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Helsinki, 7 February 2017

Substance name: Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol
EC number: 264-848-5
CAS number: 64365-17-9
Date of Latest submission(s) considered: 10 June 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)
Addressees: Registrant(s)[1] of Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), you are requested to submit the following information on the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' of the registered substance in order to clarify its PBT/vPvB properties according to the sequence and conditions presented below and further specified in Appendix 1 and 3:

1.1 Ready biodegradability; test method: CO2 in sealed vessels (Headspace test), OECD 310 using the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' as specified in Appendix 1 and 3. The concentrations of the test substance shall be analytically monitored during the test to verify the degradation;

1.2 Simulation testing on ultimate degradation in surface water; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309 at a temperature of 12 °C using the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' as specified in Appendix 1 and 3. The concentrations of the test substance shall be analytically monitored during the test to verify the degradation;

1.3 Bioaccumulation in aquatic species; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous exposure using the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' as specified in Appendix 1 and 3;

1.4 Long-term toxicity testing on aquatic invertebrates; test method: Daphnia magna reproduction test, EU C.20./OECD 211 using the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' as specified in Appendix 1 and 3. The concentrations of the test substance shall be analytically monitored during the test to verify the concentrations and stability of the test substance in the test solutions;

[1] The terms Registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

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1.5 Conclusion on the overall PBT/vPvB potential.

The clarification of the PBT/vPvB concern requires consideration of all the relevant endpoints (P, B, T). Therefore a sequential testing approach is requested in accordance with ECHA guidance[2].

You shall provide an update of the registration dossier(s) containing the requested information, including robust study summaries, full study reports, and, where relevant, an update of the Chemical Safety Report **by the following timelines**. The deadlines take into account the time that you, the Registrant(s), may need to agree on who is to perform any required tests, and they have been set to allow for sequential testing.

- Requirement 1.1: If the results (1.1) of the ready biodegradability test demonstrates (see Appendix 1 for details) that monoesters of the registered substance do not fulfil the P screening criterion according to the PBT guidance[2] and this is confirmed by the measured concentrations of the substances during the test, no further testing according to information requests 1.2, 1.3 and 1.4 is required and the information required according to point 1.1 shall be generated and provided, together with information required in point 1.5, **by 14 November 2017**.

- Requirement 1.2: If the results (1.2) of the simulation biodegradation test demonstrates (see Appendix 1 for details) that monoesters of the registered substance do not fulfil the P criterion (according to Annex XIII of REACH) and this is confirmed by the measured concentrations of the substances during the test, no further testing according to information request 1.3 and 1.4 is required and the information required according to point 1.2 shall be generated and provided, together with information required in points 1.1 and 1.5, **by 14 May 2019**.

- Requirement 1.3: If the results (1.3) of the bioaccumulation test demonstrates (see Appendix 1 for details) that monoesters of the registered substance do not fulfil the B criterion (according to Annex XIII of REACH) and this is confirmed by the measured concentrations of the substances during the test, no further testing according to information request 1.4 is required and the information required according to point 1.3 shall be generated and provided, together with information required in points 1.1, 1.2 and 1.5, **by 14 February 2020**.

- Requirement 1.4: The information required according to point 1.4 shall be generated and provided, together with information required in points 1.1, 1.2, 1.3 and 1.5, **by 16 November 2020**.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

You may adapt the testing requested above according to the general rules contained in Annex XI, including section 1.5 (Grouping of substances and read-across approach), of the REACH Regulation. Any such adaptation will need to have a scientific justification and an adequate and reliable documentation. Further information on adaptations is provided

[2] ECHA. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 2.0 November 2014.

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in Appendixes 1 and 3.

2. Who performs the testing

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all Registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

3. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol (hereinafter HRPE) and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the evaluation on whether the substance constitutes a risk to the environment. This new information would contribute to improved risk management measures by enabling identification of substances of very high concern (SVHC), possibly followed by authorisation or classification and labelling (T).

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the concern for PBT/vPvB properties.

Background

HRPE is a UVCB substance for which it is concluded that some of the ester constituents may have PBT/vPvB properties, depending on the level of esterification. The conclusion is, however, based on limited available information.

Experimental data is available only for the UVCB substance as such or its analogues in the rosin ester category (ready biodegradation tests, acute ecotoxicity tests and toxicity tests). There are no experimental data on bioaccumulation. QSAR predictions (and log Kow and water solubility values) on the main constituents of HRPE (mono-, di-, tri and tetra-esters) show that the PBT properties of the constituents may differ significantly.

The testing strategy presented by you, concerning standard information requirements, comprises of categorizing rosin substances, testing of representative substances and applying read-across to other analogue substances. HRPE belongs to a category of 12 chemically related rosin ester substances and hence experimental study results of other category members have also been included in the substance evaluation.

Assessment approach

The PBT/vPvB assessment shall take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products. In general, constituents and transformation/degradation products are considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). The registered substance includes mono-, di-, tri-, and tetraesters of hydrogenated rosin acids with pentaerythritol; all of these fractions are present at concentrations of ≥0.1 w/w.

Within each level of esterification, there is a high number of individual ester compounds, with different rosin acid moieties (See Appendix 6). There is considerable structural similarity between the ester compounds and therefore a read-across within the whole fraction of each level of esterification using selected constituents as source substances is considered appropriate [4].

[4] The structural differences in the rosin acid moieties do not indicate significant differences for persistence, bioaccumulation or toxicity. The final hydrolysis products, rosin acids (Tukes 2015*) and pentaerythritol (based on information on biodegradation available in the IUCLID dossier, Pentaerythritol, EC 204-104-9, CAS No 115-77-5, (Source: European Chemicals Agency, http://echa.europa.eu/)), are

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To focus the assessment on the constituents that display a PBT/vPvB concern, constituents representing the different fractions of the registered substance were profiled using QSAR models. As QSAR models require an exact structural formula of the constituent to be known, there was a need to select representative constituents within each level of esterification.

