Joint Communication from *HARRPA*, *H4R Consortium* and *PCA* on the ongoing Classification and Labelling assessment for Rosin and selected Rosin Derivatives

Dear Stakeholders,
We are reaching out to inform you about the ongoing assessment of rosin resins and their derivatives under the European Union's REACH regulation. A CLH assessment has been initiated by the European Chemicals Agency (ECHA) and focuses on the potential classification of these substances due to perceived concerns by authorities with respect to reproductive toxicity.

Rosin is a substance derived from pine trees and used in many everyday products including adhesives, inks, tyres, chewing gum, and paper. It is critical to many industries due to its unique properties. Additionally, as a renewable, bio-based resource, it contributes to decarbonization and helps industry in the transition away from fossil-based resources.

Why is this assessment happening?
ECHA has flagged rosin and rosin derivatives for further regulatory assessment. This assessment was conducted by the Norwegian Member State Competent Authority (MSCA), resulting in CLH proposals for 9 rosin and rosin derivative substances (8 managed by H4R) based on perceived effects on reproductive toxicity. The CLH proposals were submitted to ECHA by Norway, as indicated on the Registry of CLH Intentions until Outcome[1]. ECHA is now conducting an accordance check on the submitted CLH dossiers. Once that process is completed, the CLH dossiers will be published by ECHA on their website, starting the public consultation phase of the CLH assessment process. This is expected early 2025.

Our position
The producers of rosin and its derivatives, represented by HARRPA, the H4R Consortium and the Pine Chemicals Association International strongly believe that there is no scientific basis for classifying these substances as toxic to reproduction. The H4R Consortium is carrying out additional studies, which are expected to provide the definitive proof that rosins do not represent a threat to reproduction.

Next steps
The full assessment process is expected to take about two years. We encourage all stakeholders to participate and contribute their views when the public consultation period opens, which we expect to happen in early 2025, and will be open for 60 days.

How you can help?
We are currently gathering additional Information on the use of rosin resins and derivatives to reinforce our position. If you have information related to toxicity (which is not yet in the REACH dossiers), safety, exposure, or the use of rosin resins, we kindly ask you to share this with us. Your input will be crucial in presenting a robust, science-based response to the authorities. This will strengthen our collective position as we work to protect this essential and sustainable industry and its products across the entire supply chain.

For further information, please refer to the detailed H4R Consortium's position paper attached as an annex. We will continue to update you as this process progresses and remain fully committed to ensuring that the classification accurately reflects the safety of these materials.

We are engaging in active and transparent communication, as we believe it is important to demonstrate the scientific base of our assessment and the economic, social, and environmental impact of this process. Thank you for your ongoing support and collaboration.

On behalf of the members of HARRPA, H4R Consortium and PCA

[1] *https://echa.europa.eu/registry-of-clh-intentions-until-outcome*

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H4R Position on the ongoing CLH assessment of Rosin and its Derivatives

Executive Summary:

In August 2023, ECHA published an Assessment of Regulatory Needs (ARN) document for Rosin and its derivatives[1]. This ARN has led to a Harmonized Classification and Labelling (CLH) assessment on the substances by the Norwegian Environmental Protection Agency (the national Member State Competent Authority [MSCA] on REACH in Norway). Norway has registered its intentions to propose CLH for reprotox for some of these substances, but its interpretation of the data is unclear at the moment as the dossiers have not been published yet. Therefore, the basis for the intentions is not understood, especially since reprotox classification is not warranted based on the available scientific evidence on these substances. Nevertheless, Norway have published CLH intentions[2] for the following specific substances:

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

Note that these are indeed intentions, and still need to follow the full regulatory process before a final opinion is reached.

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

This paper provides the background necessary to understand the reasons for H4R's position on this issue and is also intended to share some insights on the next possible steps.

1. Introduction

What are Rosin Derivatives?[3]

Rosin derivatives are manufactured from rosin, a light amber and glassy solid derived from pine trees. Chemically, rosin is comprised of a complex mixture of diterpenic structures generally referred to as resin acids. Rosins are mostly harvested from living trees (gum rosin) or obtained as a by-product from the paper industry (Tall Oil Rosin). Thanks to its unsaturation and carboxylic acid

[1] https://echa.europa.eu/documents/10162/5a44835f-a02b-d56d-f97d-d34cd9d848af
[2] https://echa.europa.eu/registry-of-clh-intentions-until-outcome
[3] In chemical nomenclature the terms "rosin" and "rosin acids and resin acids" are essentially synonymous.

functionality, Rosin can be made to react with many other chemicals, such as hydrogen, alcohols and others, to form adducts and esters making a wide range of bio-based products for industrial and consumer end uses. As such, the rosin industry is one of the best examples of renewable chemistry adding sustainable value to society, and has been in operation already for centuries.

