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

New Substances Notification No. 19917: Carbomonocycledicarboxylic acid, polymers with pentaerythritol, diethylene glycol, phthalic anhydride, tetraethylene glycol, triethylene glycol (Confidential Accession No. 19378-6)

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 carbomonocycledicarboxylic acid, polymers with pentaerythritol, diethylene glycol, phthalic anhydride, tetraethylene glycol, triethylene glycol (Confidential Accession No. 19378-6). 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 activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use in the manufacture of polyurethane. No other activities 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 (>30% over 28 days). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient (log K_{ow} 0-3).

Ecological assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity in fish (median lethal concentration (LC_{50}) 1-100 mg/L), low acute toxicity in aquatic invertebrates (LC_{50} > 100 mg/L), and moderate chronic toxicity in algae (no-observed-effect-concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and species sensitivity variation, 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 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 vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 10-100 µg/L, and from manufacturing of the substance and use in polyurethane manufacturing by release of the substance to water resulting in a PEC in the range of 1-10 µg/L. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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 on two principal monomers, the substance is expected to have moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight), low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight) and very high acute toxicity by inhalation route (LC_{50} ≤0.5 mg/L). It is expected to have low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >2000 mg/kg bw/day) and very high subchronic toxicity following repeated inhalation doses in mammalian test animals (28-day NOAEL <0.6 mg/L). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >300 mg/kg bw/day). It is not expected to be a skin sensitizer. The substance is expected to have low carcinogenicity toxicity following repeated oral doses in mammalian test animals (2-year NOAEL >1000 mg/kg bw/day). It is not expected to be 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 1000-10 000 µg/kg bw/day based on the NOAEL of the oral carcinogenicity 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 the manufacture of polyurethane, 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 0.1-1 µg/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, 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.