comments from the Registrant on the draft decision.

ECHA considered the Registrant's comments received. On basis of the comments and also due to the new information received on the other members of the category and relevant for the current decision, Section II (testing required) was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 March 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision relating to the Sub-chronic toxicity study (90-days) and Pre-natal development toxicity studies was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Testing required

The Registrant has requested to carry out the required tests using analogue substances as part of a read-across and grouping approach, in accordance with Annex XI, 1.5. ECHA emphasises that any final determination on the validity of the read-across, including the grouping approach proposed by the Registrant would be premature at this point in time. The eventual validity of the read-across hypothesis and grouping approach should be assessed by the Registrant once the requested information from studies is available. Nevertheless, based on the information currently submitted, ECHA considers that the approach proposed by the Registrant is reasonable and necessary in order to obtain sufficient information upon which a scientifically plausible read-across can be based. In the light of this assessment ECHA has taken the following decision:

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 indicated below:

1. Sub-chronic toxicity study (90-days) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408) on the analogue substances Rosin, CAS No. 8050-09-7 (EC No. 232-475-7), Rosin hydrogenated (CAS No 65997-06-0) and Rosin, reaction products with formaldehyde (CAS No 91081-53-7); 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) on the analogue substance Rosin, CAS No. 8050-09-7 (EC No. 232-475-7).

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.

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. The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI. If the Registrant considers that testing is necessary to fulfill this information requirement, 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.

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 registered substance.

In relation to the testing proposals subject to the present decision, the Registrant has proposed to use a read-across and grouping approach, in accordance with Annex XI, 1.5, and to perform the proposed tests on analogue substance(s) that are members of the same category. To the extent that all proposed testing relies upon an identical read-across justification, ECHA has considered first the scientific validity of the proposed read-across and grouping approach (preliminary considerations; Section 0, below), before assessing the testing proposed (Section 1 and 2, below).

0. Grouping of substances and read-across approach (preliminary considerations)

0.1. Legal Background on ECHA's assessment of the grouping of substances and read-across approach brought forward by the Registrant

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by Registrants are appropriate to fulfill the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards.

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "provided that the conditions set out in Annex XI are met".

According to Annex XI, 1.5 there needs to be structural similarity among the substances within a group or a category such that the relevant properties of a substance within the group can be predicted from the data for reference substance(s) within the group by interpolation.

The Registrant has submitted testing proposals, based on a grouping and read-across approach, intended to fulfill information requirements for sub-chronic toxicity (90-days; Annex IX, Section 8.6.2.), pre-natal developmental toxicity (Annexes IX and X, Section 8.7.2.).

The first Recital and the first Article of the REACH Regulation establish the "promotion of alternative methods for assessment of hazards of substances" as an objective pursued by the Regulation. In accordance with that objective, ECHA considers whether a prediction of the relevant properties of the substance subject to this decision by using the results of the proposed tests is sufficiently plausible based on the information currently available.

0.2. Grouping of substances and read-across hypothesis as proposed by the Registrant

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.

The Registrant considers substances that fulfill the following criteria as members of the category:

- There is commonality in the resin acids present in the various category members: abietic, dehydroabietic and pimaric acids tend to dominate, with the highest concentrations present in Rosin.
- Dihydro and tetrahydro abietic acid are present in all category members, with the highest concentrations present in Rosin, hydrogenated.
- Rosin dimers can be present in all of the substances included in the category, with highest levels occurring in Rosin, oligomers; rosin trimmers occur only in Rosin, oligomers.
- While methyl dehydro abietic acid is present only in Rosin, reaction products with formaldehyde, the remaining compositional aspects of this category member resembles those of Rosin and Rosin, hydrogenated.
- The neutral fraction and labdane acids are present in all category members.

The Registrant did not provide a fully detailed read-across hypothesis. However in ECHA's understanding, based on the content of the dossier, the Registrant's working read-across hypothesis is that the substance(s) selected for higher tier testing can address the limited structural diversity within the category, and this will enable prediction of the toxicological properties within the category. Additionally, the Registrant assumes, based on chemicals similarity and currently limited other data, that substances will exhibit similar toxicity, and that bioavailability and toxicity of the substances belonging to this category are relatively low.

