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

New Substances Notification No. 19037: Octadecanoic acid, 12-hydroxy-, reaction product with alkenediamine and alkanoic acid

**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 chemical is octadecanoic acid, 12-hydroxy-, reaction product with alkenediamine and alkanoic acid (Confidential Accession No. 19241-9), and is a substance referred to as of unknown or variable composition, complex reaction products and biological materials (UVCB).

**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 the notified use in industrial paints and coatings. Potential uses are expected to be similar to those notified.

**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 not expected to be persistent in water, soil or sediment based on its susceptibility to biodegradation (10-30%). The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

**Ecological assessment**

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute in fish and aquatic invertebrates (median lethal loading rate ($LL_{50}$) and median effective loading rate ($EL_{50}$) >100 mg/L) and high chronic toxicity in algae (10% effective concentration ($EC_{10}$) <1 mg/L). The substance is expected to have moderate chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) 0.1-10 mg/L) and low chronic toxicity in fish (no adverse effects observed in saturated solution). The substance is expected to have low acute toxicity in soil invertebrates ($LC_{50}$ >100 mg/kg dry soil) and low chronic toxicity in plants and soil microorganisms (NOEC >10 mg/kg dry soil). Using the $EC_{10}$ from the most sensitive organism (algae) and by applying an assessment factor of 2 to address species sensitivity variation, the predicted no-effect

concentration (PNEC) was calculated to be between 10 and 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. Environmental exposure from the notified activities is expected to be mainly from formulation and use in industrial paints and coatings by release of the substance to water at rates of 0.1 to 1 kg/day/site. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water at rates of 1 to 10 kg/day/site. The predicted environmental concentration (PEC) is estimated to be between 0.1 and 1 µg/L for notified activities and between 1 and 10 µg/L for other potential activities.

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 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 the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (14-day no-observed-adverse-effect level (NOAEL) >1000 mg/kg-bw/day). The notified substance is expected to have low potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/d with no biologically significant effects). It is not a skin sensitizer (>10% effective concentration to induce a stimulation index of 3 (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in industrial paints and coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated in a stable polymer 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 low because significant environmental release is not anticipated and the notified substance and its components are not expected to persist in the environment.

If the substance is used in paints, coatings, sealants or adhesives for consumer use, direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation. Exposure by the dermal route is expected to be low given the low concentration of the substance in consumer products (≤3.5%) and the expected octanol-water partition coefficient values of the substance components which will limit the ability of the substance to cross biological membranes. Exposure by inhalation is expected to be low given the very low vapour pressure of the substance (≤$1.3 \times 10^{-6}$ Pa). Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on the low toxicity 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.

**Assessment conclusion**

When the substance is used as notified or for other identified potential uses, it 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 *Hazardous Products Regulations* for products intended for the workplace.