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# Q&A on the ongoing Classification and Labelling assessment for rosin and selected rosin derivatives

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### 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 (see summary of socio-economic analysis conducted in 2026 here). 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 when including biogenic carbon, 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 Proposals?

**A8:** In 2022, ECHA started an Assessment of Regulatory Needs (ARN) 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 (*HARRPA,* H4R and PCA still believe these proposed classifications are unjustified as all effects observed can be explained by maternal undernutrition and are therefore not real reproductive effects. Consequently, HARRPA, H4R and PCA will remain committed to working towards a non-classification including generating new data to support our scientific position. This common position has been confirmed by two new studies (see Q13) that was not available to the Norwegian authorities at the time of the submission of the CLH dossiers.

**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. Following the public consultation the dossiers were discussed at the ECHA Risk Assessment Committee Working Group on CLHs in June 2026 and expressed its formal opinion, during the RAC-78 plenary session in September 2026.

HARRPA, H4R and PCA still believe these proposed classifications are unjustified as all effects observed can be explained by maternal undernutrition and are therefore not real reproductive effects. Consequently, HARRPA, H4R and PCA will remain committed to working towards a non-classification including generating new data to support our scientific position. This common position has been confirmed by two new studies (see Q13) that was not available to the Norwegian authorities at the time of the submission of the CLH dossiers.

***Table 1***

| Substance | Dossier Submitter Proposal | RAC Final Opinion | HARRPA-PCA-H4R position[1] |
|---|---|---|---|
| Rosin (EC 232-475-7, CAS 8050-09-7) | Cat 1B (H360Df) | Cat 2 (H361fd) | No classification |
| Rosin, hydrogenated (EC 266-041-3, CAS 65997-06-0) | Cat 2 (H361f) | Cat 2 (H361f) | No classification |
| Rosin, oligomers (EC 500-163-2, CAS 65997-05-9) | Cat 1B (H360Df) | Cat 1B (H360Df) | No classification |
| Rosin, fumarated (EC 266-040-8, CAS 65997-04-8) | Cat 2 (H361f) | Cat 2 (H361f) | No classification |
| Rosin, maleated (EC 232-480-4, CAS 8050-28-0) | Cat 1B (H360D) | Cat 2 (H361d) | Cat 2 (H361d) |
| Fatty acids, tall-oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium zinc salts (EC 500-451-8, CAS 160901-14-4) | Cat 2 (H361f) | Cat 2 (H361f) | No classification |
| RARA, fumarated, esters with glycerol (EC 307-051-0, CAS 97489-11-7) | Cat 2 (H361d) | Cat 2 (H361d) | No classification |
| RARA, maleated, esters with pentaerythritol (EC 305-516-2, CAS 94581-17-6) | Cat 2 (H361fd) | Cat 2 (H361f) | No classification |

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

**A9:** ECHA's Risk Assessment Committee (RAC) has adopted its formal opinion, during the RAC-78 plenary session in September 2026, see table under Q8. This will inform the European Commission's decision and any subsequent adaptation of the CLP Regulation. The European Commission will deliberate with Member States and stakeholders in 2027 on the inclusion of rosins and rosin derivatives in Annex VI of CLP, with a final decision towards the end of the year and publication in early 2028. As transition periods apply, any change to the classification and labelling of rosins and rosin derivatives will come into application by 2030.

## 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 (see Q13). 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.

[1] H4R and its members, as registrants of the substances, are currently reviewing the self-classification of all substances. This process is pending a final decision by the European Commission on the proposed harmonised classifications.

**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, not as a presumed reprotoxicant (Cat 1B) nor as a suspected reprotoxicant (Cat 2).

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

**A12:** 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.

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 :

1. 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.

Additionally, H4R made available to ECHA in April 2026, ahead of the RAC deliberations:

2. The 2 mechanistic study reports.
3. A peer-reviewed article published in the Journal Reproductive Toxicity (available here). The publication is an important milestone in our defense strategy, as it makes new and robust data publicly available to support our case. Furthermore, the learnings on substance-independent maternal undernutrition could benefit the global regulatory toxicology community when similar effects are observed in toxicological studies on other substances.
4. An independent blinded peer-review of rosin and derivative substance reproductive: 5 panelists with extensive expertise in the domain and no conflict of interest went through multiple rounds of review and reached a strong agreement that reproductive and developmental effects observed in rosin and rosin resin toxicity studies are non-specific secondary consequences of reduced maternal food intake.

**Q14: What are the regulatory consequences of Reprotoxicity classification?**

**A14:**

*Table 2*

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

**Q15: What are the Socio-Economic consequences of Reprotoxicity classification?**

**A15:** HARRPA has commissioned a Socio-Economic Analysis that was completed by Ricardo. The summary of this SEA is available on the HARRPA website (here) and the full report 'Socio-economic analysis of a proposed harmonised classification of rosin and rosin derivatives' is available on request from the HARRPA secretariat (dated 19 June 2026).

The analysis concludes that the harmonised classification of rosin and rosin derivatives, as category 1 or 2, could impose substantial costs on EU industry and the wider economy, whilst delivering only modest and uncertain human health benefits. In addition, negative environmental impacts could be associated with these options, if petrochemical-based alternatives are used to replace rosin.

**Q16: Will a classification for rosin impact the classification of rosin and its derivatives outside of the EU?**

**A16:** 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.

**Q17: Will a classification for rosin impact the availability and production of rosin in Europe, and outside of Europe?**

**A17:** A 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.

**Q18: 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?**

**A18:** 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.

**Q19: What can I do as downstream user to support H4R in the CLH Process?**

**A19:** The Public Consultation closed on 31 October 2025. Downstream users can now support the process by:

- Providing clarifications on technical uses and risk-management measures.
- Supporting outreach activities to regulators.

If you are interested on supporting HARRPA, PCA and H4R, please contact: manager@h4rconsortium.com and jwi@cefic.be

**Q20: What is the next important regulatory step?**

**A20:** RAC Opinion was adopted during the RAC-78 Plenary on 11 September (meeting minutes available here). The current Legal deadline for opinion adoption is the 24 December 2026.

**Q.21: What is a RAC opinion?**

**A21:** 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.22: Does the European Commission necessarily follow the RAC opinion?**

**A22:** Important to recall that a RAC opinion, even one supporting classification, is a scientific recommendation rather than the final legislative outcome. The legally binding decision lies with the European Commission and is taken only after consultation with Member States. HARRPA, H4R and PCA will therefore remain fully engaged throughout the remaining stages of the process, ensuring that the conclusions of the SEA, alongside the scientific evidence, are available to inform that decision and that the real-world consequences of any classification are properly understood.

**Q23: How to access the documents submitted by H4R, PCA and HARRPA during public consultation?**

**A23:** 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.

**Q24: Can I still safely use rosin and its derivatives?**

**A24:** Yes, rosin and rosin derivatives can still be used safely following recommendations documented in the safety datasheet provided by your supplier.