

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

New Substances Notification No. 18204: 2,5-furandione, polymer with alkene, hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester-initiated

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

2,5-furandione, polymer with alkene, hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester-initiated (Confidential Accession Number 19054-1) is a polymer that can be classified as a poly(alkyl). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because of the presence of acid anhydride groups.

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 automotive original equipment manufacturer (OEM) coatings. Potential uses are expected to be similar to those notified, and 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 water, soil and sediment. While the substance contains functional groups that are expected to hydrolyze in water, the substance is expected to be persistent in these compartments based on the half-lives of the hydrolysis products (>182 days in water and soil and >365 days in sediment). The substance is not expected to bioaccumulate based on its high molecular weight making it unable to cross biological membranes.

Ecological Assessment

Based on the available hazard information on surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in aquatic invertebrates and algae (median effective concentration >100 mg/L). Calculation of a predicted no-effect concentration was not considered necessary given the low ecotoxicity.

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 during use, transportation and disposal is not expected and any releases would readily hydrolyse in an aqueous environment. The predicted environmental concentration for notified activities was not calculated. No other potential activities were identified.

Based on the predicted low toxicity to aquatic organisms and low potential for environmental exposure, 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-bw).

When used in automotive OEM coatings, direct exposure of the general population is expected to low as the substance will be chemically reacted to the stable matrix of the coating and will not be readily released. Indirect exposure of the general population from environmental media such as drinking water is considered unlikely.

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