

## Assessment of regulatory needs

**Authority:** European Chemicals Agency (ECHA)

**Group Name:** Resin and Rosin and its derivatives

**General structure:** -

### Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	16 August 2023	

Table 1: Substances within this group

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Sub-group 1-Resin/rosin acids and hydrogenated resin/rosin acids and salts</b>			
208-178-3	514-10-3	Abietic acid	C&L notification
217-102-8	1740-19-8	[1R-(1 $\alpha$ ,4 $\alpha$ $\beta$ ,10 $\alpha$ )]- 1,2,3,4,4 $\alpha$ ,9,10,10 $\alpha$ -octahydro-7- isopropyl-1,4 $\alpha$ -dimethylphenanthren- 1-carboxylic acid	C&L notification
232-475-7	8050-09-7	Rosin	Full, >1000
232-694-8	9007-13-0	Resin acids and Rosin acids, calcium salts	Full, >1000
232-716-6	9008-34-8	Resin acids and Rosin acids, manganese salts	Full, not (publicly) available
248-873-9	28161-39-9	Sodium [1R-(1 $\alpha$ ,4 $\alpha$ $\beta$ ,10 $\alpha$ )]- 1,2,3,4,4 $\alpha$ ,9,10,10 $\alpha$ -octahydro-7- isopropyl-1,4 $\alpha$ -dimethylphenanthren- 1-carboxylate	Not registered
263-075-0	61789-65-9	Resin acids and Rosin acids, aluminum salts	Full, not (publicly) available
263-142-4	61790-50-9	Resin acids and Rosin acids, potassium salts	Full, >1000
263-144-5	61790-51-0	Resin acids and Rosin acids, sodium salts	Full, >1000
266-041-3	65997-06-0	Rosin, hydrogenated	Full, >1000
269-142-0	68188-14-7	Resin acids and Rosin acids, barium salts	Full, >1000
269-825-3	68334-35-0	Resin acids and Rosin acids, calcium zinc salts	Full, not (publicly) available
270-461-2	68440-56-2	Resin acids and Rosin acids, magnesium salts	Full, not (publicly) available
271-402-3	68554-12-1	Resin acids and Rosin acids, hydrogenated, calcium salts	Full, not (publicly) available
272-037-2	68649-89-8	Resin acids and Rosin acids, ammonium salts	Full, not (publicly) available

<sup>1</sup> Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
273-572-4	68990-01-2	Resin acids and Rosin acids, hydrogenated, potassium salts	C&L notification
273-574-5	68990-02-3	Resin acids and Rosin acids, hydrogenated, sodium salts	Full, not (publicly) available
500-163-2	65997-05-9	Rosin, oligomers	Full, >1000
810-810-3	68425-02-5	Hydrogenated rosin, zinc salt	Full, not (publicly) available
911-238-8	-	Reaction mass of Rosin, hydrogenated and [1R-(1 $\alpha$ ,4 $\alpha\beta$ ,10 $\alpha\alpha$ )]- 1,2,3,4,4 $\alpha$ ,9,10,10 $\alpha$ -octahydro-7- isopropyl-1,4 $\alpha$ -dimethylphenanthren- 1-carboxylic acid	Full, 100-1000
915-568-3	-	Reaction mass of Resin acids and Rosin acids, hydrogenated, sodium salts and sodium [1R-(1 $\alpha$ ,4 $\alpha\beta$ ,10 $\alpha\alpha$ )]- 1,2,3,4,4 $\alpha$ ,9,10,10 $\alpha$ -octahydro-7- isopropyl-1,4 $\alpha$ -dimethylphenanthren- 1-carboxylate	Not registered
915-657-7	-	Reaction mass of Resin acids and Rosin acids, hydrogenated, potassium salts and potassium [1R- (1 $\alpha$ ,4 $\alpha\beta$ ,10 $\alpha\alpha$ )]-1,2,3,4,4 $\alpha$ ,9,10,10 $\alpha$ - octahydro-7-isopropyl-1,4 $\alpha$ - dimethylphenanthren-1-carboxylate	Not registered
920-105-3	-	Resin acids and Rosin acids, dimers, calcium zinc	Full, not (publicly) available
947-943-2	-	Reaction products of Resin acids and Rosin acids, sodium salts and barium chloride	Full, not (publicly) available
-	471-74-9	(-)-Sandaracopimaric acid	Not registered
<b>Sub-group 2-Esters from Resin/rosin acids</b>			
204-832-7	127-25-3	Methyl abietate	Full, not (publicly) available
232-476-2	8050-15-5	Resin acids and Rosin acids, hydrogenated, Me esters	Full, 100-1000
232-478-3	8050-25-7	Resin acids and Rosin acids, esters with triethylene glycol	Full, >1000

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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
232-479-9	8050-26-8	Resin acids and Rosin acids, esters with pentaerythritol	Full, >1000
232-482-5	8050-31-5	Resin acids and Rosin acids, esters with glycerol	Full, >1000
264-848-5	64365-17-9	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol	Full, 100-1000
266-042-9	65997-13-9	Resin acids and Rosin acids, hydrogenated, esters with glycerol	Full, >1000
268-884-2	68153-38-8	Resin acids and Rosin acids, esters with diethylene glycol	Full, 100-1000
269-035-9	68186-14-1	Resin acids and Rosin acids, Me esters	Full, not (publicly) available
270-986-7	68512-65-2	Resin acids and Rosin acids, esters with ethylene glycol	Cease manufacture
271-996-4	68648-53-3	Resin acids and Rosin acids, hydrogenated, esters with triethylene glycol	Full, 100-1000
284-009-7	84776-83-0	Resin acids and Rosin acids, esters with trimethylolpropane	Full, not (publicly) available
613-868-6	65997-12-8	Resin acids and Rosin acids, polymd., esters with pentaerythritol	Full, not (publicly) available
614-523-2	68475-37-6	Resin acids and Rosin acids, polymd., esters with glycerol	Full, not (publicly) available
685-540-0	208126-52-7	Reaction product of resin acid and rosin acid, 12-Hydroxyoctadecanoic and stearic acid with dipentaerythritol	Full, not (publicly) available
<b>Sub-group 3-Resin/rosin acids fumarated/maleated and their salts</b>			
232-480-4	8050-28-0	Rosin, maleated	Full, >1000
266-040-8	65997-04-8	Rosin, fumarated	Full, >1000
269-228-8	68201-60-5	Resin acids and Rosin acids, maleated, sodium salts	Full, >1000

