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

New Substances Notification 20495: 2-Propenoic acid, 2-hydroxyalkyl ester, reaction products with *O,O*-bis(1,3-dialkylalkyl) hydrogen phosphorodithioate and dialkyl phosphonate (Confidential Accession No. 19492-0)

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, 2-hydroxyalkyl ester, reaction products with *O,O*-bis(1,3-dialkylalkyl) hydrogen phosphorodithioate and dialkyl phosphonate (Confidential Accession No. 19492-0), and is considered 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 an additive in lubricants. Following listing on the Domestic Substances List, the substance can be manufactured in Canada, but no other uses are anticipated.

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 with some lower molecular weight components partitioning to water. The substance is expected to be persistent in these compartments based on its ready/inherent biodegradation (≤10% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration and bioaccumulation factors (<250 L/kg) and the high molecular weight of most components, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance has high acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) < 1 mg/L), moderate acute toxicity to fish (median lethal concentration 1-100 mg/L), low acute toxicity to algae (median effective loading rate > 100 mg/L) and low chronic toxicity to algae (10% effective loading rate > 10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) 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 1-10 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 activity is expected to be mainly from formulation and cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.1-1 µg/L. For potential activities such as industrial manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µ/L.

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 ecological harm in Canada.

Human health risk 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 moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is not a dermal sensitizer (0% response (Buehler test)). 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 10-100 µg/kg-bw/day based on the NOAEL of 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 an additive in lubricants, direct exposure of the general population is expected to be mainly by contact with the skin. However, exposures will be infrequent and brief, the concentration of the substance in the end-use products is expected to be low and absorption is not anticipated. Indirect exposure of the general population from environmental media such as drinking water and air is not expected given the low potential for environmental release. Potential activities include manufacture of the substance in Canada, 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 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.