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

New Substances Notification 20578: Octadecanoic acid, 12-hydroxy-, polymer with aziridine, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, reaction products with heteropolycycle disubstituted (Confidential Accession No. 19519-7)

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 octadecanoic acid, 12-hydroxy-, polymer with aziridine, 2-oxepanone and tetrahydro-2*H*-pyran-2-one, reaction products with heteropolycycle disubstituted (Confidential Accession No. 19519-7). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially 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 uses as a dispersing agent in industrial applications. No other uses are anticipated in Canada.

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 soils and sediments. The substance is expected to be persistent in these compartments based on its high molecular weight and lack of accessibility to environmentally hydrolysable groups. The substance is not expected to bioaccumulate based on its high molecular weight and potentially cationic charge 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 acute toxicity to aquatic invertebrates (median effective loading rate > 100 mg/L). Under environmental conditions when mitigated by dissolved organic carbon, the substance is expected to have low to moderate acute toxicity to fish (median lethal concentration (LC_{50}) > 1 mg/L) and low acute toxicity to algae (median effective concentration > 100 mg/L) and aquatic invertebrates (LC_{50} > 100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 100 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 □g/L, which was used to estimate the ecological risk.

The notified and 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 are expected to be minimal, as no significant releases are expected and high removal efficiency from wastewater treatment is anticipated. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1 for the potential activities. This along with the low potential for environmental exposure and ecotoxicity for the notified activities, the substance is unlikely to cause ecological harm 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). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features of concern associated with mammalian toxicity.

When the notified substance is used in coatings and inks, consumers may come into contact with end-use products containing the substance; however, direct exposure is expected to be low 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 is expected to be low given the specialized industrial use of the substance, which results in little or no release to the environment. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the absence of structural features associated with adverse human health effects and 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 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.