According to your comments it is not possible to analytically identify the individual constituents and therefore the exact concentrations of individual ester compounds in the registered substance are not known. In addition, you have informed that the production process causes changes in the double bonds of the rosin acid moieties so that the relative proportions of the individual rosin acid moieties in the registered substance can differ from the proportions of the respective rosin acids in the starting material (hydrogenated rosin acid mixture) used for production.

Considering the uncertainty of the exact composition of the UVCB substance, as well as the similarity of the constituents within each level of esterification, the selection of constituents was based on the concentrations of the fractions of the different levels of esterification in the registered substance, the concentrations of the rosin acids in the mixture of hydrogenated rosin acids used to prepare the registered substance, and structural features of the rosin acids.

Mono-, di-, tri- and tetraesters in which the hydrogenated rosin acid moiety/ies are either only dihydroabietic acid (DHAA) or only tetrahydroabietic acid (THAA), were chosen as representative structures for the assessment. DHAA was selected as a representative constituent as it is the most common rosin acid in the mixture of rosin acids used to prepare the registered substance. THAA was chosen as a representative constituent as it is the most hydrogenated rosin acid, therefore expected to be the most stable rosin acid, as hydrogenation generally increases stability. Both DHAA and THAA represent abietic-type acids which form a major part of the hydrogenated rosin acids.

The monoester fraction was identified as the fraction with the highest potential for PBT/vPvB, on the basis of its apparent bioaccumulation potential indicated by the QSAR analyses. Therefore the persistence and toxicity assessments as well as the data requests were focussed on the monoester fraction.

The clarification of the PBT/vPvB concern requires consideration of all the relevant endpoints (P, B, T). The reasoning for new information requirements is presented below for each endpoint.

Adaptation of the required testing

ECHA notes that normally testing is expected to be conducted with the registered substance. However, the REACH Regulation provides also the possibility to use adaptations, such as read-across approach.

In the present case, the information is requested on the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' of the registered substance.

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not PBT/vPvB. The structural elements next to the carboxyl group forming the ester bond are similar between the different rosin acids (Appendix 6). The water solubility, molecular dimensions and partition coefficient (based on Log Kow) are relatively similar between different rosin acids.
(*Tukes 2015. Hazard Assessment Outcome Document for Rosin, hydrogenated. EC No 266-041-3 CAS No 65977-06-0. 30 March 2015. Version 1.2. Finnish Safety and Chemicals Agency. Available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/8102/del/50/col/staticField_-104/type/asc/pre/6/view)

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You have indicated in your comments to the draft decision that it is not possible to obtain a sample that contains 100% monoester constituents. Therefore, testing would be conducted with a sample that is enriched in monoester constituents, and the process of synthesising and isolating mono-ester constituents is very challenging. For the glycerol ester, a sample containing ~70% monoesters was obtained following extensive trials carried out. However, for the pentaerythritol ester isolating the monoester constituents will be much more challenging. You expect that with the more complex pentaerythritol ester, the challenge becomes even bigger and that the final percentage of monoester that can be achieved for a sample of the pentaerythritol ester will be lower, which would make analytical determination of monoester constituents much more challenging in the proposed studies.

ECHA agrees that obtaining a sufficiently enriched sample of the monoesterified pentaerythritol constituents for testing can be challenging. The sample to be tested can thus be a fraction of the registered substance enriched for monoesterified pentaerythritol constituents as far as technically possible.

In your comments to the draft decision you have also suggested that a read-across from a similar substance 'Resin acids and Rosin acids, hydrogenated, monoesters with glycerol' could be used to 'Resin acids and rosin acids, hydrogenated, monoesters with pentaerythritol'.

To support the read-across, you have noted that HRPE is a member of the same category of 'Rosin esters' as HRGE, and a read-across approach has been developed for members of this category, based on structural as well as physico-chemical similarities. They further noted that this approach has already been accepted by ECHA for mammalian toxicology endpoints, and a mammalian toxicology test programme is currently in progress on this basis. As the read-across approach is considered to be acceptable for category members for mammalian toxicology endpoints, you consider that a similar approach would be acceptable to ECHA for environmental endpoints as well. You also mention that read-across between the two constituents is considered to be appropriate based on an assessment of the structures of the constituents. It is mentioned that "with monoester constituents, there is hardly any steric hindrance, because the remaining free hydroxyl functions are relatively far away from the ester function."

In reply ECHA points out that at the present stage of the substance evaluation process the validity of the proposed read-across cannot be evaluated by the evaluating MSCA since the requested study/studies is/are not available and (an) endpoint specific justification(s) for the proposed read-across are not yet available.

You are reminded that they may consider adapting the testing requested above according to the general rules contained in Annex XI, including section 1.5 (Grouping of substances and read-across approach) of the REACH Regulation. After receiving the final decision and if you consider that read-across adaptation is appropriate, they can submit all information necessary to justify the read-across. The evaluating MSCA will then assess and decide in the course of the follow up of the substance evaluation process in accordance with Article 46(3) of the REACH Regulation whether the adaptation fulfils the information requirements to address the concerns, provided that such adaptation has a valid scientific justification and an adequate and reliable documentation. It is stressed that any adaptation needs to be justified specifically for each endpoint. For example, for degradation, the same read-across justifications as for toxicity are not necessarily valid as the biological mechanisms differ between those endpoints.

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Further information on read-across adaptation is provided in Appendix 3.

ENDPOINT 1 - PERSISTENCE (P, vP)

The Concern(s) Identified

The persistence assessment was focused on the pentaerythritol monoesters of the hydrogenated rosin acid, as the monoesters have a potential to fulfill the B criterion. A read-across approach is applied to the monoester constituents. Pentaerythritol monoesters with tetrahydroabietic acid and dihydroabietic acid (DHAA-monoPE, THAA-monoPE) were selected as representative constituents for persistence assessment.

