

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

New Substances Notification No. 18284: Tall oil, maleated

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, 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.

Substance Identity

Tall oil, maleated (Chemical Abstracts Service Registry No. 68152-93-2) is a chemical of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as a rosin derivative.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as an emulsifier for oil drilling fluids. No other activities are anticipated in Canada.

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 based on the presence of large complex reaction products and components resistant to biodegradation resulting in slow biodegradation and half-lives in water and soil of greater than 182 and 365 days, respectively. The substance is not expected to bioaccumulate based on its bioaccumulation factor (< 5000 L/kg) and large size, which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information and surrogate data on structurally related chemicals, the substance has low to moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) > 1 mg/L), and moderate acute toxicity in algae (EC_{50} 1-100mg/L). Its chronic toxicity is moderate to low in fish and aquatic invertebrates (lowest-observed-effect-concentration > 0.1 mg/L), and low in benthic invertebrates (no-observed-effect concentration > 10 mg/kg). Using the LC_{50} from the most sensitive organism

(fish) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 10-100µg/L, which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from cleaning of transport containers released to water at levels of 1-10 kg/day. Environmental exposure from potential activities could be from manufacturing releases to water at levels of 1-100 kg/day. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10µg/L, while the PEC for other potential activities such as manufacturing is estimated to be 10-100µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg) and a low potential for subchronic and reproductive/developmental toxicity following repeat doses in mammalian test animals (35-day no-observed-adverse-effect level >1000 mg/kg-bw/d). It may be a strong sensitizer and it is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as an emulsifier for oil drilling fluid systems, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be low given that the substance is expected to degrade over time and irreversibly adsorb to organic matter. No other potential uses have been identified.

Based on the low potential for exposure, in conjunction with the low oral acute and subchronic toxicity, 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.

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.