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

New Substances Notification 21064: Alkanoic acid, trialkyl-, mixed polyesters with alkylalkanoic acid and poly(substituted alkyl)alkanepolyol (Confidential Accession Number 19501-9)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. Order 2023-87-03-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 157, No. 5 on March 1, 2023. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is alkanoic acid, trialkyl-, mixed polyesters with alkylalkanoic acid and poly(substituted alkyl)alkanepolyol (Confidential Accession Number 19501-9), 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 of less than 10 000 kg/yr for the notified use in industrial lubricating applications. Potential uses may include consumer cleaning products and personal care products.

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 sediments. The substance is not expected to be persistent in these compartments based on inherent biodegradation (10-30%, over 28 days). The substance

is not expected to bioaccumulate based on its low measured bioconcentration factor (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is not expected to have adverse effects in saturated solutions in fish, aquatic invertebrates, and algae. A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 and potential activities is expected to be minimal. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

Based on the low potential for ecotoxicity and environmental exposure, 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 low acute toxicity by the oral and dermal route (median lethal dose > 300 mg/kg body weight with no deaths observed at the highest dose tested) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/day). The substance has a low reproductive toxicity (NOAEL > 300 mg/kg-bw/day) and a moderate developmental toxicity (NOAEL 30-300 mg/kg-bw/day) following repeated oral doses in mammalian test animals. It is not a dermal sensitizer (stimulation index < 3 in a local lymph node assay). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a lubricant in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. Based on the low potential for exposure when used as notified, 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.

However, if the substance is used in personal care products, an increased level of direct exposure may occur, and the substance is expected to be by contact with skin or oral ingestion may occur at levels in the range of 100-10 000 µg/kg-bw/day for children and adults, while inhalation exposure could occur at levels in the range of 0.1-10 µg/kg-bw/day for children and adults. If the substance is used in consumer cleaning products, direct exposure of the general population is expected to be in the range of 100-1000 µg/kg-bw/day for adults.

Indirect exposure of the general population for the notified use from environmental media such as drinking water is estimated to be at levels in the range of 0.01-0.1 µg/kg bw/day for children and adults. Indirect exposure of the general population from environmental media for potential

uses is expected to be similar to that of the notified use. These levels of exposure do not pose a risk to human health.

A target margin of exposure (MOE_T) was calculated to be 300 for direct exposure from potential uses based on a point of departure (POD) derived from the available hazard information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population.

The derived margin of exposure (MOE_D) is the ratio of the POD value to the available exposure doses and is compared to the target margin of exposure (MOE_T). The MOE_D for oral and dermal personal care products was calculated to be in the range of 10-1500 based on the NOAEL from the oral subchronic and developmental toxicity studies. Because the MOE_D is less than the MOE_T for various personal care products, it was determined that the potential use of the substance in personal care products could significantly alter the exposure dose resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

The assumptions made in the assessment and the risk management measures applied 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, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to systemic and developmental repeated dose toxicity if the substance were to be used in cosmetics and personal care products, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities can occur. Order 2023-87-03-01 was published in the *Canada Gazette* Part II, Vol. 157, No. 5 on March 1, 2023.

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.