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

New Substances Notification 20160: 9-Octadecenoic acid (*Z*)-, compound with (*Z*)-*N*-9-octadeceny1-1,3-propanediamine (Chemical Abstracts Service registry number 40027-38-1)

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 determined that the substance is 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in Ministerial Condition No. 20160 published in the *Canada Gazette* Part I, Vol. 154, No. 5 on February 1, 2020.

Substance identity

The notified chemical is 9-octadecenoic acid (*Z*)-, compound with (*Z*)-*N*-9-octadeceny1-1,3-propanediamine (Chemical Abstracts Service registry number[1] 40027-38-1).

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 as a friction modifier in engine oils and transmission oils. Potential uses may include manufacture and use as a surfactant in metal working fluids, paints and coatings, textile finishing products, and mining processes.

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, where it will dissociate into two components, and then partition to sediments. The substance and its components are not expected to be persistent in water or sediments based on moderate biodegradability (30-60% in 28 days). The substance is expected to bioaccumulate based on its high bioaccumulation and bioconcentration factors (>5000 L/kg).

Ecological assessment

Based on the available hazard information, the substance has high acute toxicity to aquatic invertebrates (median effect concentration (EC_{50}) <1 mg/L) and high chronic toxicity to algae (10%

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effective concentration <0.1 mg/L). The substance is expected to have high acute toxicity to fish (median lethal concentration <1 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 20 to account for acute to chronic extrapolation and mode of action, the predicted no effect concentration (PNEC) was calculated to be in the range of 0.1-1 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 cleaning of transportation vessels and formulation by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 µg/L and 0.001-0.01 µg/L, respectively. For potential activities such as manufacturing, coating formulation and use, and asphalt emulsion formulation, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified use. However, if the substance is used as a metalworking fluid or a mineral processing agent, an increased exposure potential may exist from release of the substance to water that could result in a PEC in the range of 0.1-1 µg/L. If the substance is used as a textile finishing agent, an increased exposure potential may exist from release of the substance to water that could result in a PEC in the range of 1-10 µg/L.

Based on the potential for environmental exposure, combined with the high acute and chronic aquatic toxicity, the substance is anticipated to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight) and is expected to have high subchronic toxicity following repeated oral doses in mammalian test animals (28- and 90-day no-observed-adverse-effect level (NOAEL) <30 and 10 mg/kg-bw/day, respectively). It is not expected to be a skin sensitizer. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 1-10 µg/kg bw/day based on the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as a friction modifier in engine oils and transmission oils, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is conservatively estimated to be at levels in the range of 0.001-0.01 µg/kg bw/day for children and adults. Potential uses of the substance include engine and transmission oils available to consumers and paints and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin. However, dermal absorption and subsequent systemic distribution is considered to be low. Indirect exposure is conservatively estimated to be at levels in the range of 0.01-0.1 µg/kg bw/day for children and adults.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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.

Other considerations

A group of aliphatic amine substances was prioritized for assessment under phase 3 of the Chemicals Management Plan (Environment and Climate Change Canada/Health Canada 2020). The draft screening

assessment report is scheduled for publication in 2020. The amine component of the notified substance is on the Domestic Substances List and is specifically identified in this assessment.

Assessment conclusion

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (*a*), but is not suspected to constitute a danger to the environment on which life depends according to the criteria under paragraph 64 (*b*), or constitute a danger to human health according to the criteria under paragraph 64 (*c*) of the Act.

Due to the identified risk to the environment related to the aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use in order to mitigate these potential risks. Ministerial Condition No. 20160 was published in the *Canada Gazette* Part I, Vol. 154, No. 5 on February 1, 2020.

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.