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

New Substances Notification 20270: Castor oil, polymer with 1,1'-methylenebis[isocyanatobenzene] and polypropylene glycol, polyalkoxymetalloid-*N*-[(polyalkoxymetalloid) alkyl]-1-propanamine-blocked (Confidential Accession Number 19482-0)

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 castor oil, polymer with 1,1'-methylenebis[isocyanatobenzene] and polypropylene glycol, polyalkoxymetalloid-*N*-[(polyalkoxymetalloid) alkyl]-1-propanamine-blocked (Confidential Accession No. 19482-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains terminal aromatic isocyanate groups.

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 food packaging materials. Potential uses may include industrial coatings, adhesives, and polyurethane foam.

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 sediment. The substance is expected to be persistent in these compartments because it reacts with water to form high molecular weight, insoluble complexes that are resistant to degradation. The substance is not expected to bioaccumulate based on its low water extractability and high molecular weight, which will limit its ability to cross biological membranes.

Ecological assessment

Based on its low water extractability (<2%), the substance is expected have low bioavailability. Therefore, a predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activity is not expected as the substance will be chemically reacted to form a stable matrix once cured and will be highly removed during wastewater treatment. For potential activities such as use in

industrial coatings, adhesives, and polyurethane foam, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and low ecotoxicity.

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

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). Polymeric methylenediphenyl diisocyanate (MDI) has been associated with adverse human health effects including carcinogenicity, respiratory effects including sensitization, and dermal sensitization; however, it is anticipated that there is low potential for exposure of the general population.

When the notified substance is used in food packaging materials, direct exposure of the general population is not anticipated due to the industrial nature of the use and because the substance is contained within a matrix in finished products from which it is not readily released. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance and high degree of removal when in waste water, which results in little or no release to the environment. Potential uses of the substance include adhesives, paints and coating formulations available to consumers; however direct and indirect exposure of the general population is expected to be at levels that do not pose a human health concern.

Based on the low potential for 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

The substance 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.