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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
272-035-1	68649-83-2	Resin acids and Rosin acids, fumarated, potassium salts	C&L notification
287-094-9	85409-27-4	Resin acids and Rosin acids, maleated, potassium salts	Full, not (publicly) available
293-625-5	91081-22-0	Resin acids and Rosin acids, fumarated, compds. with triethanolamine	Full, not (publicly) available
294-402-5	91722-01-9	Resin acids and Rosin acids, maleated, calcium salts	Full, not (publicly) available
305-795-0	95009-65-7	Rosin, fumarated, reaction products with formaldehyde	Cease manufacture
500-451-8	160901-14-4	Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	Full, not (publicly) available
700-751-0	-	Reaction Product of Rosin, fumarated, Tall-Oil Rosin, Ca(OH) <sub>2</sub> and MgO	Full, not (publicly) available
940-281-5	-	Fatty acids, tall oil and rosin reacted with maleic anhydride	Full, not (publicly) available
-	68554-16-5	Rosin, fumarated maleated	Not registered
<b>Sub-group 4-Esters from Resin/rosin acids fumarated/maleated</b>			
296-047-1	92202-14-7	Rosin, fumarated, reaction products with glycerol and pentaerythritol	Full, >1000
305-514-1	94581-15-4	Resin acids and Rosin acids, fumarated, esters with pentaerythritol	Full, >1000
305-515-7	94581-16-5	Resin acids and Rosin acids, maleated, esters with glycerol	Full, not (publicly) available
305-516-2	94581-17-6	Resin acids and rosin acids, maleated, esters with pentaerythritol	Full, 100-1000
307-051-0	97489-11-7	Resin acids and Rosin acids, fumarated, esters with glycerol	Full, 100-1000
925-698-2	-	Rosin, maleated, esterified with sorbitol	Full, not (publicly) available

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EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>1</sup>
<b>Sub-group 5-Reaction products of resin/rosin acids with formaldehyde and their salts</b>			
293-631-8	91081-28-6	Resin acids and Rosin acids, reaction products with formaldehyde, sodium salts	Full, not (publicly) available
293-659-0	91081-53-7	Rosin, reaction products with formaldehyde	Full, >1000
295-855-1	92129-53-8	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	Full, 100-1000
696-130-6	1364681-45-7	Resin acids and Rosin acids, reaction products with formaldehyde, calcium salts	C&L notification
<b>Subgroup 6-Reaction products of resin/rosin acids with acrylic acid</b>			
280-192-2	83137-13-7	Rosin, reaction products with acrylic acid	Full, not (publicly) available
434-230-1	144413-22-9	Complex reaction mass of Chinese gum rosin post reacted with acrylic acid	Full, 1-10

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

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## Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)<sup>2</sup>. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level<sup>3</sup>. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

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<sup>2</sup> [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

<sup>3</sup> Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website<sup>4</sup>.

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<sup>4</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

## Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RDT	Repeated dose toxicity
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing proposal evaluation

## 1 Overview of the group

*Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.*

ECHA has grouped together structurally similar substances based on the starting material resin rosin used for their manufacturing.

The term “resin” may be used in different contexts and may refer to different substances usually soft solids or highly viscous substances. The term “natural resins” is generally used for describing tree and plant exudates, fossil resins, mined resins, and shellac. They often have been altered from their original state during isolation and processing. For some applications, the resins have been chemically modified to increase their industrial utility. Natural resins, except for shellac, are mixed condensation products of naturally occurring terpenoids and flavonoids contained in trees. Shellac is a product of insect secretion.

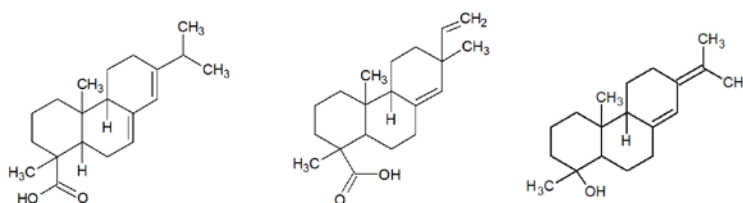
Rosin, a natural resin, is isolated from pine trees. Three main types of processes are used to obtain rosins that result in gum, wood and tall oil rosin. The rosins obtained via these processes have been registered together.

The composition of rosin is complex and may vary depending on the pine species, the geographical area where the pine is grown, climate, season and the process used for extracting the rosin. It consists of a complex mixture of monocarboxylic acids of alkylated hydrophenanthrene nuclei. These constituents, known as resin acids, represent about 90% of rosin, and are subdivided into two types, based on their skeletal structure. The abietic-type acids contain an isopropyl group pendent from the carbon numbered 13. The pimaric-type acids have a methyl and vinyl group pendent from the same carbon atom.

The group mainly consists of UVCB substances obtained via different reactions such as salification, esterification and Diels-Alder reactions.

The composition of these substances includes a multitude of diterpenes mainly consisting of resin acids and their derivatives. The composition of resin rosin includes also a minor fraction (~10%) consisting of alcohols, aldehydes, esters.

Examples of the structures that may be found in the composition of resin rosin are given below:



The starting material used for manufacturing the substances included in this group may be obtained by blending rosins obtained via different process type, e.g. tall oil rosin and gum rosin.

The substances within this group have been subdivided into six subgroups, based on their derivatisation process:

1-Resin/rosin acids and hydrogenated resin/rosin acids and their salts

- 2-Esters from resin/rosin acids
- 3-Resin/rosin acids fumarated/maleated and their salts
- 4-Esters from resin/rosin acids fumarated/maleated
- 5-Reaction products of resin/rosin acids with formaldehyde and their salts
- 6-Reaction products of resin/rosin acids with acrylic acid

For these substances ECHA received 52 full registrations and 5 C&L notifications, for two substances manufacture ceased and five substances are not registered.