No guideline test data is available for concluding on hydrolysis for the registered substance or for the selected constituents. Based on other available data (a non-guideline abiotic hydrolysis test and HYDROWIN QSAR models (HYDROWIN v2.00, U.S. Environmental Protection Agency, 2010), it is highly unlikely that abiotic hydrolysis rates in environmentally relevant conditions would be sufficiently high to rule out the P/vP concern for the registered substance or for the monoester constituents.

Based on the ready biodegradation tests the registered substance is not readily biodegradable (degradation was 3-8.7% during 28 days) and therefore fulfills the screening criterion for persistence. There is no experimental information available for degradation of the individual constituents in the registered substance or in analogous substances.

No strong conclusions can be made on the selected constituents on the basis of BIOWIN models (BIOWIN 4.10, U.S. Environmental Protection Agency, 2010). BIOWIN 1-4 models are poorly applicable for the selected constituents as only a part of the molecular fragments is included in the models. BIOWIN 5 and 6, which are applicable, give somewhat conflicting results. For the pentaerythritol monoesters DHAA-monoPE and THAA-monoPE the BIOWIN 5 and 6 results as a whole are somewhat more towards the outcome "readily biodegradable" than "not readily biodegradable"
(DHAA-monoPE: BIOWIN 5, 0.8151 (Readily degradable); BIOWIN 6, 0.4932 (Not Readily Degradable); THAA-monoPE: BIOWIN 5, 0.8351 (Readily degradable), BIOWIN 6, 0.4983 (Not Readily Degradable).

Microbial transformation prediction for the selected constituents (DHAA-monoPE, THAA-monoPE,) using EAWAG database (EAWAG Aquatic Research Biocatalysis/Biodegradation Database (http://eawag-bbd.ethz.ch/predict/) predicts primary degradates that include the rosin acids DHAA or THAA, and pentaerythritol, which are not PBT/vPvB as mentioned above (see footnote 4), as well as some other degradates for which PBT/vPvB status has not been evaluated.

In conclusion, the registered substance as well as the selected constituents should be considered potentially P/vP. No definitive conclusion can be done based on the available data.

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Why new information is needed

Further information on P/vP is needed on these the monoesterified pentaerythritol constituents, because the registered substance screens as P/vP and these constituents screen as P and B.

Considerations on the test method and testing strategy

i. Ready biodegradability; test method: CO2 in sealed vessels (Headspace test), OECD 310 using the test substance as specified in Appendix 3. The concentrations of the test substance shall be analytically monitored during the test to verify the degradation.

Test substance: monoesterified pentaerythritol constituents of HRPE.

Details of test substance and analytical techniques: see Appendix 3.

This test is appropriate to conclude whether the registered substance screens as PBT/vPvB.

Of the different ready biodegradation test protocols (OECD 301A-F, OECD 310), the CO2 in sealed vessels (Headspace test) (OECD 310), has been selected taking into consideration the information obtained from you during the evaluation period and in your comments on the draft decision. You have informed that they have conducted preliminary biodegradation testing with a sample of a test item containing ~70% 'Resin acids and Rosin acids, hydrogenated, monoesters with glycerol' and that OECD 310 study seems to be the most appropriate method for this sample. ECHA agrees that the OECD 310 test is appropriate for the purposes of this decision.

You may consider extension of the duration of the ready test up to 60 days and techniques to determine the biodegradability of poorly water-soluble chemicals in accordance with ECHA guidance [5]. The extent of biodegradation can be used as supporting information by you when planning the implementation of the next steps of the sequential testing requirements.

When performing, documenting and interpreting the test you need to consider the likely situation that the test substance is not a pure monoester fraction but it may contain constituents (e.g., rosin acids, pentaerythritol), which can be also produced in the degradation of the monoesters.

In the OECD 310 test, the CO_2 evolution is determined by measuring the inorganic carbon (IC) produced. According to the test guideline the DOC (dissolved organic carbon) removal and/or the extent of primary biodegradation of the test substance can also be measured (see Appendix 3.6 for further details).

To support the use of ultimate degradation result of the test substance for the persistence assessment of the monoesters, you can present a justification why they consider it can be concluded that >60% ThIC production (or >70% DOC removal) of the monoesters is achieved based on the test results even though the

[5] ECHA. Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b: Endpoint specific guidance. Version 3.0 February 2016. Appendix R7.9-3.

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inorganic carbon produced from the monoesters (or DOC removal due to the degradation of the monoesters) cannot be analytically separated from the inorganic carbon (or DOC removal) resulting from the degradation of the other constituents.

In case it cannot be demonstrated that >60% of the ThIC production (or >70% DOC removal) of the monoesters has been achieved, their primary degradation rate can be used to evaluate whether the substance does not screen as P/vPas the final hydrolysis products of the monoesters are not PBT/vPvB (footnote 4). Therefore, in this specific case, primary degradation measurements in the ready biodegradability test, in addition to respirometric measurements, can potentially be used to evaluate whether the registered substance screens as PBT/vPvB.

If primary degradation rate is used to conclude on the further testing needs on P/vP, information on transformation products is necessary to verify that the decrease in concentration of the monoesters is really due to degradation and that there is no PBT/vPvB concern with the degradates. The transformation products would then need to be analysed to the extent needed to demonstrate that there is no PBT/vPvB concern (i.e. that primary degradation does not lead to transformation products with PBT/vPvB properties). To quantify the amount of the relevant transformation products produced during the test, in particular the known hydrolysis products of rosin esters, their initial concentrations in the test substance need to be known. In addition, if primary degradation measurement is used for the conclusion, sterile control experiment is necessary to verify the contribution of abiotic phenomena including adsorption processes.

A toxicity control should be included and if inhibition by test substance is suspected the test can be repeated as instructed in the test guideline, using, e.g., a lower test substance concentration.

