December 2025

Q&A on the ongoing Classification and Labelling assessment for Rosin and selected Rosin Derivatives

Disclaimer: The information shared in this document is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information currently available, it is to be relied upon at the user's own risk. No representations or warranties are made regarding its completeness or accuracy, and no liability will be accepted by HARRPA, H4R and/or PCA nor any of their members for damages of any nature whatsoever resulting from the use of this information.

Q0a: What is a CLH intention?

A0a: The Harmonised Classification and Labelling (CLH) proposal assessment process is formally started when a Member State Competent Authority (MSCA) files an intention for a CLH proposal. This intention includes the substance name with details concerning the proposed classification.

Q0b: What is a CLH report?

A0b: A CLH report is a formal proposal submitted to the European Chemicals Agency (ECHA) by a member state. Its purpose is to establish a hazard classification for a chemical substance across European Union, replacing individual self-classifications by companies. It forms the basis for Risk Assessment Committee (RAC) evaluation.

Q1: What is Rosin?

A1: Rosin is a bio-based substance derived from pine trees, used as a starting material for a wide range of specialty chemicals used predominantly in industrial products and articles.

Q2: What are the three types of Rosin, and how are they produced?

A2: The three types of Rosin are:

- **Gum Rosin:** Extracted by steam distillation of the pine oleoresin collected from tapping living pine trees.
- **Tall Oil Rosin:** Obtained as a byproduct of the kraft pulping process at pulp mills, where Crude Tall Oil (CTO) is fractionated into several products, including Tall Oil Rosin.
- **Wood Rosin:** Extracted from the stumps of pine trees using solvents. This is a relatively small-scale production method globally.

Q3: Why is Rosin critical in the Pine chemicals value chain?

A3: Rosin plays a crucial role because it is the key value driver in the Pine Chemicals value chain, and its production is intertwined with that of various products from pine trees. Independent of the source / starting material (gum rosin, wood rosin or tall oil rosin), Rosin is registered and managed under REACH as one substance (see: H4Rconsortium.com: Position on Rosin as one substance under REACH), and that one substance serves as a starting material for producing many value-added chemicals, including esters, resins, and salts, which are critical for downstream industries. Any disruption in the Rosin business can potentially unbalance the entire Pine chemicals industry.

NB: as a comparison, you cannot produce diesel without producing gasoline and other. The same applies to the Pine Chemicals industry, where during distillation of one of the rosin sources, one fraction cannot be produced without producing the other fractions. For example, from the distillation of pine oleoresin collected from tapping pine trees, both Gum Rosin and Gum Turpentine Oil are obtained – and one can't be produced without producing the other, hence any potential impact on one of them would immediately have further consequences for both the production of gum rosin derivatives and the precursors of terpenic resins. Another example is the distillation of Crude Tall Oil, which produces 5 different fractions (Tall Oil Heads, Tall Oil Fatty Acids, Distilled Tall Oil, Tall Oil Rosin, and Tall Oil Pitch) at different temperatures. Again, one cannot, for example, produce Tall Oil Pitch without producing the other 4.

Therefore, any disruption in the Rosin business can unbalance the entire Pine chemicals industry, affecting upstream sectors like paper mills and forestry, which are vital to the economies of certain EU member states.

Q4: How does Rosin contribute to the EU's Green Deal?

A4: Rosin is a critical bio-based chemical that contributes to reducing CO2 emissions without competing with the food chain. It has a negative CO2 emission profile on a cradle-to-gate basis, helping to meet the ambition of the EU's Green Deal. Rosin's role in the Pine chemicals industry supports the Green Deal's objectives by providing sustainable alternatives to fossil-based chemicals. The rosin and rosin derived chemicals industry is part of an industrial symbiosis with other industries in the value chain, ensuring that 'nothing goes to waste', and produces products with unique sustainable product performance contributing to environmental and health protection, In many of these applications, rosin or rosin derivatives are essential components with no or only regrettable substitutions.

Q5: Who is HARRPA?

A5: HARRPA is a sector group of CEFIC that represents the European based producers of Hydrocarbon Resins, Rosin Resins and Pine Chemicals. The resins are based on natural and petrochemical raw materials. HARRPA represents 12 member companies in Europe with a total yearly production of more than 1 million tons and a total turnover around 1,5 billion euros. The members have 30 production sites in Europe and employ more than 3000 people.

Q6: Who is H4R?

A6: H4R is a group formed by European manufacturers of Rosin and its derivatives to ensure compliance with REACH regulations. It was established by members of the Hydrocarbon Resins, Rosin Resins & Pine Chemicals Producers Association (HARRPA). The consortium leads the effort to proactively ensure regulatory compliance for the industry: it has a testing strategy in place (see Q10) to provide the necessary data to meet regulatory requirements while minimizing unnecessary animal testing, and applies these data to advise on – and ensure – safe production, distribution and use of the substances it produces.

Q7: Who is PCA?