Based on information reported in the REACH registration dossiers, the uses of all substances of the group are overall homogeneous and encompass 34 product categories. The main uses of the substances are e.g. in varnishes, inks (e.g. printing inks), paper sizing, paper photocopying and laser printing, adhesives, polymer compositions, soap, soldering fluxes, sealing wax, products to increase friction (music, sport). The substances are used in mixtures and articles by industrial users, professional users, and consumers. Due to the high tonnage and the extent of the uses, there is a high potential for releases and exposure. The uses are concluded to be wide dispersive. Furthermore, it is assumed that the substances can be used as substitute to each other since the chemical structures and technical functions are similar.

Two members of the group (EC 264-848-5 and EC 266-042-9) are or were evaluated under substance evaluation (SEv) process due to initial PBT/vPvB concern. Substance evaluation for the PBT/vPvB hazards is still on-going for EC 264-848-5, where degradation testing has been requested. In addition, four members of the group (EC 232-475-7, EC 232-480-4, EC 263-144-5, EC 266-041-3) were assessed in voluntary PBT assessments. It was concluded that none of these substances have PBT/vPvB hazards, except possibly the 'light ends fraction' for EC 266-042-9 (a fraction that is also present, at least in EC 264-848-5), which still needs to be further investigated. Further, in the SEv conclusion, the evaluating MS (FI) noted that, under anaerobic conditions, potentially P/vP transformation products could form from the fraction 'resin acids and rosin acids'.

So far, none of the substances in the group underwent any regulatory risk management process under REACH or CLP.

## 2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g. strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document may be updated and conclusions and actions revisited.

**Table 2: Conclusions and proposed actions**

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
All substances in the group	Known or potential hazard for reproductive toxicity, ED, skin sensitisation (skin sens 1) and respiratory sensitisation	Known or potential hazard for PBT/vPvB and for ED  Inconclusive hazard for aquatic toxicity and for PMT	Widespread uses: industrial, professional and consumer uses in many product types, article service life (e.g. coatings and paints, adhesives and sealants, polishes and wax blends, washing and cleaning products, etc; see Annex 2)	<p><b>First step:</b></p> <p>CLH (Repr.) for subgroups or individual substances for which data already sufficient/read-across justified. DEv/SEv to be considered for substances for which more information is needed before CLH.</p> <p>CCH to address the PBT/vPvB.</p> <p>TPE for aquatic toxicity.</p> <p>DEv/SEv to be considered to clarify potential ED properties.</p> <p><b>Next step (if hazard confirmed after data generation):</b> SVHC identification for PBT/vPvB if data generated through CCH confirms this hazard</p>

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				<p><b>Last foreseen action suggested: Restriction</b></p> <p><u>Justification:</u>                      Harmonised classification as Repr. 1B would trigger the restriction entry 30 and thereby ensure that the use of the substances in consumer mixtures is below the limits specified in that entry.</p> <p>The substance has different professional uses with relatively low levels of operational controls and risk management measures. Restriction of professional uses is suggested instead of authorisation because it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.</p> <p>Potential exposure from industrial uses and articles needs further investigation. The need for restriction for industrial uses and articles uses may be considered as part of the restriction.</p> <p>If PBT/vPvB is confirmed, further restriction may be considered, aiming at minimisation of releases.</p>

### 3 Justification for the need for regulatory risk management action at EU level if hazards confirmed

#### **Suggested regulatory risk management actions for all substances if reproductive toxicity (and later PBT/vPvB) hazards are confirmed**

##### Potential reproductive toxicity

Based on the information available in the registration dossiers, there is a concern on reproductive toxicity.

For development, it is considered that the data may already be sufficient for classification, potentially as Repr. 1B, for all substances in subgroups 1, 3 and 4. For subgroups 2, 5 and 6 there is less data available and therefore it is more uncertain whether classification for the whole subgroup or individual substances could be warranted. A more in-depth assessment of the data and potential read-across is needed to conclude. If following this assessment, the data will not be sufficient for classification, further data generation should be considered, where appropriate.

For sexual function and fertility, consistent effects are seen in subgroups 1, 3 and 4. Although not always seen for all substances in each subgroup, they may be sufficient for classification.

Indeed, effects on sexual function and fertility are seen for one of the substances in subgroup 1. The effects are consistent with those seen in subgroups 3 and 4 (see below) and are considered relevant for classification. For development, effects that are considered relevant for classification are seen with all substances in subgroup 1.

In subgroup 2, two of the substances show effects on development that could warrant classification. One of them shows reductions in pup and litter body weight. Those are effects that are consistently seen also in other subgroups and are considered relevant for classification. For the other substances in subgroup 2, limited data is available and for some substances, no effects warranting classification are seen in the available studies. It should be noted that different studies (PNDT or screening studies) are available for the different substances and some of the studies are poorly reported, which makes the assessment, comparison between the substances and conclusions uncertain. Detailed assessment of the data and read-across is needed to conclude on potential classification of the whole subgroup. If following this further assessment, it is considered that read across to the substances where effects are seen is justified, the substances without effects/data could also warrant classification. If not, further data generation should be considered.

For subgroup 3, effects that could warrant classification for sexual function and fertility are seen for one substance, while effects that could warrant classification for development are seen for all substances. Some of the developmental effects are seen consistently for several substances.

In subgroup 4, there are consistent effects on sexual function and fertility seen for all but one substance, and effects on development for all substances. For some studies, there is however a lack of details and some unclarity in the study description, which makes the assessment uncertain.



For subgroup 5, limited, poorly reported data for reproductive toxicity are available with the substances. These data indicate no effects. However, the substances in subgroup 5 are structurally similar to rosin and other substances in subgroup 1 and they should therefore be considered for read across together with subgroup 1 as also suggested by the registrant(s) in the registration dossiers..

For subgroup 6, no data on reproductive toxicity are available but read across to other subgroups could potentially be justified due to structural similarities.

The first step of the regulatory risk management action proposed is to confirm, via harmonised classification (CLH) the potential reproductive toxicity properties for adverse effects on development and, where appropriate, also for sexual function and fertility, for those subgroups or individual substances where there is already sufficient data for classification. Due to poor/unclear reporting (e.g., no numerical values), it is difficult to confirm for some available studies the conclusions of "no observed effects" made by the registrants and/or whether some of the recorded developmental effects are secondary to maternal toxicity. The uncertainties related to the poor reporting of the available studies could be assessed during the CLH process.