The analytical techniques used need to have a sufficient sensitivity to analyse and quantify the monoesterified pentaerythritol constituents as well as any other constituents relevant for determining the degradation of the monoester constituents and to identify and quantify possible transformation products relevant for PBT/vPvB assessment.

Consideration of comments received from the Registrant(s)

Use of read-across adaptation

It is noted that in your comments you have suggested that testing should be conducted with the constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with glycerol (HRGE)', with the results read across to the test substance 'Resin acids and rosin acids, hydrogenated, monoesters with pentaerythritol' of this decision.

Responses to the comments concerning read-across adaptation have been provided above (see 'Adaptation of the required testing' in Appendix 1 and further information on read-across adaptation is in Appendix 3.

Extension of test duration

In your comments you propose that the need for extension of test duration of the

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ready biodegradation test will be determined over the course of the study based on initial results. ECHA considers that this proposal is acceptable and also in line with the original draft decision as the extension of test duration is not a mandatory requirement but an option that the you can consider.

Information on transformation products and interpretation of ultimate biodegradation result

In your comments you indicate your agreement concerning the need for assessment of transformation products if primary degradation of the mono-ester constituents is used as the basis for assessing persistence in the ready biodegradation study. However, you propose that if >60% ultimate degradation is achieved by the test item (in this case a read-across substance ~70% 'Resin acids and Rosin acids, hydrogenated, monoesters with glycerol'), this will be sufficient to conclude that the monoester constituents are not persistent and in this situation assessment of transformation products would not be required.

In response to this comment ECHA notes that for concluding "not P/vP" it has to be demonstrated that the monoesters undergo sufficient degradation. If it can be demonstrated without information on transformation products that the pass level of the test guideline is achieved specifically for monoesters (i.e. in OECD 310 >60% of the ThIC production (or >70% DOC removal) of the monoesters is achieved) then information on transformation products is not necessary.

The OECD 310 test is based on CO_2 evolution resulting from the ultimate aerobic biodegradation of the test substance. DOC removal can be included as an optional parameter. Degradability and carbon content may vary between the different constituents of the test substance and therefore the different constituents of the test substance may have degraded to a varying extent when the pass level is achieved at the level of test substance. Therefore, ECHA recommends that for the assessment of the degradability of monoesters, you should report and take into consideration also other relevant information, in addition to the ultimate degradation of the test substance in the OECD 310 test. This should include especially carbon content of the test substance (weight percentage of carbon) and general structural formulas for each of the components of the test substance (such as rosin acids and tetra-, tri-, di-, and monoesters of pentaerythritol) (see Appendix 3.6 for further information).

ii. Simulation testing on ultimate degradation in surface water; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309 at a temperature of 12 °C.

Test substance: monoesterified pentaerythritol constituents of HRPE.

Details of test substance and analytical techniques: see Appendix 3.

If the results of the OECD 310 ready biodegradability test (information requirement 1.1) do not confirm that the registered substance is not P/vP, a degradation half-life must be determined for the purpose of P/vP assessment.

A correctly conducted study using either the OECD Guidelines 307 (soil), 308 (water/sediment) or 309 (water), as described in Section R.7.9.6 of the ECHA

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guidance, with the degradation half-life calculated for the appropriate compartment would allow direct comparison to the P/vP criteria. Even with a correctly conducted study, however, results can be difficult to interpret, particular where partitioning between phases and/or aerobic/anaerobic conditions can arise[6]. In order to limit interpretation difficulties raising from partitioning between different phases, the OECD 309 surface water simulation degradation test is the preferred test to be conducted first provided that this is technically possible.

The obtained results must include degradation half-life and allow a comparison to the P/vP criteria established in Annex XIII to the REACH Regulation.

As determination of a mineralization half-life is recommended for comparing with the P/vP criteria, the use of radiolabelled test substance would be the most advantageous in the present case. However, based on communication with the Registrant(s) the production of radiolabelled constituent 'Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol' may not be technically possible. If radiolabelling is not possible, specific chemical analysis has to be used to determine degradation and also determination of transformation products is necessary. It is noted that according to the OECD 309 test guideline higher concentrations of the test substance (e.g. >100 µg/l) should normally be used for identification and quantification of major transformation products due to analytical limitations.

When performing, documenting and interpreting the test you need to consider the likely situation that the test substance is not a pure monoester fraction but it may contain constituents (e.g., rosin acids, pentaerythritol), which can be also produced in the degradation of the monoesters. Therefore, if primary degradation rate is used to conclude on P/vP, information on transformation products is necessary to verify that the decrease in concentration of the monoesters is really due to degradation and that there is no PBT/vPvB concern with the degradates. To quantify the amount of the relevant transformation products produced during the test their initial concentrations in the test substance need to be known. In addition, if primary degradation measurement is used for the conclusion, sterile control experiment is necessary to verify the contribution of abiotic phenomena, including adsorption processes.

The analytical techniques used need to have a sufficient sensitivity to analyse and quantify the monoesterified pentaerythritol constituents as well as any other constituents relevant for determining the degradation rate, extent, and half-life of the monoester constituents and to identify and quantify possible transformation products relevant for PBT/vPvB assessment.

Alternative approaches and Proportionality of the request

Without the information on persistence no definitive conclusion can be made on the PBT properties of the registered substance. The requests for degradation testing are suitable and necessary to obtain information that will allow to clarify whether the suspected concern may be realised or not. More explicitly, there is no equally suitable alternative

[6] ECHA. Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b: Endpoint specific guidance. Version 3.0 February 2016. Pages 224-225

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way available of obtaining this information.

Consideration of comments received from the Registrant(s)

Responses to the comments concerning read-across adaptation have been provided above (see 'Adaptation of the required testing' in Appendix 1 and further information on read-across adaptation is in Appendix 3.

