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

New Substances Notification 14503: Aliphatic alkyl diester of succinic acid (Confidential Accession No. 17818-7)

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. Significant New Activity Notice No. 14503 [PDF] outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 143, No. 9 on February 28, 2009. 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 aliphatic alkyl diester of succinic acid (Confidential Accession No. 17818-7).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial paints and coatings. Potential uses may include specialty consumer coatings.

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, sediment and soil. The substance is expected to be persistent in these compartments based on its low experimental biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) 1-100 mg/L) and low to moderate acute toxicity to algae (EC_{50} >1 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for acute to chronic

extrapolation and extrapolation from a maximum acceptable toxicant concentration to a predicted no-effect concentration (PNEC), the PNEC was calculated to be in the range of 10-100 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 and formulation vessels by release of the substance to water resulting in predicted environmental concentration (PEC) in the range of 0.1 to 1 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 1 to 10 µg/L, with the exact value being below the PNEC value. For potential activities such as formulation, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.1 to 1 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 risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight), moderate acute toxicity by the inhalation route (LC_{50} 1-5 mg/L/4hr) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is a dermal sensitizer (estimated concentration required to produce a stimulation index of 3 <10% (local lymph node assay)). 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 0.01 to 0.1 mg/kg-bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used in industrial paint and coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for release to the environment. However, potential uses of the substance include in consumer coatings, where an increased level of direct exposure may exist, and is expected to be by dermal contact.

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, based on the potential for increased dermal exposure combined with indications that the substance has dermal sensitization effects, the potential use of the substance in consumer applications could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment according 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 known dermal sensitization if the substance were to be used in consumer applications, 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 are undertaken. SNAc Notice No. 14503 was published in the *Canada Gazette* Part I, Vol. 143, No. 9 on February 28, 2009.

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.