

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

New Substances Notification No. 18829: Alkenes, polymers with 2,5-furandione and 1,2-ethanediol

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 alkenes, polymers with 2,5-furandione and 1,2-ethanediol (Confidential Accession No. 19231-9). 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 Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a fuel additive. Potential uses are expected to be industrial in nature.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment because it is not readily biodegradable. The substance is expected to be moderately bioaccumulative based on its molecular weight and moderate octanol-water partition coefficient ($\log K_{ow}$ 3-6).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in aquatic invertebrates and algae (median effective loading >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 low. The substance will be present in end use products at low concentrations (<3%) and will be completely consumed during use. A predicted environmental concentration was not estimated given the low potential for environmental exposure. No other activities have been identified.

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

Human Health Assessment

Based on the available hazard information 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 body weight). It is a moderate dermal sensitizer (29-64% response (guinea pig maximization test)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in industrial applications, the substance is intended to be used industrially and direct exposure of the general population is not expected. Consumers may come into direct dermal contact with products containing the substance; however, exposure is expected to be infrequent, the substance will be present in end-use products at low concentrations (<3%), and dermal uptake is not expected as its low water solubility will limit its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be low as the substance will be completely consumed during use. Potential uses of the substance are expected to be industrial in nature and will not result in direct or indirect exposure scenarios significantly different than for the notified use.

Based on the low potential for direct or indirect 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.

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