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

New Substances Notification 21032: Hexanedioic acid, polycycloalkyl ester (Confidential Accession Number 19724-2)

**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 hexanedioic acid, polycycloalkyl ester (Confidential Accession Number 19724-2).

**Notified and potential uses**

The substance is proposed to be imported into and manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in plastics, caulks and sealants. Potential uses may include use as an additive in industrial oils, lubricants, hydraulic fluids, and adhesives.

**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 sediments. The substance is not expected to be persistent in this compartment based on ready biodegradability (60-85% over 28 days). The substance is not expected to bioaccumulate based on its low expected bioconcentration factor (< 250 L/kg).

**Environmental risk assessment**

Based on the available hazard information, the substance is expected to have low acute toxicity to fish (no adverse effects observed in saturated solutions), low to high acute toxicity to aquatic invertebrates (median effective concentration [$EC_{50}$] < 1mg/L; no adverse effects observed in saturated solutions in another study), low to high chronic toxicity to aquatic invertebrates (maximum acceptable toxicant concentration [MATC] < 0.1 mg/L; lowest-observed-effect-loading-rate > 10 mg/L), and low chronic toxicity to algae ($EC_{50}$ > 10 mg/L). Using the MATC from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor

of 2 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

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 activity is expected to be mainly from manufacturing and cleaning of transportation vessels resulting in predicted environmental concentrations (PECs) in the range of 0.1-1 µg/L. For potential activities such as manufacturing in a different facility, environmental exposure is expected to be mainly from the release of the substance to water resulting in a PEC in the range of 1-10 µg/L, with the exact value being below the PNEC.

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). It is not a dermal sensitizer (0-8% response in a guinea pig maximization test). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in caulks and sealants, consumers may come into contact with end-use products containing the substance; however, direct exposure is limited because the substance is expected to be contained within a cured matrix and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release and ready biodegradability of the substance. Potential uses of the substance include as an additive in industrial or commercial oils, lubricants, hydraulic fluids, and plastics, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

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.

The assumptions made in the assessment are considered to be adequately protective of 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 the *Hazardous Products Regulations* for products intended for the workplace.