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

New Substances Notification 21068: Alkanoic acid, 12-hydroxy-, compound with heteromonocycle polymer with N^1-(2-aminoalkyl)-1, alkylamine, 12-hydroxyoctadecanoic acid, 2-oxepanone and tetrahydro-2*H*-hetermonocycle (Confidential Accession Number 19671-9)

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 alkanoic acid, 12-hydroxy-, compound with heteromonocycle polymer with N^1-(2-aminoalkyl)-1, alkylamine, 12-hydroxyoctadecanoic acid, 2-oxepanone and tetrahydro-2*H*-hetermonocycle (Confidential Accession Number 19671-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains amine functional groups of concern.

Notified and potential uses

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

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 soil and sediments. The substance is expected to be persistent in soil and sediments based on its high molecular weight and complex structure, which will limit hydrolysis and biodegradation potential. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish, aquatic invertebrates, and algae (median lethal concentration, median

effective concentration (EC_{50}), and median effective loading rate > 1 mg/L) under environmental conditions when toxicity is mitigated by dissolved organic carbon. The substance is expected to have moderate chronic toxicity to algae (no-observed-effect-concentration > 0.1 mg/L) under environmental conditions when toxicity is mitigated by dissolved organic carbon. Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 20 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 100-1000 µg/L, which was used to estimate the risk to the environment.

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 activities is expected to be mainly from equipment and transport vessel cleaning by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 100-1000 µg/L, with the exact value being below the PNEC value. No potential activities that could significantly increase environmental risks compared to those notified were identified.

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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight). The substance could be a mild or moderate dermal irritant; however, it is not expected to be a dermal sensitizer (0% response in a Buehler test). It is not expected to be mutagenic *in vitro* and, therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used industrially in coatings and printing inks, the general public 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 cured and will be unavailable for uptake. Potential uses of the substance include commercial and consumer coatings and inks, where direct exposure of the general population is expected to be mainly by contact with the skin. When the substance is used commercially, direct exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use. When the substance is used in consumer products, consumers may come in contact with the substance; however, exposure will be limited by the frequency and duration of use, the low concentration of the substance in the products, and the limited ability of the substance to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be at low levels given the low potential for environmental release.

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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified, 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 the *Hazardous Products Regulations* for products intended for the workplace.