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

New Substances Notification No. 19892: Amines, bis(C_{11-14}-branched and linear alkyl), 3-[[bis(2-methyl propoxy)phosphinothioyl]thio]-2-methylpropanoates (Chemical Abstracts Service No. 1255680-66-0)

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 amines, bis(C_{11-14}-branched and linear alkyl),3-[[bis(2-methylpropoxy) phosphinothioyl]thio]-2-methylpropanoates (Chemical Abstracts Service No.1255680-66-0), 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 manufactured in and/or imported into Canada in quantities greater than 1 000 kg/yr for the notified use as an additive in lubricant. 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 soil and sediment. The substance is expected to be persistent in these compartments based on its very low biodegradation potential (≤10% at 28 days). The substance is not expected to bioaccumulate because of charges contained in its structure, which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solutions), and low chronic toxicity in algae (10% effective loading rate (EL_{10}) >10 mg/L). Using the EL_{10} from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1000-10 000 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 1-10 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by 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 and dermal route (median lethal dose >2000 mg/kg body weight) and moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is a moderate dermal sensitizer (28-64% response in guinea pig maximization test). It is not expected to be mutagenic or clastogenic *in vitro.* Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 0.01-0.1 mg/kg bw/day based on the NOAEL from the oral subchronic toxic study in mammalian test animals.

When the notified substance is used as an additive in lubricant, 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 not expected given the specialized industrial use of the substance, which results in little or no release to the environment. For potential activities such as manufacturing, 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^{-4}-10^{-3} mg/kg-bw/day for children and adults. Direct exposure is expected to be similar to that of the notified use. No potential consumer uses were identified.

Based on the 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.