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

New Substances Notification 20124: Plant-based oil, polymer with diethylene glycol, glycerol, pentaerythritol, terephthalic acid, tetraethylene glycol and triethylene glycol
(Confidential Accession No. 19161-9)

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 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 polymer is plant-based oil, polymer with diethylene glycol, glycerol, pentaerythritol, terephthalic acid, tetraethylene glycol and triethylene glycol (Confidential Accession No. 19161-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains a high percentage of low molecular weight components and its number average molecular weight is less than 1000 daltons.

Notified and potential uses

The substance is proposed to be manufactured in and imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a component in the manufacture of polyurethane foam. No other uses are anticipated in Canada.

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. The substance is not expected to be persistent in water, sediment or soil based on inherent biodegradation. The substance is not expected to bioaccumulate based on its low to moderate octanol-water partition coefficient (log K_{ow} <5).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity to fish (median lethal loading rate > 100 mg/L) and invertebrates (median effective loading rate > 100 mg/L), and moderate chronic toxicity to algae (no-observed-effect concentration (NOEC) 0.1 to 10 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 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 transport vessels and manufacturing by release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 10-100 μg/L. For potential activities such as formulation without a closed system, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 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 assessment

Based on the available hazard information for analogue substances, the notified substance is expected to have low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) 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). The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.1-1 mg/kg bw/day based on the NOAEL of the 28 day repeated oral 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 as a component in the manufacture of polyurethane foam, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into 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 conservatively estimated to be at levels in the range of 10^{-4}-10^{-3} mg/kg bw/day. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Because the estimated human exposure is less than the PTDI, meaning at levels that do not pose a concern, 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 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 *Hazardous Products Regulations* for products intended for the workplace.