No specific comments were received from you. However, you welcome the opportunity to discuss the methodology with the evaluating MSCA and ECHA prior to the starting the studies to ensure that the approach followed is acceptable to all.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the constituent Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol as specified in this Appendix as test substance subject to this decision if triggered in the sequential approach described in this decision:

> Ready biodegradability; test method: CO2 in sealed vessels (Headspace Test), OECD 310. The concentrations of the test substance shall be analytically monitored during the test to verify the degradation.
>
> Simulation testing on ultimate degradation in surface water; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309 at a temperature of 12 °C.

ENDPOINT 2 - BIOACCUMULATION (B, vB)

The Concern(s) Identified

Based on the log Kow values predicted by KOWWIN model for selected individual structures (Table 1), it can be stated that monoesterified pentaerythritol constituents of HRPE screen as B/vB in accordance with ECHA guidance on PBT/vPvB assessment [7], whereas the structures with a higher degree of esterification (di-, tri, and tetraesters of pentaerythritol) have log Kow values exceeding 10 and indicating lower potential for bioaccumulation.

The experimental log Kow results on the registered (UVCB) substance (HRPE) range from 4.6 - 7.3 ([redacted]) and thus support the conclusion that constituents of HRPE screen as B/vB, although this experiment does not give information on the differences in log Kow values of the different fractions or the individual constituents of the registered substance as the analytical peaks have not been identified.

[7] ECHA. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 2.0 November 2014

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Based on predicted log Kow values for individual constituents, it can be concluded that the monoesterified pentaerythritol constituents meet the B/vB screening criterion (log Kow > 4.5).

The QSAR predictions for bioconcentration factors (BCFs) further support that the monoesterified pentaerythritol constituents screen as B/vB, whereas for di-, tri- and tetraesters of pentaerythritol the predictions show BCF values below B/vB criterion (Table 2).

Table 1. Log Kow values predicted by EPISuite KOWWIN for representative HRPE constituents.

Parameter	THAA-mono-PE	DHAA-mono-PE	DHAA-diPE	DHAA-triPE	DHAA- tetra-PE
Log Kow (KOWWIN)	5.78	5.70	12.16	19.22	27.71

Table 2. BCF values predicted by EPISuite BCFBAF for representative HRPE constituents (L/kg) (in bold when exceeding B criterion).

Parameter/ EPISuite BCFBAF model	THAA-mono-PE	DHAA-mono-PE	DHAA-diPE	DHAA-triPE	DHAA-tetra-PE
regression based	**3038**	**2669**	39.31	3.162	3.162
Arnot-Gobas, upper trophic, 10.7 % lipids*	174	165.8	0.974	0.893	0.893
Arnot-Gobas, upper trophic, 5 % lipids*	81.3	77.5	0.455	0.417	0.417
Arnot-Gobas, upper trophic, 10.6 % lipids**	**19300**	**18340**	1.479	0.893	0.893
Arnot-Gobas, upper trophic, 5 % lipids**	**9019**	**8570**	0.691	0.417	0.417
Biotransformation half-life normalized to 10 g fish (days)	0.46	0.43	68.8	16740	11220000

*) including biotransformation rate estimates

**) zero biotransformation

In conclusion, the monoesterified pentaerythritol constituents and thus the registered substance should be considered potentially B/vB. No definitive conclusion can be done based on the available information.

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Why new information is needed

There are no experimental data on the bioconcentration or bioaccumulation of HRPE or constituents of HRPE in fish (or other species). Because the monoesterified pentaerythritol constituents of HRPE screen as P and B, further information on bioaccumulation is needed on these constituents, unless it is demonstrated by information request 1.1. (ready biodegradation test OECD 310) or information request 1.2 (simulation testing on ultimate degradation in surface water) that the monoester constituents do not fulfil the P screening criterion or the P criterion based on simulation degradation testing, respectively.

Considerations on the test method and testing strategy

i. Bioaccumulation in aquatic species; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous exposure.

Test substance: monoesterified pentaerytritol constituents of HRPE.

Details of test substance and analytical techniques: see Appendix 3.

The test shall be performed with aqueous exposure.

According to ECHA guidance (ECHA 2014), for strongly hydrophobic substances (log Kow > 5 and a water solubility below ~ 0.01-0.1 mg/L), testing via aqueous exposure may become increasingly difficult. However, an aqueous exposure test is preferred for substances that have a high log Kow but are still appreciably water soluble with respect to the sensitivity of available analytical techniques, and for which the maintenance of the aqueous concentration as well as the analysis of these concentrations do not pose any constraints. In case of monoesterified pentaerythritol ester constituents, the water solubility (Table 3) is considered sufficient to conduct the bioaccumulation test with aqueous exposure. A flow-though system is recommended, and solvents can be applied in accordance with the test guideline.

It should be noted that the dietary test yields a dietary biomagnification factor (BMF) rather than a bioconcentration factor (BCF). Unlike BCF values, the BMF values are not directly comparable to REACH Annex XIII B/vB criteria. Calculation methods are available to estimate a kinetic BCF value from data generated in the dietary study, but these estimations are related with considerable uncertainty. Therefore, the bioaccumulation test is requested to be performed with aqueous exposure. Only if it is justified that the test is technically impossible to conduct with aqueous exposure, the test can be conducted with dietary exposure.

It is noted that as the test substance is an enriched (monoesterified pentaerythritol ester) fraction of the registered UVCB substance, it may turn out more feasible to analyse the concentrations of the monoesterified pentaerythritol ester constituents in the bioaccumulation test (where a steady water concentration can be maintained in flow-through conditions and concentrations in the fish increase if the substance accumulates) as compared to the simulation degradation test (where concentrations are diminishing during the test).

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Therefore, you may choose to perform the bioaccumulation testing before the simulation degradation testing, if this can be justified.

Table 3. QSAR predictions for water solubility of HRPE constituents.

