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

New Substances Notification No. 18895: 2-Propenoic acid, butyl ester, polymer with 1,3-cyclohexanedimethanamine, reaction products with Bu glycidyl ether

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 polymer, 2-Propenoic acid, butyl ester, polymer with 1,3-cyclohexanedimethanamine, reaction products with Bu glycidyl ether (Chemical Abstracts Service Registry No. 1257085-86-1), can be classified as a poly(amide-amine-cycloalkyl). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because of its low molecular weight.

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 curing agent. Potential uses may include specialty paints and coatings.

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 expected to be persistent in soil and sediment based on its low biodegradability (10-30%) and lack of hydrolysable functional groups. The substance is not expected to bioaccumulate based on predicted low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish (median lethal concentration 1-100 mg/L) and moderate to high acute toxicity in aquatic invertebrates and algae (median effective concentration (EC_{50}) <100 mg/L). Using the EC_{50} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the

predicted no-effect concentration (PNEC) was calculated to be 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 not expected. The substance will be chemically reacted into a polymer matrix once cured and unavailable for release. Environmental exposure from other potential activities is expected to be mainly from the cleaning of manufacturing equipment and transportation vessels by release of the substance to water. The predicted environmental concentration (PEC) is estimated to be 10-100 µg/L for these potential activities.

Based on the low potential for environmental release from notified activities and by comparing the PEC with the PNEC for other potential activities, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a moderate potential for systemic toxicity following repeat oral doses in mammalian test animals (no-observed-effect level (NOEL) 30-300 mg/kg-bw/d with no systemic or reproductive/developmental effects observed at the highest tested dose). It is a moderate dermal sensitizer (estimated concentration to produce a stimulation index of 3 (EC3) of 1-10% (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 1000-10 000 µg/kg-bw/d based on the NOEL from repeated oral dose subchronic and reproductive/developmental toxicity study. The acceptable exposure level (AEL) for skin sensitization effects was calculated to be 1-10 µg/cm^2 based on the EC3 value from the local lymph node assay.

When the notified substance is used as an industrial curing agent, consumers may come into contact with coated products/structures, however direct exposure is not expected because the substance will be chemically reacted into a stable matrix once cured and will be unavailable for dermal uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.1-1 µg/kg-bw/d.

The substance has potential to be used in specialty paints and coatings available to consumers. Dermal exposure from use in consumer paints and coatings was estimated to be 1000-10 000 mg/kg-bw/event and 1000-10 000 µg/cm^2. Indirect exposure of the general population from environmental media such as drinking water from potential manufacturing activities is expected to be at levels of 0.1-10 µg/kg-bw/d for both adults and children.

Based on a comparison of the PTDI to the estimated human exposure for the notified use, and considering other available lines of evidence, 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.

Although the direct exposure estimated per event for potential uses using exposure models for consumer paints and coatings was close to the PTDI and greater than the AEL, dermal uptake is

expected to be limited based on rapid curing, low frequency of use and application methods of the specialty paints in which the substance could be used. Based on a comparison of the PTDI to the predicted indirect exposure, no significant health risks to the general population is expected via indirect exposure and the substance is unlikely to be harmful to human health for potential uses.

Assessment Conclusion

When the substance is used as notified or for other identified potential uses, it is not suspected 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.