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

New Substances Notification No. 17978: 2,5-Furandione, telomer with ethenylbenzene and (1-methylethyl)benzene, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-aminopropyl Me ether, 2-(alkyloxmethyl) oxirane-quaternized, benzoates (salts)

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, telomer with ethenylbenzene and (1-methylethyl)benzene, 3-(dimethylamino)propyl imide, imide with polyethylene-polypropylene glycol 2-aminopropyl Me ether, 2-(alkyloxmethyl) oxirane-quaternized, benzoates (salts) (Confidential Accession No. 18886-4) is a polymer that can be classified as a cationic polymer. The substance does not meet the Reduced Regulatory Requirement criteria according to the New Substances Notification Regulations because it contains cationic quaternary ammonium functional 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 as an additive used in printing inks and coatings. Potential uses may include corrosion inhibition and dispersing agent.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, sediment and soil. The substance is expected to be persistent in these compartments because the poly(alkyl) backbone is expected to be resistant to environmental degradation processes such as hydrolysis, photolysis and biodegradation. The substance is not expected to bioaccumulate based on its large molecular weight making it unable to cross biological membranes.

Ecological Assessment

Based on the available hazard information on a structurally related polymer, the substance has moderate (median effective concentration (EC_{50}) 1-100 mg/L) acute toxicity in aquatic

organisms when adjusted for expected mitigation due to the presence of dissolved organic carbon in the environment. The predicted no effect concentration was calculated to be 100-1000 µg/L using the adjusted 72h EC_{50} for the most sensitive organism (green algae), which was used to estimate the ecological risk.

The notified and other potential activities (for example, as corrosion inhibitors or dispersing agents) 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 from the release of the substance to waste water treatment plants from blending, and the cleaning of equipment and transportation or storage vessels. The predicted environmental concentration for notified activities is estimated to be 0.1-1 µg/L.

Based on the low exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on a structurally related polymer, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight). The chemical structure is not associated with any documented health hazards and there are not expected to be any significant health risks to the general population due to its notified or potential uses (for example, as corrosion inhibitors or dispersing agents).

Based on 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 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 the *Hazardous Products Regulations* for products intended for workplace use.