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

New Substances Notification No. 18748: 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester

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 chemical, 1,2,4-benzenetricarboxylic acid, 1,2,4-trinonyl ester (Chemical Abstracts Service Registry No. 35415-27-1), can be classified as a trimellitate.

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 plasticizer in industrial applications. Potential uses may include a variety of plastics applications and consumer products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in soil and sediment based on biodegradability observed for an analogue substance. The notified substance is not expected to bioaccumulate based on estimated low bioconcentration and bioaccumulation factors (<250 L/kg) for the notified substance and an analogue substance.

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration (EC_{50}) >100 mg/L) and low chronic toxicity in aquatic invertebrates (21-day EC_{50} >10 mg/L). A predicted no-effect concentration was not calculated given the low ecotoxicity.

The notified and 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 low. The substance is intended for industrial use only and is

expected to be encapsulated in the polymer matrix of end-use products. Other potential uses of the substance could include a variety of plastics applications and consumer products. These other potential uses could result in higher environmental releases of the substance than expected for the notified use, but increased environmental concern is not expected given its low potential for ecotoxicity, bioaccumulation and persistence. A predicted environmental concentration for notified or potential activities was not estimated given the low ecotoxicity.

Based on the low potential for environmental release and the ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >30 mg/kg-bw/d). The substance is expected to have a moderate potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >100 mg/kg-bw/d), and some estrogenic activity was observed *in vitro*; however, findings were equivocal. It is not expected to be a skin sensitizer (0% response (Buehler scale) and negative in a human repeated insult patch test). It is not expected to be mutagenic *in vitro*, or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 1-10 mg/kg-bw/d based on the NOAEL of the oral reproductive toxicity study in mammalian test animals of 250-1000 mg/kg-bw/d, which is expected to account for any estrogenic activity and the no-observed-effect level of 30-300 mg/kg-bw/d in a preliminary reproductive toxicity screening test.

When the notified substance is used as a plasticizer for flexible vinyl, 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 the stable matrix once cured and is not expected to migrate significantly out of the matrix. Dermal uptake will be further mitigated by the very high octanol-water partition coefficient ($\log K_{ow}$ >8), low water solubility (0.01-10 mg/L) and relatively high molecular weight of the substance which will limit its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. A worst-case scenario for ingestion of dust from household/construction plastics via the oral route of exposure is considered to be 0.001-0.01 mg/kg-bw/d for toddlers and 0.00001-0.0001 mg/kg-bw/d for adults.

Other potential uses of the substance include a variety of plastics applications and consumer products. The use of the substance in consumer products would result in the highest potential for direct exposure of the general population mainly by the dermal route of exposure with some oral exposure. The total exposure for potential consumer use was conservatively estimated (assuming 100% dermal absorption) to be 0.1-1 mg/kg-bw/d by the dermal route, and 0.1-1 mg/kg-bw/d by the oral route.

Based on a comparison of the estimated PTDI to the estimated 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 uses, it is not expected 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.