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

New Substances Notification 19652: 1,4-Dioxane-2,5-dione, 3,6-dialkyl-, (3*S*,6*S*)-, polymer with *N*1-(2-aminoalkyl)-1,2-alkanediamine, aziridine, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, dodecanoate (ester), *N*-acetyl derivatives, acetates (salts) (Confidential Accession Number 19312-0)

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 1,4-dioxane-2,5-dione, 3,6-dialkyl-, (3*S*,6*S*)-, polymer with *N*1-(2-aminoalkyl)-1,2-alkanediamine, aziridine, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, dodecanoate (ester), *N*-acetyl derivatives, acetates (salts) (Confidential Accession No. 19312-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic amines.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial coatings and inks. Potential uses may include consumer coating and ink applications.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water, soil and sediment. The substance is expected to be persistent in these compartments based on the low biodegradability of structurally similar substances (10-30% over 28 days) and because the substance is anticipated to be resistant to hydrolysis due to its large molecular size and complex structure. The substance is not expected to bioaccumulate based on its high molecular weight and cationic nature which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low to moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration (EC_{50}) >1 mg/L) and low to moderate chronic toxicity in algae (no-observed-effect-concentration 0.1-10 mg/L; lowest-observed-effect-concentration >10 mg/L) under environmental conditions when mitigated by dissolved organic carbon. Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 50 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect

concentration (PNEC) was calculated to be in the range of 0.1-1 mg/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. Environmental exposure from the notified activities is expected to be mainly from processing and use from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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 acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is not expected to be a dermal sensitizer. It is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings and inks, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels that do not pose a concern, given the low potential for environmental release.

Potential uses of the substance include consumer coatings and inks, where direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation at low levels due to its high molecular weight and cationic nature which will limit its ability to cross biological membranes, the low concentration of the substance in end-use products (<10%), the small amount of product containing the substance used during some consumer applications, and the application of safety precautions during use as instructed for end-use products. Additionally, the substance will be encapsulated within a stable matrix once the product is cured and unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern, 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 activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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.