Parameter	THAA-monoPE	DHAA-monoPE	DHAA-diPE	DHAA-triPE	DHAA-tetraPE
Water solubility, mg/L WSKOW	0.02478	0.03017	1.254e-009	4.389e-017	8.0×10^{-27}
Water solubility, mg/L WatSol	6.3414	8.5167	4.1687e-006	9.9553e-007	1.3×10^{-6}

Alternative approaches and Proportionality of the request

Without the information no definitive conclusion can be made on the PBT properties of the registered substance. The request for bioaccumulation testing is suitable and necessary to obtain information that will allow to clarify whether the suspected concern may be realised or not. More explicitly, there is no equally suitable alternative way available of obtaining this information. ECHA notes that there is no experimental study available at this stage that will generate the necessary information and does not need to test on vertebrate animals.

Consideration of comments received from the Registrant(s)

Responses to the comments concerning read-across adaptation have been provided above (see 'Adaptation of the required testing' in Appendix 1 and further information on read-across adaptation is in Appendix 3.

No specific comments were received from you. However, you welcome the opportunity to discuss the methodology with the evaluating MSCA and ECHA prior to the starting the studies to ensure that the approach followed is acceptable to all.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the constituent Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol as specified in this Appendix as test substance subject to this decision if triggered in the sequential approach described in this decision:

Bioaccumulation in aquatic species; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous exposure.

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ENDPOINT 3 - TOXICITY (T)

The Concern(s) Identified

Environmental toxicity

The available short-term aquatic toxicity studies with fish (OECD 203), Daphnia (OECD 202) and algae (OECD 201), which applied water accommodated fractions (WAF) of several UVCB rosin substances belonging to the same rosin substance category, showed no toxic effects within the nominal test concentrations with loading rates up to 100 or 1000 mg/L (with the exception of one Daphnia test, EC50 27 mg/L for a structural analogue Resin and rosin acids, hydrogenated, esters with methyl) as cited in the registration dossier.

However, with HRPE only monoesters of the known constituents are slightly water soluble (0.02 - 8.5 mg/l, according to modelling results with EPISuite/WSKOW and WatSol) and hence potentially better bioavailable than di-, tri-, and tetraesters with practically no water solubility. The same is seen with other rosin ester analogues: only monoesters are slightly water soluble according to modelling results. Therefore it can be estimated that monoesterified rosin ester structures are the potentially toxic rosin ester constituents.

The stability of test substances in the test solutions seems to be rather poor and the concentration decreases significantly during the exposure, the mechanism of which has not been studied. The analytical control measurements may not be reliable for the UVCB substances as the quantification in the available reliable studies have been based only on one single chromatographic peak. Hence the actual composition and concentration of these test items in toxicity tests remains more or less unknown.

EPISuite ECOSAR tool offers very limited possibilities for predicting the ecotoxicity of HRPE as the applicability is restricted by low water solubility and high lipophilicity of the constituents. Only mono-HRPE fit the applicability domain of the ECOSAR model (class esters) for some endpoints. For these endpoints the results are above the PBT screening criterion of 0.1 mg/L (EC50 (algae) 0.162 mg/L, ChV (algae) 0.136 mg/L, ChV (Daphnid) 0.137 mg/L).

It can be concluded that the evaluated UVCB substance is not expected to cause short-term ecotoxic effects that would meet the T screening criteria in PBT assessment, with the provision that the actual availability and concentration of the test substances in the test solutions are somewhat uncertain.

No long-term ecotoxicological studies on rosin esters were available for the evaluation, but in your registration dossiers you propose a Daphnia reproduction test (Long-term toxicity testing on aquatic invertebrates; test method: Daphnia magna reproduction test, EU C.20./OECD 211) to be conducted. The testing proposal examination has been suspended as the same study is being requested under the current substance evaluation. Moreover, the substance evaluation can be considered as a more appropriate process because it is focused on the constituent of interest to clarify the PBT concern.

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Toxicity

No carcinogenicity or germ cell mutagenicity studies have been carried out, yet the studied rosin ester substance analogues were not observed to be mutagenic or clastogenic in bacterial or mammalian cells in vitro with or without metabolic activation. The available mutagenicity studies for the UVCB substances within the category of rosin esters and cited in the registration dossier are bacterial reverse mutation assays (OECD 471), mammalian cell gene mutation assays (OECD 476) and in vitro mammalian chromosome aberration test (OECD 473).

Studies on toxicity for reproduction and chronic toxicity with the UVCB substances as such have been conducted, and the findings do not indicate that these rosin ester substances would fulfil the toxicity criteria. The available studies cited in the registration dossier are repeated dose 28-day (non-guideline) and repeated dose 90-day oral toxicity studies (equivalent or similar to OECD 408), and reproductive/developmental toxicity studies (OECD 421, OECD 422).

The results of all available toxicity information including the on-going pre-natal developmental toxicity study (OECD 414, Decision on a testing proposal 14 August 2014) shall be considered in the T assessment together with the the results of the ecotoxicity studies.

Why new information is needed

Aquatic long-term toxicity testing is required according to the sequential testing approach if the the biodegradation and bioaccumulation tests demonstrate that the test substance fulfils the criteria of being persistent (P) and bioaccumulable (B) in order to conclude the PBT/vPvB assessment.

Considerations on the test method and testing strategy

i. Long-term toxicity testing on aquatic invertebrates; test method: Daphnia magna reproduction test, EU C.20./OECD 211

Test substance: monoesterified pentaerythritol constituents of HRPE.

Details of test substance and analytical techniques: see Appendix 3.

OECD Guidance on the testing of difficult substances shall be considered [8].

