
H4R Position on ECHA's ARN on Rosin Derivatives

TO WHOM IT MAY CONCERN

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Executive Summary:

The H4R Consortium notes that ECHA has recently published an Assessment of Regulatory Needs (ARN) document for Rosin and its derivatives¹. This document raises potential human health and environmental concerns and proposes that some substances might be possible candidates for harmonized classification due to toxicity to reproduction². The H4R consortium disagrees strongly with this ECHA recommendation which is proposed to MSCA³. 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?⁴

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 functionality, Rosin can react with many other chemicals such as hydrogen, alcohols and other chemicals to form adducts and esters making a wide range of products for industrial and consumer end uses. As such, the rosin industry is one of the best examples of sustainable, biobased and renewable chemistry and has been in existence 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 (endorsed by regulators in Europe, USA and Asia – see Chapter "EFSA and FDA position") and as ingredients in chewing gum base approved by US FDA 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.

¹ <https://echa.europa.eu/documents/10162/5a44835f-a02b-d56d-f97d-d34cd9d848af>

² The ARN also alludes to harmonized classification for skin sensitization. However, this hazard is already well-understood, and the impacted chemicals are already self-classified for this hazard.

³ Member State Competent Authority.

⁴ In chemical nomenclature the terms "rosin" and "rosin acids and resin acids" are essentially synonymous.

H4R Consortium

The H4R consortium was founded in 2008 by manufacturers⁵ of Hydrocarbon Resins, Rosin Resins and Pine Chemicals materials ("HARRPA"). Its aim is to ensure continued REACH⁶ compliance of these materials, supported by existing and newly generated safety studies in line with the REACH requirements. Since the start of REACH in 2010, the H4R Consortium members have successfully registered more than 45 substances within the European Union, many of them at > 1000 T/y. Additionally, H4R provides information on REACH-like registrations in Turkey, Korea and the UK.

The H4R consortium is managed by Penman Consulting⁷, a specialist consultancy providing a range of regulatory, technical, toxicological and scientific services to companies in the chemical, petrochemical, plant protection and fine chemical industries.

2. Health assessment for reproduction of Rosin derivatives

What is an ARN?

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 does not constitute a final judgment of hazard or risk for human health. Instead, the stated aim is to stimulate MSCA to take the initiative and perform further evaluations to form their own independent view. Member States may also decide not to proceed further with the recommendation. The ARN process is not covered by REACH or any other European law.

EFSA and FDA positions

Two separate regulatory agencies have independently concluded that certain rosin derivatives are sufficiently safe that they can be consumed by humans. These substances are chemically equivalent and/or similar to products within the H4R portfolio.

European Food Safety Authority (EFSA) has listed glycerol ester of wood rosin, a rosin derivative, in Commission Regulation (EU) No 231/2012 as an authorised food additive and classified as 'other additives than colours and sweeteners'⁸.

Independently, the US Food and Drug Administration (FDA) has stated that Glycerol ester of wood rosin, gum rosin, or tall oil rosin may be safely used in foodstuffs such as gum base for chewing-gum⁹, beverages prepared from citrus oils¹⁰, and in food contact material.

⁵ Sun Chemical Colors & Effects; LES DERIVES RESINIQUES ET TERPENIQUES (DRT) ; Synthomer; Pino Pine Produtos Quimicos S.A.; Forchem Oy; Ingevity; Kemira; Kraton Chemical B.V.; Lawter Europe BV; Mare S.p.A.; Megara Resins SA; Respol Resinas SA; Rain Carbon Germany GmbH; Siegwark Druckfarben AG & Co. KGaA; Synthos Dwory Sp. Z.o.o.; LURESA RESINAS SL

⁶ REACH: Registration, Evaluation, Authorization and Restriction of Chemicals (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.

⁷ <https://www.penmanconsulting.com/>

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R1129-20131121>

⁹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.615>

¹⁰ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=172.735>

H4R's Position on Rosin Derivatives Reprotoxicity

Multiple (>25) regulatory safety studies performed using a diverse selection of Rosin and its derivatives were submitted to ECHA in 2017. Collectively, and with only one well-understood exception, these studies demonstrate unambiguously that Rosins derivatives are without adverse effects on reproduction or development. These studies show that there is no basis for a reproduction toxicity classification of the group of substances identified by ECHA and represented by H4R. Consequently, based on the existing studies submitted in the respective registration dossiers, these substances are not classified for toxicity to reproduction by the registrants or authorities. The toxicological information from the REACH dossiers is available on the ECHA website¹¹ in the toxicity for reproduction section and can be consulted and assessed by anyone. Those REACH dossiers will be updated to address ECHA's specific concerns. H4R continues its commitment to producing products with the highest safety standards. In line with this commitment, H4R has commissioned an external expert review of the reproductive and developmental toxicology studies. This toxicological review concludes that classification is not warranted and will be shared upon request.

H4R position versus ECHA position

H4R is surprised and disappointed at the recommendation in the ARN document that several of the H4R substances might be possible candidates for harmonized classification for toxicity to reproduction. Such a position is not supported by the weight of evidence (WoE), is not in line with the REACH regulation in substance grouping, and is inconsistent with the stance adopted by other regulatory bodies. The statements in the ARN document are somewhat vague and imprecise. Therefore, it is difficult to understand the true nature of their concerns.

H4R has reanalyzed its data and its position remains unchanged that these rosin substances do not raise any concern regarding toxicity for reproduction. H4R shares its scientific analysis with ECHA and will continue to reach out to them and other regulators to provide relevant scientific input. We understand that one MSCA is initiating a Harmonized Classification and Labelling (CLH) dossier that will conclude with a formal proposal to ECHA for consideration by the Member States. It is our understanding that this review will take approximately 1 year to complete, with subsequent lengthy review and discussion. Industry will be able to review and input into the discussion.

H4R will update its stakeholders when significant developments occur.

¹¹ <https://echa.europa.eu/pt/information-on-chemicals/registered-substances>