Applications

Rosin and its derivatives are used in a wide variety of consumer and technical products. Well-known consumer uses include roles as additives in the formulation of food contact materials and articles (approved by regulators in Europe[4], USA[5] and Asia) and as ingredients in chewing gum base approved by US FDA[6] and other specific legislation in some European countries. Examples of other technical applications are paints, asphalt, paper sizing agents, adhesives, synthetic rubber emulsifiers, depilatory waxes, printing inks and detergents; in all its applications, rosin derivatives provide unique and essential product performance or contribute to environmental and health protection. Examples of these applications include, but are not limited to, low rolling resistance tyres, protective paints / varnishes / coatings to preserve building materials against wear and tear.

Sustainable value

The rosin industry is a textbook example of an industrial symbiosis with other key industry sectors in Europe, such as the pulp & paper and forest industries. In this way, the rosin industry is creating significant sustainable value with its bio-based substances produced from feedstocks and residual streams coming from these industry sectors. For several of the applications presented in the previous section, no alternatives exist. In other cases where alternatives do exist, these may be regrettable alternatives as they will either be petroleum-based substances or imported from outside Europe with negative impacts on the competitiveness of the European industry, regulatory certainty, and health and environmental protection. With its products, the rosin industry helps meet the ambition of the green transition in Europe (i.e., regional production process with low/negative CO2 footprint) and supports regulatory progress by being fully (and pro-actively) REACH compliant.

H4R Consortium

The H4R consortium[7] was founded in 2008 by HARRPA[8], a sector group of Cefic, representing manufacturers of Hydrocarbon Resins, Rosin Resins and Pine Chemicals materials. Its aim is to ensure continued compliance of these materials with the REACH Regulation[9], and demonstrating their safe use supported by existing and newly generated safety studies in accordance with the REACH requirements. Since the start of REACH in 2010, the H4R Consortium members have successfully registered more than 45 Rosin and Rosin derivative substances with the European Chemicals Agency (ECHA), many of them at the highest registration volume of > 1000 T/y. Additionally, H4R provides information on similar registration regimes in Turkey, Korea and the UK.

The H4R consortium is managed by Penman Consulting[10], a specialist consultancy providing a range of regulatory, technical, toxicological and scientific services to companies in the chemical sector.

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R1129-20131121
[5] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.735
[6] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.615
[7] https://h4rconsortium.com/
[8] https://www.harrpa.eu/
[9] REACH: **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals (REACH) is a regulation of the European Union (EU) designed to safeguard humans and the environment from the risks posed by chemicals manufactured or imported into the EU. It puts the onus on manufacturers/importers to demonstrate the safety of their substances.
[10] https://www.penmanconsulting.com/

H4R and HARRPA, supported by the global Pine Chemicals Association[11] (PCA), are committed to producing products with the highest safety standards and promoting their safe use throughout the value chain in compliance with the applicable legislation, regulations, and standards.

2. Health assessment for reproduction of Rosin and its derivatives

ARN activity

The Assessment of Regulatory Needs (ARN) is ECHA's internal *ad hoc* informal screening process for prioritizing groups of substances – *instead of single substances* – for further evaluation. It does not constitute a final judgment of hazard or risk for human health or the environment. Instead, the stated aim is to stimulate MSCA to take the initiative and perform further evaluations to form their own independent views. Member States may decide not to proceed with a recommendation made by ECHA in an ARN report. The ARN process is not regulated by REACH or any other European law; the industry may not participate in this process, which is entirely and solely under ECHA's control.

CLH assessment proposal

One of the possible regulatory actions suggested by ECHA as an outcome of the ARN activity is an assessment for potential harmonized classification and labelling (CLH). For rosin and its derivatives, ECHA has posited CLH "based on a concern on reproductive toxicity " and suggests "regulatory risk management actions for all substances *if reproductive toxicity hazards are confirmed*". As stated above, this is a "preliminary suggestion from a screening-level assessment done by ECHA with the aim to propose the next steps for further work". This has subsequently initiated a CLH process, in which the Norwegian MSCA has evaluated the available data. Based on this evaluation, Norway has published their CLH intentions for 8 substances managed by H4R as listed in Table 1, and submitted the corresponding dossiers to ECHA.