Because the difference in sensitivity between Daphnia and fish is currently not known for this substance, a lack of toxicity at or below the T criterion for the Daphnia species may not be regarded as conclusive evidence that further studies on T are not necessary. In accordance with ECHA guidance [9], if the long-term test on Daphnia provides a NOEC close to but above 0.01 mg/L, a long-term fish study is likely to be needed to confirm 'not T' unless convincing evidence exists

[8] OECD series on testing and assessment Number 23. Guidance document on aquatic toxicity testing of difficult substances and mixtures, ENV/JM/MONO(2000)6, 2000.
[9] ECHA. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB assessment Version 2.0 November 2014.

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that the fish NOEC will be higher than 0.01 mg/L. In such a case the you may wish to consider doing further testing on fish (e.g. OECD TG 210). The evaluating MSCA can consider further ecotoxicity testing in a follow-up decision as well. The information obtained from the bioaccumulation test in fish (information requirement 1.3), including the range finding toxicity test) can be useful in this consideration.

Alternative approaches and Proportionality of the request

Without the information no definitive conclusion can be made on the PBT properties of the registered substance if the test results demonstrate that the monoester constituents of the registered substance fulfil the criteria of being P and B. The request for long-term aquatic toxicity testing is suitable and necessary to obtain information that will allow to clarify whether the suspected concern may be realised or not. More explicitly, there is no equally suitable alternative way available of obtaining this information. ECHA notes that there is no experimental study available at this stage that will generate the necessary information.

Consideration of comments received from the Registrant(s)

Responses to the comments concerning read-across adaptation have been provided above (see 'Adaptation of the required testing' in Appendix 1 and further information on read-across adaptation is in Appendix 3.

No specific comments were received from you. However, you welcome the opportunity to discuss the methodology with the evaluating MSCA and ECHA prior to the starting the studies to ensure that the approach followed is acceptable to all.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the constituent Resin acids and Rosin acids, hydrogenated, monoesters with pentaerythritol, as specified in detail in Appendix 3, as test substance subject to this decision if triggered in the sequential approach described in this decision:

Long-term toxicity testing on aquatic invertebrates; test method: Daphnia magna reproduction test, EU C.20./OECD 211

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Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to environment/suspected PBT/vPvB; exposure/wide dispersive use, exposure of environment, consumer use and high (aggregated) tonnage, Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol, CAS No 64365-17-9 (EC No 264-848-5) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2015. The updated CoRAP was published on the ECHA website on 17 March 2015. The Competent Authority of Finland (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

Pursuant to Article 45(4) of the REACH Regulation the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

The evaluating MSCA considered that further information was required to clarify the following concerns: PBT/vPvB. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 17 March 2016.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took into account the comments from you, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

The evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received proposal(s) for amendment to the draft decision. They are reflected in the Reasons (Appendix 1).

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s). The Member State Committee did not take into account any comments on the draft decision as they were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 52(2) and Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was

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reached on 28 November 2016 in a written procedure launched on 17 November 2016 and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. 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 your Member State.

3. In relation to the required experimental studies, the sample of the substance to be used shall represent the monoesterified pentaerythritol constituents of HRPE. The sample to be tested can be a fraction of the registered (UVCB) substance enriched for monoesterified pentaerythritol constituents as far as technically possible. It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. It is noted that the testing requested might be subject to adaptation as explained in Appendix 1. Further guidance for building up a justification for a read-across adaptation can be found in ECHA (2008)[10]. The same guidance as for dossier evaluation can be applied under substance evaluation.

5. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

   Further advice can be found at
http://echa.europa.eu/regulations/reach/registration/data-sharing. If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.

[10] Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals. May 2008. European Chemicals Agency. Available at:
https://www.echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

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5. The analytical techniques used shall have sufficient sensitivity to analyse and quantitate the monoesterified pentaerythritol constituents (and other relevant constituents and/or transformation products) for the purposes of the tests. In practical terms, relevant constituents and transformation products need to be analysed to the extent technically possible.

6. Regarding the ready biodegradation testing (information requirement 1.1):

   If DOC and/or primary degradation measurement is used for the conclusion, sterile control experiment is necessary to verify the contribution of abiotic phenomena including adsorption processes.

   OECD 310 test guideline includes DOC removal as an optional parameter but it does not specify a pass level for that. However, the introduction to OECD degradation tests (OECD 2006*) mentions (in the context of OECD 301 test guideline) that "The pass levels of either 60% ThOD (or $ThCO_2$) or 70% DOC removal practically represent complete ultimate degradation of the test substance as the remaining fraction of 30-40% of the test substance is assumed to be assimilated by the biomass or present as products of biosynthesis. In addition, in OECD 301 test guideline** it is stated "The pass levels for ready biodegradability are 70% removal of DOC and 60% of ThOD or $ThCO_2$ production for respirometric methods. They are lower in the respirometric methods since, as some of the carbon from the test chemical is incorporated into new cells, the percentage of CO_2 produced is lower than the percentage of carbon being used." In line with these documents, ECHA considers that if DOC removal in the OECD 310 test is used to conclude on the P screening criterion, the pass level for DOC removal shall be >70%.

   The general structural formulas are needed in particular to determine the carbon content of the constituents. The general structural formulas can be estimated based on information available to the Registrant(s), e.g., on the composition of source substances which are used for the synthesis of the test substance. For example, structural formulas of the mono-, di-, and triesters in which rosin acid moieties consist of the most common rosin acid in the source substance can be used, if the carbon content is considered to be representative for the constituent fraction. According to Environment Canada (2011)*** the most common rosin acids have the structural formula C_{20} H_{30} O_2. This formula can be used if appropriate for the test substance. Experimental determination of structural formulas of the different constituents of the test substance is therefore not necessarily needed.

   *OECD (2006). OECD guidelines for the testing of chemicals. Revised introduction to the OECD guidelines for testing of chemicals. Section 3. Part 1: Principles and strategies related to the testing of degradation of organic chemicals. Degradation of organic chemicals.

