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

New Substances Notification No. 19902: Castor oil, polymer with diethylene glycol, phthalic anhydride and trimethylolethane (Chemical Abstracts Service No. 68783-29-9)

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 castor oil, polymer with diethylene glycol, phthalic anhydride and trimethylolethane (Chemical Abstracts Service No. 68783-29-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because 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 industrial adhesives. Potential uses may include use in other industrial or consumer adhesives, or as an industrial reactant to produce larger polymeric substances.

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 its complex structure will limit hydrolysis potential, and it is not anticipated to be highly susceptible to biodegradation. 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 has low acute toxicity in algae (median effective loading rate >100 mg/L). 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 is not expected as the substance will be chemically reacted into a stable matrix once cured and will be unavailable for release. For potential activities such as manufacturing or use in adhesives for other applications,

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 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).

When the notified substance is used in industrial adhesives, direct exposure of the general population is not expected due to the industrial nature of the use. 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 cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment.

If potential uses of the substance were to include consumer use adhesives, direct exposure of the general population is expected to be mainly by incidental contact with the skin at very low levels. Indirect exposure of the general population from environmental media is not expected since little or no release to the environment is anticipated.

Based on the low potential for exposure and the lack of structural features associated with adverse human health effects, 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 activites, 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.