A7: PCA is the Pine Chemicals Association, which is a global organization that represents more than 60 producers, suppliers, and stakeholders of the global Pine Chemicals industry, which has a combined revenue of more than 10 B USD per year.

Q8: What has happened in the past years with the ARN and CLH Proposal?

A8: In 2022, ECHA started an Assessment of Regulatory Needs (ARN)[1] for a large number of rosin and rosin derivatives. In 2023, the ARN report was published and the Norwegian MSCA initiated an evaluation of the available data in the REACH dossiers. Their proposed CLH intentions were published in October 2024. The Norwegian MSCA has published in August 2025 their CLH proposals for 8 substances managed by H4R (Table 1) on the ECHA registry of CLH intentions until outcome (RoI) and the 60-day Public Consultation took place from 1st September to 31st October 2025.

[1] The Assessment of Regulatory Needs (ARN) is ECHA's internal *ad hoc* informal process for prioritizing groups of substances – *instead of single substances* – for further evaluation. It is provisional and does not constitute a final judgement of hazard or risk for human health or the environment. Instead, the stated aim is to stimulate Member States Competent Authorities (MSCA) to take the initiative, perform further evaluations, and form their own independent judgement. Member States may also decide not to proceed with the recommendation as assessed as inappropriate. The ARN process is not covered by REACH or any other European law. It remains an extra-legal process. It is controlled entirely by ECHA and is initiated and conducted at ECHA's discretion. An ARN report has no legal authority.

Table 1. Rosin and rosin derivatives on the Registry of CLH Intentions as submitted by the Norwegian MSCA

CAS	EC	Substance	H4R Category	Harmonised classification at the time of the proposal	Proposed harmonised classification by the dossier submitter (Updated 8 October)
8050-09-7	232-475-7	Rosin	1	Skin Sens. 1, H317	Repr. 1B, H360Df
65997-05-9	500-163-2	Rosin, oligomers	1		Repr. 1B, H360Df
65997-04-8	266-040-8	Rosin, fumarated	3		Repr. 2, H361fd
8050-28-0	232-480-4	Rosin, maleated	3		Repr. 1B, H360D
97489-11-7	307-051-0	Resin acids and Rosin acids, fumarated, esters with glycerol	4		Repr. 2, H361d
94581-17-6	305-516-2	Resin acids and Rosin acids, maleated, esters with pentaerythrit	4		Repr. 2, H361fd
65997-06-0	266-041-3	Rosin, hydrogenated	1		Repr. 2, H361f
160901-14-4	500-451-8	Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts	Cease of Manufacture / No Active registrations		Repr. 2, H361f

H4R disagrees strongly with these proposed classifications, since, based on the available toxicological data, none of these substances, with the possible exception of Rosin, maleated, raise concern for reprotoxic hazard and therefore they do not meet the criteria for classification.

Q9: What is the current status of the regulatory assessment?

A9: Following the end of the public consultation period, ECHA's Risk Assessment Committee (RAC) began the evaluation phase in late 2025, and work will continue throughout 2026, including assessment of newly submitted mechanistic data and Weight-of-Evidence analyses.

Q10: What are the main findings from the existing toxicity studies conducted by H4R?

A10: Testing strategy was put in place to answer data gaps. In 2013, test proposals were submitted to ECHA to comply with REACH requirements, Subsequently, in 2017/2018, well before the ARN, updated test proposals were submitted to ECHA by H4R to meet standard information requirements for Annex IX and X of REACH (OECD 443 and OECD 414 in a second species). These have been placed on hold by ECHA.

With respect to reproductive toxicity, the existing studies conducted under the H4R testing strategy found that:

- The only observed effect on fertility was mildly impaired ovulation at the highest doses in some studies. This lower ovulation is believed to be due to undernourishment of female animals caused by the unpalatability of the test diet, a transient and beneficial response to undernutrition rather than a permanent, adverse one.
- The only developmental effect observed was retarded growth of fetuses or pups, which is believed to be secondary to underweight mothers rather than a direct effect on the offspring.

Both mechanisms are established and well accepted. Effects previously observed in dietary studies have been reinforced through new mechanistic evidence submitted in 2025, demonstrating that these fertility and developmental observations are secondary to maternal undernutrition and are not intrinsic properties of rosin or its derivatives. These findings are consistent across species and endpoints, and the 2025 studies confirm the reversibility and non-adverse nature of the effects.

Q11: Why do the H4R, PCA and HARRPA members disagree with the proposed classification for development and reproductive toxicity?

A11: H4R, PCA and HARRPA disagree because they believe that the observed effects (impaired ovulation and retarded growth) are not intrinsic properties of Rosin itself but are secondary to other factors like undernourishment and non-specific maternal toxicity. Therefore, based on the totality of the evidence including the newly submitted 2025 mechanistic studies, they conclude that a classification for reproductive toxicity is not warranted.

Q12: What steps has H4R taken to address the concerns raised by authorities?

