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

New Substances Notification 20853: Amines, C_{12-14}-*tert*-alkyl, di-Bu phosphates (Chemical Abstracts Service Registry Number 103213-64-5)

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, C_{12-14}-*tert*-alkyl, di-Bu phosphates (Chemical Abstracts Service Registry Number[1] 103213-64-5), 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 manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in lubricants. Potential uses of the substance include cutting fluids, metal processing, and engine lubricants.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it is assumed that it will dissociate and the ecological component of concern (amine) will tend to partition to water, soil, sediment, and air. As a surfactant, some of the amine component will also be present at the surface of the water or suspended organic matter. The amine component is not expected to be persistent in these compartments based on its expected short atmospheric oxidation half-life (0.17-1 days) and expected moderate ready biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on its low expected bioconcentration factor (< 250 L/kg for the amine component).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have high acute toxicity to fish (median lethal concentration (LC_{50}) < 1 mg/L) and aquatic invertebrates (median effective concentration (EC_{50}) < 1 mg/L), high chronic toxicity to fish (no-observed-effect concentration (NOEC) < 0.1 mg/L) and aquatic invertebrates (NOEC < 0.1 mg/L), and high chronic toxicity to algae (10% effective concentration < 0.1 mg/L). The substance is expected to have low acute toxicity to terrestrial invertebrates (LC_{50} > 100 mg/kg dry soil) and low chronic toxicity to terrestrial plants (25% effective concentration (EC_{25}) > 10 mg/kg dry soil).

Using the EC_{50} from the most sensitive aquatic organism (aquatic invertebrates) and by applying an assessment factor of 10 to account for acute to chronic extrapolation, the predicted no-effect concentration (PNEC) for the aquatic environment ($PNEC_{aquatic}$) was calculated to be in the range of 1-10 µg/L, which was used to estimate the risk to the aquatic environment. Using the chronic EC_{25} from the most sensitive soil-dwelling organisms, and by applying an assessment factor of 5 to account for species sensitivity variation, the PNEC for the soil environment ($PNEC_{soil}$) was determined to be in the range of 1-10 mg/kg dry soil, which was used to estimate the risk to the terrestrial environment.

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 mainly from cleaning of transportation and formulation vessels by release of the substance to water resulting in predicted environmental concentrations ($PEC_{aquatic}$) of 0.01 – 10 µg/L with the values being below the $PNEC_{aquatic}$ value, and by release of the substance to soil resulting in a predicted environmental concentration (PEC_{soil}) in the range of 1-10 mg/kg dry soil, with the value being below the $PNEC_{soil}$ value. No potential activities were identified that could significantly increase environmental risks compared to those notified.

Comparing the $PEC_{aquatic}$ with the $PNEC_{aquatic}$, and the PEC_{soil} with the $PNEC_{soil}$, the ratios are less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg body weight). It has high subchronic toxicity following repeated oral doses in mammalian test animals (28-day lowest-observed-adverse-effect level < 30 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level > 100 mg/kg-bw/day, with no reproductive/developmental toxicity observed at the highest dose tested). It is not a dermal sensitizer (0% response (guinea pig maximization test)). It does not induce neurotoxic effects following acute exposure (test for delayed neurotoxicity of

organophosphorus substances). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in lubricants, 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. Potential uses of the substance include use in cutting fluids, metal cooling agent for metal processing, and lubricants in combustion engines, 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 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 the *Hazardous Products Regulations* for products intended for the workplace.