If the CLH process confirms substances as being Repr. 1B for development, then the CLH will require company level risk management measures (RMM) to be in place. CLH as Repr. 1B would also lead to generic restriction of the substances in consumer mixtures by means of the restriction Entry 30.

In addition, registrants will have to update their REACH registration dossiers without undue delay following new classification and labelling. Registrants will have to establish<sup>5</sup> or update exposure scenarios for all uses including articles service life, which will facilitate the implementation of further risk management measures at workplace.

Harmonised classification will also support regulatory action under other legislations. For instance, in this specific case, if the harmonised classification as Repr. 1B will be confirmed, it will:

- trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses in cosmetics, since CMR cat. 1 are restricted by this regulation.
- trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR category 1.
- render the substances unacceptable co-formulants in plant protection products
- impact the authorisation of biocidal products containing the substances, if present at concentrations above the relevant specific concentration limits for mixtures
- trigger the restriction of use of these substances in toys according to the Toy safety directive (2009/48/EC).

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<sup>5</sup> For many substances in the group, no exposure scenario are available at all.

Furthermore, most of the registered substances have professional uses, for instance in coatings and paints, washing and cleaning products, adhesives and sealants, polishes and wax blends (see Table 4 in Annex 2). Those uses are often widespread with relatively low levels of operational controls and risk management measures but with frequent exposures with a relatively long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Consumers may be co-exposed to the substances used by professionals (washing and cleaning products, paints, sealants, biocides, plant protection products, etc). Therefore, harmonised classification and labelling may not be sufficient to address the potential exposure to those substances and further regulatory risk management might be considered.

Restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals is suggested as potential next step, immediately after harmonised classification. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability<sup>6</sup> which aims to extend to professional users under REACH the level of protection granted to consumers.

It is suggested to investigate the need to restrict possibly also industrial uses. Based on currently available information, it is difficult to identify whether, or not risks will be sufficiently controlled via CLH and OSH or if additional regulatory action would be needed. Regarding articles, the potential for exposure and releases to the environment is uncertain based on available information and therefore needs to be further investigated. It needs to be explored whether the constituents/substances are (or not) chemically modified when incorporated in the articles (e.g. articles incorporating paints, coatings, adhesives, paper treatment products). Currently, the registration dossiers state, without any justification, that the potential for release from articles is low. It is important to note that any restriction targeting articles should ensure that regrettable substitution is avoided, as well as ensure appropriate enforceability also for imported articles for which the manufacturing process is unknown, e.g. by targeting constituents that can be analytically measured in articles.

When considering further the possibility of a restriction to address the risks due to reproductive toxicity, it should be kept in mind that the list of substances targeted with the CLH might not be an exhaustive list of substances originating from the same/similar starting materials and potentially displaying similar hazards.

#### Potential PBT/vPvB

It is proposed to further investigate the PBT/vPvB potential of the substances. Several blocks of constituents<sup>7</sup> screen as potential PBT/vPvB and therefore further data generation through compliance checks is proposed to clarify these potential properties, starting with P/vP.

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<sup>6</sup> European Commission, Chemical Strategy for Sustainability Towards a Toxic-Free Environment, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

<sup>7</sup> Block of constituents – fraction of composition of a complex substance (e.g. UVCB or multi-constituent) in which the constituents are to such extent structurally similar that their degradation, bioaccumulation and toxicity properties can be predicted to follow a regular predictable pattern.

This conclusion is based on the available data and takes account of finalised and on-going substance evaluations for several substances from the group. Most of the blocks of constituents screen as potentially persistent (P), however substances EC 232-475-7, 232-480-4, 263-144-5, 266-041-3 as well as EC 266-042-9, except for one of its blocks ("light ends" fraction - a fraction that is also present, at least in EC 264-848-5) were concluded not to be PBT/vPvB during substance evaluation and/or PBT screening by Member States. These conclusions were reached by mainly ruling out bioaccumulation concern for aquatic organisms, for the aqueous exposure pathway (e.g. low bioavailability due to extremely high hydrophobicity, molecular size), and the monoester constituents were considered to be not P and not vP under aerobic conditions. However, potential bioaccumulation concern for air-breathing organisms and via dietary route of exposure for aquatic organisms has not been fully addressed in these evaluations. Therefore, further investigations are needed to identify potentially persistent blocks of constituents. To clarify potential PBT properties, CCH is proposed for several substances in the group.<sup>8</sup> In the Substance evaluation conclusion for EC 266-042-9, the evaluating Member State noted that for the 'light ends' fraction, relevant information is expected to be produced in the ongoing compliance check for turpentine, oil (EC 232-350-7). In addition to this, it is noted that, under anaerobic conditions, potentially persistent transformation products could form from the fraction 'resin acids and rosin acids'.

Should the PBT/vPvB hazard be confirmed, additional regulatory risk management action may be considered to ensure minimisation of releases to the environment. The suggested CLH and potential restriction based on reproductive toxicity would not be sufficient to address the environmental concern.

#### Other potential hazards

A potential hazard for **endocrine disrupting properties (ED)** for human health and environment has been identified for all substances in the group due to effects observed in reproductive toxicity screening and repeated dose toxicity studies, indicating potentially an ED mode of action. These include effects on adrenal gland, thyroid, thymus, epididymis, testes, ovaries and pituitary gland. These effects are not seen in a consistent pattern across all the subgroups, however at least some of them are seen in almost all the subgroups. Therefore, potential ED effects cannot be excluded. The data is currently insufficient to conclude, and further data generation would be needed to clarify this potential hazard via dossier or substance evaluation.

There is a **known skin sensitisation hazard for substances of subgroup 3 and 4**. These substances are already self-classified accordingly by the registrants, except EC 272-035-1 (C&L notification). For industrial and professional uses, sufficient and consistent self-classification by registrants require adequate risk management measures to be in place according to workplace legislation. For the use of substance EC 305-516-2 (subgroup 4) in cosmetics, sufficient and consistent self-classification by registrants would inform on the need for classification of the final product and safety assessment according to Cosmetic product regulation (EC) No 1223/2009. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substances in subgroups 3 and 4. However there has been concern in authorities about presence of skin sensitisers in consumer mixtures and the need to further investigate whether further regulatory actions are needed. Work has been initiated by Member States and ECHA which may affect the actions suggested

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<sup>8</sup> EC/List: 232-694-8, 263-142-4, 266-040-8, 269-228-8, 270-461-2, 293-659-0, 294-402-5, 500-163-2, 700-751-0

in this assessment in the future. However, the skin sensitisation endpoint may be considered in the CLH proposal together with reproductive toxicity for substances in subgroups 3 and 4.

