

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

New Substances Notification No. 19050: 2,5-Furandione, polymer with ethene and alkene, heteromonocycle alkyl imide

### 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 2,5-furandione, polymer with ethene and alkene, heteromonocycle alkyl imide (Confidential Accession No. 19164-2). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic aliphatic amine 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 the notified use as a lubricant modifier. Potential uses may include use as a solubilizing agent or an additive.

### 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 as it contains no functional groups susceptible to hydrolysis or biodegradation. The substance is not expected to bioaccumulate based on its large molecular structure and high molecular weight which will limit its ability to cross biological membranes.

### Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC<sub>50</sub>) and median effective loading rate >100 mg/L), and low chronic toxicity in algae (median effective concentration >100 mg/L). Using the LC<sub>50</sub>, from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be between 10 and 100 mg/L. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

Based on the low potential for ecotoxicity and low bioavailability based on its size and molecular weight, the substance is unlikely to cause ecological harm in Canada.

### **Human health assessment**

No mammalian toxicity data are available for the substance. The substance does not contain any structural features known to be associated with adverse human health effects.

When the notified substance is used as a lubricant modifier in consumer products, direct exposure of the general population is expected to be mainly by contact with the skin at low levels given the low concentrations of the substance in end-use products, infrequent use of products containing the substance, and the large structure and high molecular weight of the substance that 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 negligible as significant releases are not expected and the substance is not expected to be in the aquatic compartment due to its low water extractability (<2%). If the substance is used as a solubilizing agent or additive, direct and indirect exposure of the general population is expected to be 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.

### **Assessment conclusion**

When the substance is used as notified or for other identified potential uses, it 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.