0.3. Information submitted or planned by the Registrant to support the grouping of substances and read-across approach

The Registrant has provided a justification document for the category of 'Rosins and their salts'. This document contains an overview of the grouping approach proposed; additional information on the testing proposals for sub-chronic toxicity (90-days)and pre-natal developmental toxicity, including a rationale for selection of test material(s); a summary of the composition ranges and physico-chemical properties of the substance concerned by the category; information on the underlying chemistry; and an overview of planned/on-going experimental work (ex vivo absorption tests and combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests, OECD Guideline 422) intended to increase the scientific reliability of the grouping and read-across approach.

Furthermore, the Registrant has provided an oral (feeding) Reproduction/Developmental Toxicity Screening Test (OECD Guideline 421) Rosin CAS 8050-09-7. ECHA notes that following feeding of Rosin, the NOAEL for reproductive toxicity was considered to be 3000 ppm (248-309 mg/kg/day). In addition, several sub-chronic and chronic studies made with Rosin and Rosin oligomers were provided. These tests have been performed in early 1960's in test laboratories. ECHA notes that these studies cannot be fully relied on as, to ECHA's knowledge, during the time when these studies were performed, these laboratories have provided inadequate and unreliable data.

The Registrant has also provided physical-chemical data that shows no significant difference among the members of the category. For example data on physical state, density, vapor pressure and on partition coefficient suggest that there is similarity among the substances.

Furthermore, as there currently is very limited toxicological information available for the substances in this category, the Registrant commits in the testing program to address this

deficiency by conducting ex vivo absorption tests on all the substances in the category and combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests (OECD Guideline 422) on Rosin, CAS 8050-09-7, Rosin, hydrogenated, CAS 65997-06-0, Rosin, oligomers 65997-05-9, and on Rosin, reaction products with formaldehyde CAS 91081-53-7.

The Registrant intends to use the information obtained from the absorption study as a quantitative indication of uptake and as a qualitative assessment of which chemical species are absorbed. Both ex vivo absorption and OECD 422 studies are intended to support the read-across hypothesis and provide information to what extent the toxicological properties vary within the category.

0.4. ECHA analysis of the selection of substances to be tested

The Registrant has proposed to test Rosin, CAS 8050-09-7, Rosin hydrogenated (CAS 65997-06-0) and Rosin, reaction products with formaldehyde (CAS 91081-53-7) for sub-chronic toxicity, and Rosin CAS 8050-09-7 for pre-natal developmental toxicity and two-generation reproductive toxicity. The intention of the Registrant is to cover the structural variability of the category. ECHA has considered each substance proposed to be tested in the light of the corresponding structural element(s).

Firstly, ECHA notes that the substance proposed to be tested for all three endpoints, i.e. Rosin, CAS 8050-09-7, sufficiently covers the limited structural diversity within the category as defined by the Registrant.

Secondly, the comparison of the composition of substance subject to this decision and analogue substance Rosin CAS 8050-09-7, shows high similarity with respect to composition (all major constituents are present in similar concentration ranges) and other chemical properties. Furthermore, the explanation given by the Registrant that the manufacturing process yields highly similar substances is convincing: The substance subject to this decision is manufactured by adding magnesium hydroxide to Rosin CAS 8050-09-7, and the presence of magnesium does not raise toxicological concern.

Thirdly, concerning the two other substances proposed to the tested for subchronic (90 days) toxicity, Rosin hydrogenated (CAS 65997-06-0) and Rosin, reaction products with formaldehyde (CAS 91081-53-7), ECHA notes that the comparison of the substance subject to this decision and these two substances shows some differences with respect to composition. However, these differences are not such that they would prevent the Registrant from applying the read-across from these substances to the substance subject to the present decision.

0.5. ECHA analysis of the grouping approach and the read-across hypothesis of the Registrant in light of the requirements of Annex XI, 1.5

ECHA understands that the grouping approach is based on a structural similarity resulting from the common UVCB starting material Rosin with variations in the relative proportions of abietic, dehydroabietic and pimaric acid and dihydro and tetrahydro abietic acid. Furthermore, adding the metal hydroxides to Rosin is not considered to add structural variability, and therefore, concerning the substance subject to the present decision, the grouping as proposed by the Registrant is considered acceptable.

ECHA notes that currently the read-across hypothesis is based only on the assumption of structural/compositional similarity due to lack of sufficient toxicological information.

