

## **Joint Communication from HARRPA, H4R Consortium, and PCA regarding Public Consultation for Rosin and some Rosin derivatives<sup>1</sup>**

H4R and PCA have jointly submitted detailed scientific comments in the public consultation on the CLH reports for Rosin and Rosin derivatives that occurred between Sept 1 and Oct 31, 2025. We conducted a thorough analysis of test data, which includes new data, and conclude that classifications for Reproductive toxicity proposed by the Norwegian Environment Agency are not warranted (see **Annex 1**). The comments, submitted as non-confidential in the public consultation, will now undergo an evaluation by the Risk Assessment Committee (RAC) of the ECHA over the next 12 months<sup>2</sup>, after which, the RAC will make its recommendations to the European Commission.

Except for one substance, H4R and PCA believe that the data used in the CLH report did not provide clear evidence to support classification, and more data was needed. This is why we commissioned two new studies, a transiency study and a feed restriction study. The aim of these studies was to distinguish whether the findings cited in the CLH report were due to an intrinsic property of the substance or to undernourishment. The conclusion is that developmental and fertility effects are caused by maternal undernourishment. Effects occur as the rats restrict dietary intake when their food is mixed with unpalatable rosin. These studies have now been submitted to ECHA, they were not available to the Norwegian Environmental Agency at the time of drafting the CLH report but will now be available to the RAC for their evaluation. We have annexed a summary table of our submissions for each of the substances concerned.

We expect the RAC opinion to be published mid-2026, and until then we will be available to explain the reasoning stated above in more detail to interested Stakeholders in Member States and European Regulatory authorities. Now that the industry's scientific response on hazard classification have been submitted to ECHA, we will focus on obtaining accurate data on the potential exposure to rosin and derivatives.

For this purpose, H4R has initiated a tonnage and use survey for downstream users to complete. This will allow us to ensure accurate use information is included in the REACH dossiers, and eliminate potential concerns related to no longer relevant uses.

In addition, HARRPA has commissioned a study with Ricardo Group to prepare a socio-economic assessment of the impact to Industry that such a classification would have, considering various scenarios.

Downstream users are requested to share information on use for these two exercises mentioned above whenever they are contacted.

In case you have any questions or information on use and exposure to share, please contact us at [manager@h4rconsortium.com](mailto:manager@h4rconsortium.com).

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

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<sup>1</sup> Please also see our previous joint public communications : [HARRPA H4R PCA Rosin DU comm 20241114](#) and [HARRPA H4R PCA Rosin Joint Comm 20250905](#)

<sup>2</sup> The comments were non-confidential and will be available together with the CLH report on the [ECHA Registry of CLH intentions until outcome](#)

**Annex 1: Overview table** containing a summary of the responses to the Proposed Classifications of Rosin and its derivative substances.

CAS	EC	Name	Proposed CLH	Hazard code
<b>8050-09-07</b>	<b>232-475-7</b>	<b>Rosin colophony</b>	<b>Repr. Cat. 1B</b>	<b>H360Df</b>
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is the lower number of Corpora Lutea and Implantation Sites and the lower Viability Index.</p> <p>Following further review, analysis, and additional mechanistic studies, H4R and PCA conclude that fertility findings are non-adverse; and developmental findings are non-specific secondary consequences of maternal undernutrition.</p> <p>Consequently, the criteria for classification are not met, and therefore, classification of Rosin for toxicity to reproduction is not warranted.</p>			
<b>65997-05-09</b>	<b>500-163-2</b>	<b>Rosin, oligomers</b>	<b>Repr. Cat. 1B</b>	<b>H360Df</b>
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is the lower mean number of <i>Corpora Lutea</i>, decrease of Implantation Sites and the lower Birth Index.</p> <p>Following further review, analysis, and additional mechanistic studies, H4R and PCA conclude that fertility findings are non-adverse; and developmental findings are non-specific secondary consequences of maternal undernutrition.</p> <p>Consequently, the criteria for classification are not met, and classification of Rosin, oligomers for toxicity to reproduction is not warranted</p>			
<b>65997-06-0</b>	<b>266-041-3</b>	<b>Rosin, hydrogenated</b>	<b>Repr. Cat. 2</b>	<b>H361f</b>
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is the lower mean number of <i>Corpora Lutea</i> and, relatedly, decrease of Implantation Sites.</p> <p>Following further review and analysis, H4R and PCA conclude that the fertility finding is non-adverse. Consequently, the criteria for classification are not met, and classification of Rosin, hydrogenated for toxicity to reproduction is not warranted</p>			
<b>65997-04-8</b>	<b>266-040-8</b>	<b>Rosin, fumarated</b>	<b>Repr. Cat. 2</b>	<b>H361f</b>
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is the lower mean number of Implantation Sites (and the inference that <i>Corpora Lutea</i> counts are also lower).</p> <p>Following further review and analysis, H4R and PCA conclude that the fertility finding is non-adverse. Consequently, the criteria for classification are not met, and classification of Rosin, fumarated for toxicity to reproduction is not warranted.</p>			
<b>8050-28-0</b>	<b>232-480-4</b>	<b>Rosin, maleated</b>	<b>Repr. Cat. 1B</b>	<b>H360D</b>
<i>H4R and PCA comment</i>	<p>Following further review and analysis, H4R and PCA agree that several of the developmental findings appear to be adverse.</p> <p>Consequently, classification of Rosin, maleated for toxicity to reproduction at Cat 2 should be investigated further. However, the interpretation of the data is not sufficiently definitive to warrant classification at Cat 1B.</p>			
<b>94581-17-6</b>	<b>305-516-2</b>	<b>Resin acids and Rosin acids, maleated, esters with pentaerythritol</b>	<b>Repr. Cat.2</b>	<b>H361fd</b>
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is the lower number of Corpora Lutea and Implantation Sites, the dose dependent reduction in mean ovarian weight and the dose-dependent reductions in mean pup bodyweights.</p> <p>Following further review, analysis and additional mechanistic studies, H4R and PCA conclude that fertility findings are non-adverse; and developmental findings are non-specific secondary consequences of maternal undernutrition.</p> <p>Consequently, the criteria for classification are not met, and classification of Resin acids and Rosin acids, maleated, esters with pentaerythritol for toxicity to reproduction is not warranted</p>			

97498-11-7	307-051-0	Resin acids and Rosin acids, fumarated, esters with glycerol	Repr. Cat.2	H361d
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is a decrease in foetal body weights and a clear dose-response seen for several skeletal findings, especially unossified sternebrae, unossified pubis, unossified metacarpal and incomplete ossified frontal.</p> <p>Following further review, analysis, and additional mechanistic studies, H4R and PCA conclude that the developmental findings are a non-specific secondary consequence of maternal undernutrition. Consequently, the criteria for classification are not met, and classification of Resin acids and Rosin acids, fumarated, esters with glycerol for toxicity to reproduction is not warranted.</p>			
	500-451-8	Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium and zinc salts	Repro. Cat. 2	H361f
<i>H4R and PCA comment</i>	<p>The rationale provided in the CLH report for the proposed classification is at the lower mean number of <i>Corpora Lutea</i> counts and Implantation Sites in the High Dose Group, and the apparent trend for dose-responsiveness.</p> <p>Following further review, analysis, and additional mechanistic studies, H4R and PCA conclude that the fertility finding is non-adverse. Consequently, classification of Fatty acids, tall oil, oligomeric reaction products with maleic anhydride and rosin, calcium magnesium and zinc salts for toxicity to reproduction is not warranted.</p>			