There is a potential skin sensitisation hazard for substances of subgroups 1, 2, 5, and 6 related to the oxidised form of the rosin constituents. Clarifying this potential hazard would require further data generation under substance evaluation. If a harmonised classification as Repr. 1B is concluded after the CLH process, this would most probably sufficiently protect users via the proposed restrictions and the generic concentration limit which is stricter for reproductive toxicity (0.3 %) than for skin sensitisation 1/1B (1 %). Therefore, further data generation is currently considered not necessary.

Long term **aquatic toxicity** data is almost completely missing. Relevant data for aquatic toxicity will be generated under the Testing Proposal Evaluation processes, foreseen for some of the substances<sup>9</sup>. It will be considered later whether tests relevant for ED assessment should be requested.

While a PBT/vPvB concern was identified for several blocks of constituents in the group, a **PMT** concern is considered less likely. However, PMT investigations will have to be re-considered if further data generation identifies a P/vP concern but no B/vB concern for some of the substances.

For **mutagenicity, carcinogenicity** and **target organ toxicity (STOT RE)**, hazards are considered unlikely for the whole group, based on the available data. Previous Canadian assessment of the resins and rosins<sup>10</sup> (EC 217-102-8, 232-475-7, 232-476-2, 232-480-4, 232-694-8, 263-144-5, 269-035-9) also concluded that there is no evidence of carcinogenicity or genotoxicity in experimental animals or cell lines for the Resins and Rosins group.

No carcinogenicity studies are available in the IUCLID dossiers for any of the substances. The available information on repeated dose toxicity (RDT) in the group do not either indicate a potential for carcinogenicity (e.g., hyperplasia and/or pre-neoplastic lesions) except for two substances (EC 232-480-4 and EC 305-516-2) with sub-chronic studies showing minimal to moderate urothelial hyperplasia. In addition, the *in vitro* mutagenicity studies indicate an overall unlikely mutagenicity potential for the group, albeit there are three studies with positive *in vitro* results. None of these 'positive' studies have been followed up with *in vivo* studies nor has a TPE been submitted to ECHA. A compliance check is therefore proposed, to fill the data gap and confirm unlikely hazard for mutagenicity *in vivo* for these three substances (EC 810-810-3, EC 232-476-2 and EC 293-625-5).

None of the substances in the group has a STOT RE classification. OECD 408 (90-day repeated dose toxicity) studies are available for 14 substances group. The main effect observed in these studies is a decrease in the mean body weight gain which was noted in all OECD 408 studies. Other effects mainly concern organ weight changes of adrenal, kidney, liver, thymus, uterus/cervix, testes and brain. However, these effects are usually without any histopathological correlation or

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<sup>9</sup> EC/List 232-475-7, 232-476-2, 232-478-3, 232-479-9, 232-480-4, 232-482-5, 232-694-8, 263-142-4, 263-144-5, 264-848-5, 266-040-8, 266-041-3, 266-042-9, 268-884-2, 269-035-9, 269-228-8, 269-825-3, 270-461-2, 271-996-4, 284-009-7, 287-094-9, 293-631-8, 293-659-0, 294-402-5, 295-855-1, 296-047-1, 305-514-1, 305-515-7, 305-516-2, 307-051-0, 500-163-2, 613-868-6, 614-523-2

<sup>10</sup> Draft screening assessment Resins and Rosins group, Environment and Climate Change Canada, Health Canada, June 2019, <https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-resins-rosins-group.html>

reported to be within the historical control data range, with one exception as already mentioned, urothelial hyperplasia noted in two studies. However, the criteria for STOT RE classification are not fulfilled for any of the substances. Based on the overall available data an unlikely hazard for STOT RE is assumed for the group.

## Annex 1: Overview of classifications

Data extracted on 23 May 2022.

**Table 3: Overview of classifications**

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
925-698-2	-	Rosin, maleated, esterified with sorbitol	-	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 4 H413
269-142-0	68188-14-7	Resin acids and Rosin acids, barium salts	-	Self Heat. 1 H251 Acute Tox. 4 H302 Acute Tox. 4 H332 Eye Irrit. 2 H319 Skin Sens. 1B H317
232-476-2	8050-15-5	Resin acids and Rosin acids, hydrogenated, Me esters	-	Aquatic Chronic 3 H412
911-238-8	-	Reaction mass of Rosin, hydrogenated and [1R-(1 $\alpha$ ,4 $\alpha$ $\beta$ ,10 $\alpha$ )]-1,2,3,4,4a,9,10,10a-octahydro-7-isopropyl-1,4a-dimethylphenanthren-1-carboxylic acid	-	-
271-996-4	68648-53-3	Resin acids and Rosin acids, hydrogenated, esters with triethylene glycol	-	-
266-042-9	65997-13-9	Resin acids and Rosin acids, hydrogenated, esters with glycerol	-	-
273-574-5	68990-02-3	Resin acids and Rosin acids, hydrogenated, sodium salts	-	-

## ASSESSMENT OF REGULATORY NEEDS

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
<b>232-475-7</b>	8050-09-7	Rosin	Index number: 650-015-00-7 Skin Sens. 1 Statement: H317	Skin Sens. 1 H317
<b>305-516-2</b>	94581-17-6	Resin acids and Rosin acids, maleated, esters with pentaerythritol	-	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 4 H413
<b>500-163-2</b>	65997-05-9	Rosin, oligomers	-	-
<b>500-451-8</b>	160901-14-4	Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Skin Sens. 1A H317 [Article 10 (inactive)]
<b>266-041-3</b>	65997-06-0	Rosin, hydrogenated	-	-
<b>263-075-0</b>	61789-65-9	Resin acids and Rosin acids, aluminum salts	-	Self Heat. 1 H251
<b>305-514-1</b>	94581-15-4	Resin acids and Rosin acids, fumarated, esters with pentaerythritol	-	-
<b>947-943-2</b>	-	Reaction products of Resin acids and Rosin acids, sodium salts and barium chloride	-	-
<b>268-884-2</b>	68153-38-8	Resin acids and Rosin acids, esters with diethylene glycol	-	-
<b>614-523-2</b>	68475-37-6	Resin acids and Rosin acids, polymd., esters with glycerol	-	-
<b>269-825-3</b>	68334-35-0	Resin acids and Rosin acids, calcium zinc salts	-	-
<b>296-047-1</b>	92202-14-7	Rosin, fumarated, reaction products with glycerol and pentaerythritol	-	-

