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

New Substances Notification No. 19367: Phosphonic acid, dialkyl ester, polymer with 2-alkyl-2-alkyl-1,3-alkanediol and 1,6-alkanediol (Confidential Accession No. 19254-2)

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 phosphonic acid, dialkyl ester, polymer with 2-alkyl-2-alkyl-1,3-alkanediol and 1,6-alkanediol (Confidential Accession No. 19254-2), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in automotive fluids. No other uses are anticipated in Canada.

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 these compartments based on its ability to hydrolyze and its expected biodegradation over time (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low to moderate octanol-water partition coefficient (log K_{ow} <5) and its low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish (no adverse effects observed in saturated solutions), moderate acute toxicity in aquatic invertebrates (median effective loading rate 1-100 mg/L) and moderate chronic toxicity in algae (no-observed-effect-level (NOEL) 0.1-10 mg/L). Using the NOEL from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 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 cleaning of transportation vessels and formulation, with release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 1-10 µg/L 0.01-0.1 µg/L, respectively. For potential activities such as manufacturing and cleaning of other transportation vessels, environmental exposure is expected to be mainly from the release of the substance to water resulting in a PEC in the range of 10-100 µg/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 assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral end dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). 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 mg/kg-bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used in automotive fluids for industrial or commercial use, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. When the notified substance is used in consumer automotive fluids , direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.1-1 mg/kg-bw/day. Exposure will be limited by infrequent use of products containing the substance and low concentrations in end-use products. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-6}-10^{-5} mg/kg-bw/day for children and adults. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

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.

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.