While ECHA recognises the relevance of structural/compositional similarity, it concludes that the Registrant's assumption of similar toxicity of Rosin and Rosin oligomers, and the substance subject to the present decision is not confirmed by the available information. Furthermore, data from a study performed according to OECD 421 test guideline using Rosin CAS 8050-09-7 show some toxicological effects. These circumstances create uncertainties that will have to be addressed by the Registrant in order to meet the conditions set out in Annex XI, section 1.5. of the REACH Regulation.

The Registrant has recognized the necessity to provide sufficient toxicological information to substantiate the hypothesis for the substances in the category and committed to undertake additional studies intended to strengthen the toxicological information for the read-across approach. This includes the additional four "Combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests" (OECD guideline 422) on the substances with Rosin CAS 8050-09-7, Rosin oligomers CAS 65997-05-9, Rosin, reaction products with formaldehyde CAS 91081-53-7 and Rosin, hydrogenated, CAS 65997-06-0.

ECHA considers that generating this additional information on Rosin and Rosin oligomers is an essential condition for the ultimate approval of the category with regard to screening level repeated dose toxicity and toxicity to reproduction, where currently only limited information is available. ECHA considers that also testing with Rosin, reaction products with formaldehyde, and with Rosin, hydrogenated, CAS 65997-06-0 will provide relevant information for the substance subject to the present decision.

The Registrant has also committed to provide ex vivo absorption data on all members of the category. Absorption information is to be generated using an "everted gut-sac model". ECHA considers that this model is currently not validated for this type of substances, and that currently the Registrant has not demonstrated than the ex vivo absorption observed accurately predicts in vivo gastrointestinal absorption and ultimately correlates to the systemic toxicity observed in available toxicity studies. These uncertainties should be addressed by the Registrant. Nevertheless, ECHA considers that information on bioavailability is useful to strengthen any read-across argumentation and considers it to be an essential condition for the ultimate approval of read-across for the category as proposed by the Registrant.

The Registrant proposes to test Rosin, CAS 8050-09-7, Rosin hydrogenated (CAS 65997-06-0) and Rosin, reaction products with formaldehyde (CAS 91081-53-7) for sub-chronic toxicity, and Rosin CAS 8050-09-7 for pre-natal developmental toxicity and two-generation reproductive toxicity. ECHA considers that the preliminary information on structural/chemical similarities suggests that it may be possible to predict the properties of the substance subject to the present decision, based on the results of the proposed tests on Rosin CAS No. 8050-09-7, on Rosin hydrogenated (CAS 65997-06-0) and on Rosin, reaction products with formaldehyde (CAS 91081-53-7).

The Registrant proposes to test Rosin (CAS No. 8050-09-7), Rosin hydrogenated (CAS No. 65997-06-0) and on Rosin, reaction products with formaldehyde (CAS No. 91081-53-7) for sub-chronic toxicity (90-days).

Based on the results of the sub-chronic toxicity tests, the Registrant shall apply the read-across to the closest analogue to the substance subject to the present decision. The source substance selected for the read-across has to be similarly or more toxic than the substance subject to the present decision in order not to underestimate the risk posed by the substance subject to the present decision.

In the case where the result of the proposed studies performed in accordance with the present decision would not confirm the grouping and read-across hypothesis, this outcome shall not alter the obligation of the Registrant to meet the standard information requirements. Should the read-across strategy be inadequate, it is the responsibility of the Registrant to ultimately submit reliable information or adaptations which is used in a way that does not underestimate hazards of the registered substance in relation to the relevant endpoints.

Finally, the read-across adaptation based on the results of the proposed tests shall ensure that any remaining uncertainties, including results of any existing studies which might give rise to concern, are analysed, minimized, and taken into account for the purpose of classification and labeling and/or risk assessment.

In any case, following the update of the dossier submitting the information required in the present decision, ECHA will determine whether the documentation provided is sufficient to satisfactorily address the information requirements of Annexes IX and X for the substance subject to the present decision.

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 (feeding) Reproduction/Developmental Toxicity Screening Test (OECD Guideline 421) on the analogue substance Rosin CAS 8050-09-7. This study provides information about sub-acute toxicity, but does not meet the information requirement for sub-chronic toxicity (90-days) according to section 8.6.2 of Annexes IX.

In addition, the Registrant has submitted a testing proposal, based on grouping of substances and read-across, 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 analogue substance Rosin, CAS 8050-09-7, Rosin hydrogenated (CAS 65997-06-0) and Rosin, reaction products with formaldehyde (CAS 91081-53-7).

Based on ECHA's preliminary considerations on the grouping of substances and read-across approach (see Section 0, above) this approach is considered plausible.