A12: H4R has included a detailed scientific Weight of Evidence (WoE) in their REACH dossiers. by providing extensive statistical support that the observed effects are due to undernourishment. As part of the public consultation (1st September to 31st October 2025), H4R submitted a consolidated Weight-of-Evidence document including new mechanistic data, statistical reanalysis, and clarifications responding to points raised in the dossier submitter's CLH reports.

Q13: What has H4R done to further reinforce its position that a classification is not warranted?

A13: In order to support the existing toxicology dossiers, H4R — supported by PCA — commissioned two mechanistic studies in 2024, both of which were completed during 2025:

1. A transiency/reversibility study to determine whether fertility-related effects are reversible.
2. A feed-restriction mechanistic study to determine whether fertility/developmental endpoints arise from maternal undernutrition.

Both studies confirmed that the observed effects are secondary, non-adverse, and not intrinsic properties of rosin.

ECHA and the Norwegian MSCA were kept informed throughout, and full study reports were submitted during the 2025 Public Consultation period. RAC will consider these data during their 2026 assessment.

Q14: What are the regulatory consequences of Reprotoxicity classification?

A14:

Classification scenario	Indicative regulatory implications
Classification as Repr. 1B	• Mixtures containing ≥ 0.3 % w/w of these substances must be classified as reproductive toxicants. • REACH Annex XVII (Entry 30) restricts placing on the market of products for the general public above this threshold; professional use may still be allowed. • Products must carry hazard and precautionary statements (e.g. H360). • Safety Data Sheets (SDS) must be updated with appropriate risk-management measures. • Employers must assess and control worker exposure under Directive 2004/37/EC, applying substitution or closed systems where possible. • Prohibited uses include toys, cosmetics, and food-contact materials. • Waste containing ≥ 0.3 % is classified as hazardous waste under Directive 2008/98/EC.
Classification as Repr. 2	• Mixtures containing ≥ 3.0 % w/w must be classified as reproductive toxicants. • Labelling and SDS requirements apply, though product-specific restrictions are generally fewer than for Repr. 1B. • Professional use may still be allowed. • Waste containing ≥ 3 % is classified as hazardous waste under Directive 2008/98/EC.. • Consumer product bans may still apply in certain sectors (e.g. cosmetics, toys, food-contact materials).

Q15: Will a classification for Rosin impact the classification of rosin and its derivatives outside of the EU?

A15: Although EU CLP is based on the global harmonised classification and labelling system (GHS), and several other jurisdictions closely follow EU REACH, the REACH legislation is only applicable in the EU. HARRPA and PCA are monitoring developments on a global basis. We will engage with national authorities as the need arises.

Q16: Will a classification for Rosin impact the availability and production of rosin in Europe, and outside of Europe?

A16: Potential (unwarranted) classification itself does not restrict rosin production. In the case of classification, the actors in the supply chain will continue applying appropriate occupational and safety measures.

Q17: Will a possible classification of rosin have an impact on the raw materials and co-products (CTO, Pine Oleoresin, TOFA, DTO, Heads and Pitch, Gum turpentine Oil) that are used for the production of Rosin?

A17: There is no regulatory impact from a potential rosin classification; these are substances in their own right and are not connected to Rosin from a regulatory perspective. As an example, CTO is a UVCB substance registered under REACH. Pine Oleoresin is even exempt from REACH under Annex V.

Q18: What can I do as downstream user to support H4R in the CLH Process?

A18: The Public Consultation closed on 31 October 2025. Downstream users can now support the process by:

- Sharing any additional exposure, epidemiological, or workplace-monitoring information with H4R for inclusion in RAC discussions.
- Providing clarifications on technical uses and risk-management measures.
- Participating in the downstream-user survey supporting the ongoing Socio-Economic Assessment.

HARRPA, PCA and H4R recommend to share Downstream Users input with us for our consideration to the mail: manager@h4rconsortium.com and jwi@cefic.be

Q19: What is the next important regulatory step?

A19: RAC opinion which is expected mid-2026, with a current Legal deadline for opinion adoption in December 2026.

Q.20: What is a RAC opinion?

A20: A RAC opinion is the scientific assessment conducted by the Risk Assessment Committee, which is subsequently submitted to the European Commission for a final decision. For further information, please consult Committee for Risk Assessment - ECHA

Q.21: Do the European Commission necessarily follow the RAC opinion?

A21: Although uncommon for the European Commission to disagree with the RAC opinion, on rare occasion, the European Commission decided not to follow RAC opinion such as for Diethylenetriaminepentaacetic acid, for which the RAC recommended classification for reproductive toxicity 1B (2017) was rejected by the commission (2019) on the basis that further assessment by RAC was deemed necessary in view of new scientific data on toxicity for reproduction presented by the industry after the RAC opinions were forwarded to the Commission. To see complete overview of ECHA harmonised classification and labelling, please consult Harmonised Classification and Labelling - ECHA.

Q22: How to access the documents submitted by H4R, PCA and HARRPA during public consultation?

A22: The comments and documents submitted during the public consultation, including those submitted by H4R, PCA and HARRPA, are available on the Registry of CLH intentions until outcome - ECHA.