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

New Substances Notification 20159: 2-Propenoic acid, ethyl ester, reaction products with *O*,*O*-bis(polyalkylalkyl) hydrogen phosphorodithioate, *O*,*O*-dialkyl hydrogen phosphorodithioate and propylene oxide (Confidential Accession Number 19429-7)

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 chemical is 2-propenoic acid, ethyl ester, reaction products with *O*,*O*-bis(polyalkylalkyl) hydrogen phosphorodithioate, *O*,*O*-dialkyl hydrogen phosphorodithioate and propylene oxide (Confidential Accession Number 19429-7), and is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB).

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 lubricant additive. Potential uses may include other lubricant applications.

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 sediment. The substance is expected to be persistent in soil and sediments based on low biodegradability (≤10% over 28 days). The substance is not expected to bioaccumulate based on low to moderate experimental bioconcentration values (<1000 L/kg) and also having components with high molecular weights which will limit their ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity to fish (median lethal loading rate (LL_{50}) >100 mg/L and lowest observed effect concentration (LOEC) 1-100 mg/L), moderate acute toxicity to aquatic invertebrates (LOEC 1-100 mg/L), low acute toxicity to soil organisms (LL_{50} >100 mg/kg dry soil), low chronic toxicity to aquatic invertebrates (10% effective loading rate >10 mg/L) and moderate chronic toxicity to algae (LOEC 0.1-10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activity is expected to be minimal, as no significant releases are expected and the substance is expected to be effectively removed

during wastewater treatment. A predicted environmental concentration was not calculated due to the low potential for environmental exposure. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) > 300 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 1000 mg/kg-bw/day). It is not a dermal sensitizer (Buehler assay). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a lubricant additive, direct exposure of the general population is expected to be infrequent and at low levels, mainly resulting from incidental skin contact. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given the low potential for environmental release. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

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 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.