The H4R REACH Consortium has shared all relevant information with the Norwegian MSCA, including a complete reassessment of all relevant data and a Weight of Evidence (WoE) assessment which shows why CLH for rosin and its derivatives is not warranted.

H4R's conclusion on Reprotoxicity for Rosin and its Derivatives

A recent re-analysis of all available toxicological data has been conducted by toxicologists and other experts in 2023. These data include over 25 regulatory guideline studies performed using a diverse selection of rosin and its derivatives as part of the H4R testing strategy for REACH. Collectively, and with only one well-understood exception which is no longer relevant as the product has been taken off the market, these studies demonstrate unambiguously that rosin and its derivatives do not cause adverse effects on reproduction or development.

These studies show that there is no basis for a reproduction toxicity classification of rosin and its derivatives or any subgroup thereof. Based on the existing studies submitted as part of the registration dossiers of the substances concerned, none of them have been classified for toxicity to reproduction by registrants or authorities. The toxicological information from the REACH dossiers is available on the ECHA website[12] in the toxicity for reproduction section and can be consulted and assessed by anyone.

[11] https://www.pinechemicals.org/
[12] https://chem.echa.europa.eu/

Those REACH dossiers have been updated with a WoE assessment which addresses ECHA's specific concerns (which can be shared upon request). This WoE assessment confirms that any suggestion that the data possibly points to reprotoxicity is based on an erroneous interpretation that does not distinguish between primary, specific effects (so-called intrinsic properties) and secondary, non-specific effects, which are not intrinsic to the chemistry of the substance. In addition, H4R is currently conducting additional scientific work to further substantiate this hypothesis, and will submit these data to the authorities and in another dossier update.

H4R position

H4R does not agree with the CLH proposals for rosin and its derivatives listed on ECHA's RoI, as this measure is not supported by the available WoE, and is inconsistent with the assessments conducted by other regulatory bodies which have approved these substances as safe for use in sensitive end-use applications such as cosmetics and food contact materials.

H4R had all of its data reanalyzed to determine whether anything had been misinterpreted or overlooked. Based on the results, its position remains unchanged -- rosin and its derivatives do not raise any concern regarding toxicity for reproduction. H4R has shared its scientific analysis with ECHA as well as with the Norwegian MSCA, and will continue to reach out to them and other regulators to provide relevant scientific and toxicological input. Based on this, ECHA acknowledge H4Rs scientific position but has indicated that additional mechanistic evidence is required to prove the underlying hypothesis. This highlights the value of the additional mechanistic studies, and H4R will endeavor to ensure that these data are taken into account in the final CLH assessments.

In parallel, HARRPA will join efforts by leading a socio-economic analysis, which will amongst others focus on the sustainability value of the bio-based and renewable nature of rosin and derivatives and the essential uses which these substances allow. This analysis will also underpin the critical need for an unequivocal science-based CLH conclusion, rather than following a precautionary approach to classify these substances, should there be any remaining uncertainty in the data (interpretation).

3. Next steps

The Norwegian MSCA informed us that they have submitted the dossiers for these substances to ECHA in September. Their intentions were published on 8 October by ECHA, who subsequently confirmed to us that they are now conducting an accordance check. Once that process is completed, the CLH proposals will be published for public consultation. This is expected early 2025, and will be 60 days, in which input is needed from all stakeholders. Their input will be taken into account in final opinion development by the Member States in ECHA's Risk Assessment Committee. To our understanding this entire process may take until late 2026 to complete, and our industry will remain closely engaged throughout, to ensure the decision-making correctly reflects the available science.

In short, given the fact that there is a lot at stake for these companies, who create sustainable value for society with their bio-based substances which have no or only regrettable substitutes, and the fact that we are convinced that the available toxicology data demonstrate the safety of rosin and its derivatives and the products they are used in, H4R, HARRPA and PCA are fully committed with their support to ensure continued business for this exceptional industry.

H4R will update its stakeholders when significant developments occur and is willing to organize specific informative sessions to provide detailed information on any of the aspects of this case.