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

New Substances Notification No. 18435: 2,5-Furandione, polymer with 2,2-dimethyl-1,3-propanediol and 1,2-ethanediol, alkenyloxy ethyl ester

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

2,5-Furandione, polymer with 2,2-dimethyl-1,3-propanediol and 1,2-ethanediol, alkenyloxy ethyl ester (Confidential Accession No: 19055-2) is a polymer that can be classified as a poly(alkene ester). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because it contains functional groups of concern.

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 composite manufacturing. Potential uses are also expected to be industrial or commercial 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. The substance is expected to be persistent based on long half-lives in water (>182 days), soil (>182 days) and sediment (>365 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on a structurally related chemical, the substance is expected to have moderate acute toxicity in fish (median lethal concentration 1-100 mg/L). The predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/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. Potential uses of the substance include use in inks, dyes, adhesives, coatings and resins. Environmental exposure is expected to be mainly from release to water based on transportation, storage, use, and blending activities. The predicted environmental concentrations (PEC) for those activities are estimated to be 0.1-1 µg/L.

Comparing the PEC for notified and potential activities with the PNEC, the ratio is less than 1. This along with other lines of evidence including hazard, exposure and environmental fate indicates that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight). In its uncured form, the notified substance has functional groups associated with health effects such as neurotoxicity, central nervous system depression, and possibly sensitization.

When the notified substance is used in composite manufacturing, direct exposure of the general population is not expected given that the functional groups of concern become cross-linked into the composite material once the end product is cured. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. If the notified substance is used in other potential industrial or commercial applications, direct exposure of the general population is similarly not expected.

Based on the low potential for exposure and low potential for acute 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 the substance is used as notified or for other identified potential uses, itis 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.