ASSESSMENT OF REGULATORY NEEDS

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
<b>270-986-7</b>	68512-65-2	Resin acids and Rosin acids, esters with ethylene glycol	-	Repr. 2 H361 [Article 10 (inactive)]
<b>273-572-4</b>	68990-01-2	Resin acids and Rosin acids, hydrogenated, potassium salts	-	-
<b>263-142-4</b>	61790-50-9	Resin acids and Rosin acids, potassium salts	-	Eye Irrit. 2 H319
<b>920-105-3</b>	-	Resin acids and Rosin acids, dimers, calcium zinc	-	-
<b>287-094-9</b>	85409-27-4	Resin acids and Rosin acids, maleated, potassium salts	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 2 H411
<b>293-625-5</b>	91081-22-0	Resin acids and Rosin acids, fumarated, compds. with triethanolamine	-	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 4 H413
<b>263-144-5</b>	61790-51-0	Resin acids and Rosin acids, sodium salts	-	Eye Irrit. 2 H319
<b>700-751-0</b>	-	Reaction Product of Rosin, fumarated, Tall-Oil Rosin, Ca(OH) <sub>2</sub> and MgO	-	Skin Irrit. 2 H315 Skin Sens. 1 H317 Aquatic Chronic 3 H412
<b>294-402-5</b>	91722-01-9	Resin acids and Rosin acids, maleated, calcium salts	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 4 H413
<b>685-540-0</b>	208126-52-7	Reaction product of resin acid and rosin acid, 12-Hydroxyoctadecanoic and stearic acid with dipentaerythritol	-	-



## ASSESSMENT OF REGULATORY NEEDS

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
<b>613-868-6</b>	65997-12-8	Resin acids and Rosin acids, polymd., esters with pentaerythritol	-	-
<b>217-102-8</b>	1740-19-8	[1R-(1 $\alpha$ ,4 $\alpha$ $\beta$ ,10 $\alpha$ )]-1,2,3,4,4a,9,10,10a-octahydro-7-isopropyl-1,4a-dimethylphenanthren-1-carboxylic acid	-	-
<b>307-051-0</b>	97489-11-7	Resin acids and Rosin acids, fumarated, esters with glycerol	-	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 4 H413
<b>284-009-7</b>	84776-83-0	Resin acids and Rosin acids, esters with trimethylolpropane	-	-
<b>272-037-2</b>	68649-89-8	Resin acids and Rosin acids, ammonium salts	-	-
<b>208-178-3</b>	514-10-3	abietic acid	-	-
<b>940-281-5</b>	-	Fatty acids, tall oil and rosin reacted with maleic anhydride	-	Skin Sens. 1 H317 Aquatic Chronic 3 H412
<b>232-479-9</b>	8050-26-8	Resin acids and Rosin acids, esters with pentaerythritol	-	-
<b>810-810-3</b>	68425-02-5	Hydrogenated rosin, zinc salt	-	-
<b>232-694-8</b>	9007-13-0	Resin acids and Rosin acids, calcium salts	-	-
<b>272-035-1</b>	68649-83-2	Resin acids and Rosin acids, fumarated, potassium salts	-	-
<b>269-035-9</b>	68186-14-1	Resin acids and Rosin acids, Me esters	-	Aquatic Chronic 3 H412

## ASSESSMENT OF REGULATORY NEEDS

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
<b>232-716-6</b>	9008-34-8	Resin acids and Rosin acids, manganese salts	-	Self Heat. 1 H251
<b>295-855-1</b>	92129-53-8	Resin acids and Rosin acids, reaction products with formaldehyde, potassium salt	-	Eye Irrit. 2 H319
<b>293-659-0</b>	91081-53-7	Rosin, reaction products with formaldehyde	-	-
<b>293-631-8</b>	91081-28-6	Resin acids and Rosin acids, reaction products with formaldehyde, sodium salts	-	Eye Irrit. 2 H319
<b>305-515-7</b>	94581-16-5	Resin acids and Rosin acids, maleated, esters with glycerol	-	Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 4 H413
<b>434-230-1</b>	144413-22-9	Complex reaction mass of Chinese gum rosin post reacted with acrylic acid	Index number: 607-682-00-4 Aquatic Chronic 4 Statement: H413	Aquatic Chronic 4 H413
<b>280-192-2</b>	83137-13-7	Rosin, reaction products with acrylic acid	-	Skin Irrit. 2 H315 Skin Sens. 1B H317
<b>266-040-8</b>	65997-04-8	Rosin, fumarated	-	Aquatic Chronic 4 H413 [Article 10 (inactive)] Skin Sens. 1 H317 [Article 10 (inactive)] Eye Dam. 1 H318 [Article 10 (inactive)]
<b>232-482-5</b>	8050-31-5	Resin acids and Rosin acids, esters with glycerol	-	-
<b>270-461-2</b>	68440-56-2	Resin acids and Rosin acids, magnesium salts	-	-
<b>269-228-8</b>	68201-60-5	Resin acids and Rosin acids, maleated, sodium salts	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 2 H411

ASSESSMENT OF REGULATORY NEEDS

EC / List Number	CAS Number	Substance Name	Harmonised classification	Classification in registrations
<b>271-402-3</b>	68554-12-1	Resin acids and Rosin acids, hydrogenated, calcium salts	-	Self Heat. 2 H252
<b>305-795-0</b>	95009-65-7	Rosin, fumarated, reaction products with formaldehyde	-	Skin Sens. 1 H317 [Article 10 (inactive)] Eye Dam. 1 H318 [Article 10 (inactive)]
<b>204-832-7</b>	127-25-3	methyl abietate	-	Skin Irrit. 2 H315
<b>232-480-4</b>	8050-28-0	Rosin, maleated	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 2 H411
<b>232-478-3</b>	8050-25-7	Resin acids and Rosin acids, esters with triethylene glycol	-	-
<b>696-130-6</b>	1364681-45-7	Resin acids and Rosin acids, reaction products with formaldehyde, calcium salts	-	-
<b>264-848-5</b>	64365-17-9	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol	-	-

(\*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

## Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 23/05/2022 (all substances except EC 273-574-5) and 11/07/2022 (EC 273-574-5).

