

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 16521: Tall oil acids, reaction products with dialkyleneamine and acid anhydride, compounds with polyalkylene glycol hydrogen maleate alkyl ethers (Confidential Accession No. 18326-2)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined based on the available information, that when used as notified, the substance is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Order No. 2012-87-02-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 146, No. 12 on June 6, 2012. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified polymer is tall oil acids, reaction products with dialkyleneamine and acid anhydride, compounds with polyalkylene glycol hydrogen maleate alkyl ethers (Confidential Accession No. 18326-2). The substance meets the Reduced Regulatory Requirements (RRR) criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)*.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use in architectural and industrial coatings. Potential uses may include household cleaners or personal care products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, soil and sediment. The substance is not expected to be persistent in these compartments based on hydrolysis data on the anionic polymer portion of the substance. The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient, high water solubility and surfactant nature.

Environmental risk assessment

No ecological toxicity data are available for the substance. Polymers that meet the RRR criteria, such as the notified substance, are considered to be of low concern.

Based on the low potential for ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is expected to be a dermal sensitizer (sensitization effects observed at lowest concentration tested (local lymph node assay)).

When the notified substance is used as a component of industrial and architectural coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake.

Potential uses include consumer paint products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels that do not pose a concern given its large molecular structure, which will limit its ability to cross biological membranes. Additionally, the substance will be present at low concentrations in end-use products (<10%) and it is expected that use of end-use products will be infrequent.

However, if the substance is used in household cleaners or personal care products, an increased level of direct exposure may exist, and is expected to be by dermal contact at moderate to high levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels for both notified and potential activities given the low potential for release to the environment.

Based on the low potential for exposure when used as notified, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

However, based on the potential for increased dermal exposure combined with indications that the substance has dermal sensitization potential, the potential use of the substance in household cleaners or personal care products could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Other considerations

The anionic portion of the notified substance, poly(oxy-alkanediyl), α -(carboxy-oxo-alkenyl)- ω -hydroxy-alkyl ethers (Confidential Accession No. 16329-3), has been previously assessed by Health Canada, and was found to be a dermal sensitizer and to meet the criteria of significant consumer exposure for potential uses. [Order 2010-87-10-01](#) [PDF] was published in the *Canada Gazette* Part II, Vol. 144, No. 21 on October 13, 2010.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to dermal sensitization potential if the substance were to be used in household cleaners or personal care products, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order No. 2012-87-02-01 was published in the *Canada Gazette* Part II, Vol. 146, No. 12 on June 6, 2012.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.