

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

New Substances Notification No. 18072: Tall oil, polymerized, oxidized

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 that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined that it 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, or that constitutes or may constitute a danger to the environment on which life depends, or that constitutes or may constitute a danger in Canada to human life or health.

Substance Identity

Tall oil, polymerized, oxidized (Chemical Abstracts Service Registry No. 68815-17-8) is a chemical of unknown or variable composition, complex reaction product and biological material (UVCB) that can be classified as a rosin derivative.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use in oil field applications. Potential uses are expected to be similar to those notified.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment the substance will tend to partition to water, sediment and soil. The substance is expected to be persistent in these compartments because it is anticipated to resist hydrolysis and biodegradation. The substance is not expected to bioaccumulate based on its water solubility and rate of metabolism in biological systems.

Ecological Assessment

Based on the available hazard information on the substance, the substance has low-moderate) acute toxicity in aquatic organisms (median effective concentration (EC₅₀) ≈ 100 mg/L. The predicted no-effect concentration was calculated to be 0.1-1 mg/L using the 48-hr EC₅₀ for the most sensitive organism (aquatic invertebrates), which was used to estimate the ecological risk.

No significant releases are expected from the notified or potential uses, such as off-shore oil field applications, of the substance. Given the low potential hazard associated with the substance, calculation of a predicted environmental concentration was not required.

Based on the low potential for ecological hazard and low potential for exposure from notified uses of the substance, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2 000 mg/kg body weight). It is a mild eye irritant (maximum average score = 2.3-15) and a slight skin irritant (primary irritation index = 0.6-1.5). It is not mutagenic *in vitro* and is therefore unlikely to cause genetic damage. Available read-across information on related substances including tall oils, rosins, and rosin derivatives suggest the substance is not a skin sensitizer and is unlikely to be genotoxic or carcinogenic. The substance is expected to have a low to moderate potential for systemic repeated oral toxicity (no-observed-adverse-effect level (NOAEL) >30 mg/kg bw/d), and a low to moderate potential for reproductive and developmental toxicity (NOAEL >250 mg/kg bw/d) with repeated exposure.

When used in oil field applications, direct exposure of the general population is expected to be negligible. Indirect exposure of the general population from environmental media such as drinking water is low. Direct and indirect exposures for potential uses (off-shore oil field applications) are not expected to differ significantly from those of the notified use.

Based on the negligible to low anticipated exposure, the substance is not likely to pose a significant health risk to the general population.

Assessment Conclusion

When used as notified or for other identified potential uses, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 the *Hazardous Products Regulations* for products intended for workplace use.