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. However, the Registrant has stated in the technical dossier for Rosin (CAS 8050-09-7) that reduced food consumption and associated reduction in body weight gain was observed in oral feeding studies (e.g. the OECD 421 studies) which may stem from low palatability of the feed. If the Registrant has reasons to assume that food consumption is significantly reduced in the oral studies, ECHA advises the Registrant to consider that oral administration via intubation (gavage) for sub-chronic toxicity is the most appropriate.

b) Consideration of the information received during third party consultation

ECHA did not receive third party information concerning the testing proposal on this endpoint during the third party consultation.

c) 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 analogue substances Rosin, (CAS No. 8050-09-7), Rosin hydrogenated (CAS No 65997-06-0) and Rosin, reaction products with formaldehyde (CAS No 91081-53-7).

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.

ECHA notes that the Registrant has submitted an oral (feeding) Reproduction/Developmental Toxicity Screening Test (OECD Guideline 421) on the analogue substance Rosin CAS 8050-09-7. This study provides screening information on reproduction and developmental toxicity, but does not meet the information requirement for Pre-natal developmental toxicity study according to section 8.7.2 of Annex IX.

In addition, the Registrant has submitted a testing proposal, based on grouping of substances and read-across, for Pre-natal developmental toxicity study (OECD Guideline 414), proposed to be carried out, in rats, via the oral route with the analogue substance Rosin, CAS 8050-09-7.

Based on ECHA's preliminary considerations on the grouping of substances and read-across approach (see Section 0, above) this approach is considered plausible.

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 that testing with the rat or the rabbit as a first species is appropriate. With regard to the route of administration, the Registrant has stated in the technical dossier for Rosin (CAS 8050-09-7) that reduced food consumption and associated reduction in body weight gain was observed in oral feeding studies (e.g. the OECD 421 studies) which may stem from low palatability of the feed. Furthermore, according to EU B.31/OECD 414 "*the test substance is usually administered orally by intubation*" (gavage). Therefore, ECHA considers that testing by the oral route via intubation (gavage) is most appropriate.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation.

Third party information 1:

A third party refers to column 2 of Annex IX and X of Regulation (EC) No 1907/2006 according to which the study does not need to be conducted if "the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure".

ECHA points out that while the existing data suggest that rosin is of low toxicity, mild signs of toxicity have been observed in repeated dose toxicity studies (effects on liver weight and histology of the kidneys). Therefore, the first criteria of Annex IX, 8.7, column 2 does not apply. Secondly the available data on absorption suggests that the bioavailability is below 5%, and thus it can not be proved that no systemic absorption occurs. Furthermore, these toxicokinetic data have been obtained by using a substance which does not belong to the category specified by the Registrant (see above). Thirdly, from the data provided it can be preliminary concluded that the human exposure is low. However, since there is multitude of uses of rosin and rosin based products it can not be claimed that "*there is no or no significant human exposure*". It is also noteworthy that the Registrant has not claimed that these criteria of column 2 would apply to the registered substance.

Therefore, due to the reasons explained above, the information provided by third parties is not sufficient to fulfil this information requirement.

c) 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 analogue substance Rosin, CAS No. 8050-09-7.

d) Notes for consideration by the Registrant

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

When considering the need for a testing proposal for a pre-natal developmental toxicity study in a second species, the Registrant should take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if Weight of Evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that the conditions for adaptations are not fulfilled, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the

conclusion that the conditions for these adaptations can be fulfilled, he should update his technical dossier by clearly stating the reasons for proposing to adapt the standard information requirement of Annex X, 8.7.2. of the REACH Regulation.

3. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the deadline to provide the requested information was 36 months from the date of adoption of the decision. In his comments on the draft decision of 22 November 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, number of tests to be performed and need for sequential testing, ECHA concludes that there are justified reasons to extend the deadline. Therefore, the deadline was extended to 48 months in the draft decision communicated to the Member State Competent Authorities. This deadline took into account the fact that the draft decision also requested a reproductive toxicity study (Annex X, 8.7.3). As the testing proposal for this study is not addressed in the present decision, ECHA considers that a reasonable time period for performing the remaining test(s) is 36 months from the date of the adoption of the decision. Therefore, ECHA changed the deadline from 48 months 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, or the information submitted by other registrants of the same substance, has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

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(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 recognized 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 recognized 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.

[redacted]
Leena Ylä-Mononen
Director of Evaluation