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

New Substances Notification No. 18131: Alkanoic acid, mixed polyesters with ethylalkanoic acid, alkanoic acid, pentaerythritol and alkanoic acid

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 that 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

Alkanoic acid, mixed polyesters with ethylalkanoic acid, alkanoic acid, pentaerythritol and alkanoic acid (Confidential Accession No. 18585-0) is a chemical that can be classified as a polyol ester.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a component of specialty lubricant products. Potential uses may include personal care products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is not expected to be persistent in water, soil or sediments based on its estimated half-life of <180 days. The substance is not expected to be persistent in air because it is expected to be readily oxidized by hydroxyl radicals in air. The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors of <250 L/kg.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low to moderate acute toxicity in aquatic organisms (median effective concentration (EC_{50}) >1 mg/L). While the most sensitive species (green algae) has a moderate acute toxicity (EC_{50} 1-100 mg/L), this value is greater than the water solubility of the notified substance, and therefore ecotoxicity is expected to be low. A predicted no-effect concentration was not calculated for this substance given its low potential for ecological hazard.

No significant releases are expected from the notified uses of the substance, and given the low potential hazard associated with the substance, calculation of a predicted environmental concentration was deemed unnecessary.

Based on the low potential for ecological hazard and releases of the substance, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >2000 mg/kg bw) and low acute toxicity by the dermal route of exposure (LD_{50} >2000 mg/kg bw). The substance has a low potential for subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg bw/day). Further information indicated that the substance is not likely to be a skin irritant or sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as a component of specialty lubricant products, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is not anticipated.

If used in personal care products, direct oral exposure of the general population could be high. Indirect exposure from environmental media such as drinking water for this potential use is not expected.

Based on the low likelihood of exposure in conjunction with the low hazard potentials, the substance is not likely to pose a significant direct or indirect health risk to the general population, and is therefore unlikely to be harmful to human health.

However, if the substance is used as a component in personal care products, an increased direct exposure potential through oral ingestion may exist, but based on its low potential for toxicity it remains unlikely to be harmful to human health.

Assessment Conclusion

When used as notified or for other identified potential uses, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 workplace use.