

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

New Substances Notification 21214: Rosin, reaction products with polyalkylene-polysubstituted-terephthalic acid polymer (Confidential Accession Number 19673-1)

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 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

The notified polymer is rosin, reaction products with polyalkylene-polysubstituted-terephthalic acid polymer (Confidential Accession Number 19673-1). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in coatings for hydraulic fracturing applications and as a component of adhesive material in industrial applications. Potential uses may include use in coatings for industrial equipment and in hot melt and pressure-sensitive adhesives in industrial applications.

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 soil and sediment. The substance is expected to be persistent in these compartments because it does not contain any functional groups that are susceptible to hydrolysis or biodegradation. The substance is not expected to bioaccumulate based on the predicted bioconcentration factor (250-1000 L/kg) and its potentially cationic charge, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the low water extractability (< 2%), the substance is expected have low bioavailability and bioaccumulation. Therefore, a predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly by release of the substance to water at low rates. A predicted environmental concentration was

not calculated due to the low potential for environmental exposure. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for environmental exposure, 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 low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). High molecular weight water insoluble polymers have been linked to irreversible lung damage, however, which is believed to arise from long-term chronic exposure.

When the notified substance is used in coatings for hydraulic fracturing applications or in adhesive material in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be at low levels given the low potential for environmental release. Potential uses of the substance include use in coatings for industrial equipment and in hot melt and pressure-sensitive adhesives in industrial applications, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for exposure, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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 the workplace.