**Table 4: Overview of uses**

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants,	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate	
<b>Subgroup 1 - Resin/rosin acids and salts</b>																																			
232-475-7	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C	F, I, P, C	F, I, P, C	F, P, C	F, C	F, I, P, C	F, C	F, C	F, I, P, C	F, I, P, C	F, I, P, C	F, C	F, I, P, C	F, C	F, I, P, C	F, C	F, I, P, C	F, I	F		F		F			F, I, C	F, I		F, I, P	F, I	
263-144-5	F, I, P, C, A	F, I, P, C, A	F, I	F, I, P	C	C	F, I, P, C	C	C	I, P, C	C	C	C	C	I, P, C	F, P, C	C	I, P, C	C	I, P, C	P, C	F, C												I, P	F, I
263-142-4	I, P, C	C	I	F, I, P, A	C	C	F, I, P, C	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C	C	C												I, P	I
232-694-8	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	I, P, C	F, I, P, C	F, I, P, C	I, P, C	F, I, P, C	I, P, C	F, I, P, C	I, P, C	I, P, C	I, P, C	I, P, C	F, C	C	F, I, P, C	P, C	I, P, C	F, I, P, C	F, I, P, C, A		I	P			I				I	F, I, P	I	
500-163-2	F, I, P, C	F, I, P, C	I, A	F, I, P, C	P, C	F, I, P, C	I, P, C	I, C	I, C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	F, I, P, C	C	C			I								I, P	I	

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate	
	C, A			C		C	A			A										C, A															
266-041-3	F, I, P, C, A	F, I, P, C, A	I, P, C	F, I, P, C, A	I, P, C	I, P, C	F, I, P, C, A	C	C	I, P, C	F, I, P, C	C	C	C	I, P, C	F, I, P, C	C	I, P, C	C	F, I, P, C	C	F, C											I, P	I	
911-238-8	I, P, C	F, C	I	I, P, A	C	C	C	C	C	C	C	C	C	C																			I, P	I	
269-825-3	I, P, C	C	I	F, I, P	C	C	I, P, C	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C	C	C											I, P	I	
270-461-2	F, I, P, C	F, I, C	I	F, I, P	C	C	I, P, C	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C	C	C											I, P	I	
273-574-5	I, P, C, A	C	I, A	F, I, P	C	C	I, P, C, A	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C, A	C	C											I, P	I	
920-105-3	I, P, C, A	C	I, A	F, I, P	C	C	I, P, C, A	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C, A	C	C											I, P	I	
269-142-0	F, I, P, C	F, I, C		F, I, C, A																															
232-716-6	F,	F,	A	F,																															

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate				
	I, P, C	I, C, A		I, C, A																																		
263-075-0	F, I, P, C	F, I, C, A	A	F, I, C, A																																		
271-402-3	F, I, P, C	F, I, C, A	A	F, I, C, A																																		
272-037-2			I					I																														
810-810-3	F																																					
947-943-2	F, I, P, C	F, I, P			C	C										F, P, C																						
<b>Subgroup 2 - Esters from resin/rosin acids</b>																																						
232-479-9	F, I, P, C, A	F, I, P, C, A	F, I, P, A	F, I, P	C	F, I, P, C	F, I, P, C, A	I, P, C	I, P, C	I, P, C	I, P, C	I, P, C	I, P, C	I, C	I, P	F, I, P, C	F, I, P, C	I, P, C	C	I, C	C	P, C													F, I, P	I		
232-482-5	F, I, P, C, A	F, I, P, C, A	F, I, P, A	F, I, P	C	F, I, P, C	F, I, P, C, A	I, C	I, C	F, I, C	C	I, C	C	C	I, P	F, I, P, C	C	I, P, C	C	I, C	C	C			I		I								I, P	F, I		
232-478-3	F, I, C	F, I, C	F, I, C	F, I, C	C	F, I, C	F, I, C	C	I, P, C	C	C	C	C	C	I, P	I, P, C	C	I, P, C	C	C	C	C													F, I, C	I		

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate	
	P, C, A		P, A	P		P, C	P, C, A		C							C		C																P	
266-042-9	F, I, P, C, A	F, I, P, C	I, A	F, I, P	C	C	F, I, P, C, A	C	C	C, A	C	C	C	C	I, P	F, C	C	I, P, C	C	C, A	C	F, C												I, P	I
268-884-2	F, I, P, C, A	C	F, I, A	F, I, P	C	F, I, P, C	I, P, C, A	C	I, P, C	C	C	C	C	C	I, P	P, C	C	I, P, C	C	C	C	C											I, P	I	
232-476-2	F, I, P, C, A	F, I, P, C	I, A	F, I, P	C	C	F, I, P, C, A	C	C	C	C	C	C	C	I, P	F, I, P, C	F, I, P, C	I, P, C	C	C	C	C											F, I, P	I	
271-996-4	F, I, P, C, A	F, I, P, C	I, A	F, I, P	C	C	F, I, P, C, A	C	C	C	C	C	C	C	I, P	F, I, P, C	C	I, P, C	C	C	P, C	F, I, P, C											I, P	I	
269-035-9	F, I, P, C, A	F, I, P, C	I, A	F, I, P	C	C	F, I, P, C, A	C	C	C	C	C	C	C	I, P	F, I, P, C	P, C	I, P, C	C	C	P, C	F, I, P, C											I, P	I	
614-523-2	I, P	C	I, A	F, I	C	C	I, P	C	C	C	C	C	C	C	I, P	P, C	C	I, P	C	C	C	C											I, P	I	