   ** OECD guideline for testing of chemicals. 301. Adopted by the Council on 17th July 1992. Ready biodegradability.

   ***Environment Canada (2011). Screening Assessment for the Challenge - Resin, hydrogenated; Resin acids and rosin acids, hydrogenated, esters with pentaerythritol; Resin acids and rosin acids, hydrogenated, esters with glycerol; Resin acids and rosin acids, hydrogenated, esters triethylene glycol. p. 3, available at: https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=8E8373E7-1

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Appendix 4: List of registration numbers for the addressees of this decision. This appendix is confidential and not included in the public version of this decision.

EC number: 264-848-5
CAS number: 64365-17-9
Public name: Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol

This decision is addressed to the Registrant(s) of the above substance with active registration pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided below.

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Appendix 5: Structural formulas of rosin acids.

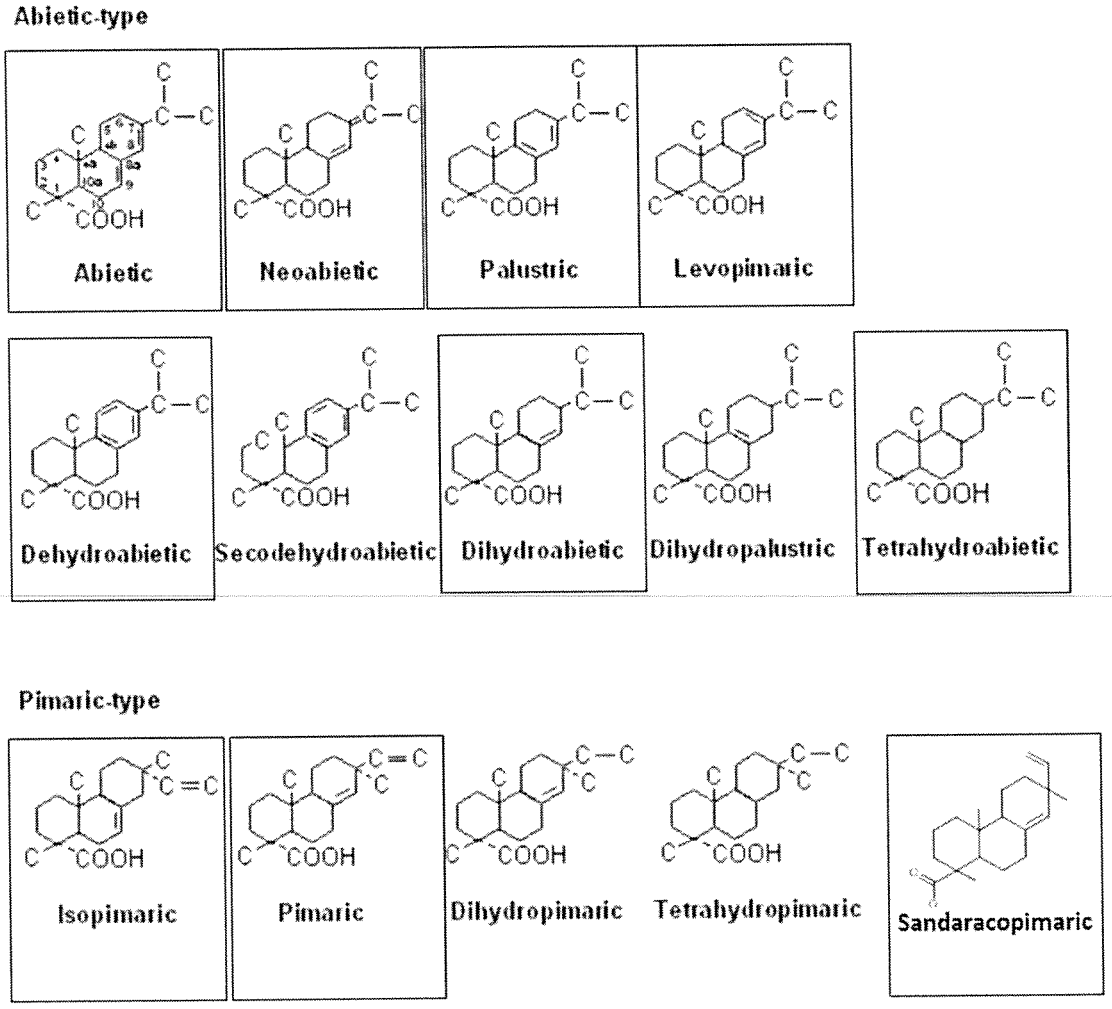

Figure 1. Structural formulas of rosin acids (modified from http://www.eastman.com/Online_Publications/WA79/wa7903.htm) (accessed 11 January 2016). The framed structures were detected (>0.1%) in the hydrogenated rosin acid used to prepare HRPE according to the registration dossier)

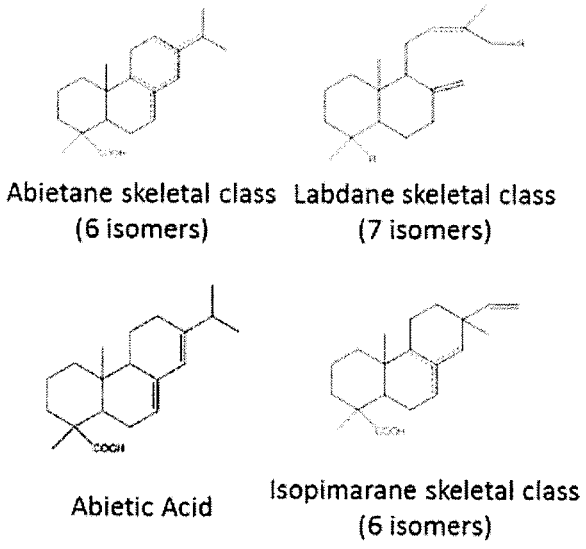

Figure 2. The skeletal classes of rosin acids [redacted])