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate				
	C, A			P			C, A										C																					
264-848-5	F, I, P, C, A	F, I, P, C	I, A	F, I, P	C	C	F, I, P, C, A	C	C	C	C	C	C	C	I, P	F, I, P, C	C	I, P, C	C	C	C	F, C						C						I, P	I			
284-009-7	I, P, C, A	C	I, A	F, I, P	C	C	I, P, C, A	C	C	C	C	C	C	C	I, P	C	C	I, P, C	C	C	C	C											I, P	I				
613-868-6	I, P, C, A	C	I, A	F, I, P	C	C	I, P, C, A	C	C	C	C	C	C	C	I, P	C	C	I, P, C	C	C	C	C											I, P	I				
685-540-0																F, P, C																						
204-832-7								C								I, P, C	I, C	C	C								I, C						I	F, I				
<b>Subgroup 3 - Resin/rosin fumarated and maleated</b>																																						
266-040-8	F, I, P, C, A	F, I, P, C	F, I, A	F, I, P, A	C	I, P, C, A	F, I, P, C, A	C	P, C	I, P, C	C	C	C	C	I, P							F, I												F, I, P	I			
269-228-8	I, P, C	C	F, I, A	I	C	F, I, P	I, P, C	C	C	I, P, C	C	C	C	C																			I					



ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate				
						C, A																																
232-480-4	F, I, P, C	F, I, P, C	F, I, A	F, I, P, A	I, P, C	I, P, C, A	I, P, C	I, C	I, P, C	I, P, C	C	C	C	C	I, P								F, I											F, I, P	I			
700-751-0	F, I, P, C	F, I, P, C																																				
940-281-5																							I															
293-625-5			F, I																																			
294-402-5	I, P, C, A	C	I, A	F, I, P	C	P, C, A	I, P, C, A	C	C	I, P, C	C	C	C	C	I, P																		I, P	I				
287-094-9	I, P, C, A	C	F, I, A	F, I, P	C	F, P, C, A	I, P, C, A	C	F, C	F, I, P, C	C	C	C	C	I, P																		I, P	I				
500-451-8	I, P, C	I, P, C	I, C, A	I, C	C	P, C	I, P, C	C	C	I, P, C	C	C	C	C									I											I				
<b>Subgroup 4 - Esters from resin/rosin fumarated and maleated</b>																																						
305-514-1	F, I, P, C	F, I, C, A	F, I	F, I, P	C	F, I, P, C	F, I, P, C, A	C	C	C	C	C	C	C	I, P																			I, P				

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	PC 9a: Coatings and paints, thinners, paint removers	PC 18: Ink and toners	PC 26: Paper and board treatment products	PC 32: Polymer preparations and	PC 9c: Finger paint	PC 9b: Fillers, putties, plasters, modelling clay	PC 1: Adhesives, sealants	PC 31: Polishes and wax blends	PC 15: Non-metal-surface treatment products	PC 24: Lubricants, greases, release products	PC 34: Textile dyes, and impregnating products	PC 23: Leather treatment products	PC 4: Anti-freeze and de-icing products	PC 8: Biocidal products	PC 13: Fuels	PC 39: Cosmetics, personal care products	PC 28: Perfumes, fragrances	PC 35: Washing and cleaning products	PC 3: Air care products	PC 38: Welding and soldering products, flux	PC 12: Fertilisers	PC 27: Plant protection products	PC 20: Products such as ph-regulators, flocculants, chemicals	PC 37: Water treatment chemicals	PC 14: Metal surface treatment products	PC 29: Pharmaceuticals	PC 17: Hydraulic fluids	PC 40: Extraction agents	PC 25: Metal working fluids	PC 2: Adsorbents	PC 11: Explosives	PC41: Oil and gas exploration or production	PC 21: Laboratory chemicals	PC 19: Intermediate				
296-047-1	I, P, C, A	C, A	I	F, I, P	C	C	I, P, C, A	C	C	C	C	C	C	C	I, P																		I, P	I				
305-516-2	I, P, C, A	F, C	F, I	F, I, P	C	C	I, P, C, A	C	C	C	C	C	C	C	I, P	C	C																I, P	I				
307-051-0	I, P, C, A	C	F, I, P	F, I, P	C	P, C	F, I, P, C, A	C	C	C	C	C	C	C	I, P														I				I, P	I				
305-515-7	I, P, C, A	C			C	C	I, P, C, A	C	C	C	C	C	C	C																			I, P					
925-698-2			F, I																																			
<b>Subgroup 5 - Reaction products of resin/rosin acids with acrylic acid</b>																																						
293-659-0	F, I, P, C, A	F, I, C	I, A	F, I, P, A	F, C	F, C	F, I, P, C, A	F, C	F, C	F, I, P, C	F, C	F, C	F, C	F, C	F, I, P, C	F, C	F, C	F, I, P, C	F, C	F, I, P, C	F, C	F, C												I, P	I			
295-855-1	I, P, C	C	I, C	F, I, P	C	C	I, P, C	C	C	I, P, C	C	C	C	C	I, P, C	C	C	I, P, C	C	I, P, C	C	C												I, P	I			
293-631-8	I, P	C	I	F, I	C	C	I, P	C	C	I, P	C	C	C	C	I, P	C	C	I, P	C	I, P	C	C												I, P	I			

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types																																						
PC 9a: Coatings and paints, thinners, paint removers	C																																					
PC 18: Ink and toners																																						
PC 26: Paper and board treatment products																																						
PC 32: Polymer preparations and	P																																					
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PC 9b: Fillers, putties, plasters, modelling clay																																						
PC 1: Adhesives, sealants	C																																					
PC 31: Polishes and wax blends																																						
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PC 8: Biocidal products																																						
PC 13: Fuels	C																																					
PC 39: Cosmetics, personal care products																																						
PC 28: Perfumes, fragrances																																						
PC 35: Washing and cleaning products	C																																					
PC 3: Air care products																																						
PC 38: Welding and soldering products, flux	C																																					
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PC 2: Adsorbents																																						
PC 11: Explosives																																						
PC41: Oil and gas exploration or production																																						
PC 21: Laboratory chemicals																																						
PC 19: Intermediate																																						
<b>Subgroup 6 - Reaction products of resin/rosin acids with formaldehyde</b>																																						
434-230-1																																						
280-192-2																																						

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

### **Annex 3: Overview of completed or ongoing regulatory risk management activities**

**Table 5: Overview of completed or ongoing regulatory risk management activities**

There are no relevant completed or ongoing regulatory risk management activities.