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

New Substances Notification No. 18563: 2-Propenoic acid, 2-methyl-, 2-[(1,1-dimethylethyl)amino]ethyl ester, polymer with methyl 2-methyl-2-propenoate, 2-propenoic acid and *N*-(1,1,2,3-tetramethylbutyl)-2-propenamide

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, 2-methyl-, 2-[(1,1-dimethylethyl)amino]ethyl ester, polymer with methyl 2-methyl-2-propenoate, 2-propenoic acid and *N*-(1,1,2,3-tetramethylbutyl)-2-propenamide (Chemical Abstracts Service Registry No. 164292-06-2), can be classified as an amphoteric acrylic polymer. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because of the presence of potentially cationic aliphatic amine groups.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a component of consumer products. Potential uses may include coating compositions and printing products.

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 because it does not contain functional groups that are susceptible to biodegradation. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available surrogate data on structurally related chemicals, the substance is expected to have low chronic toxicity in algae (chronic value >10 mg/L). The substance is considered to have generally low acute ecotoxicity due to its low water extractability (≤1%). Using a chronic

value from the most sensitive organism (algae) for a structurally related polymer 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 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 the rinsing of products containing the substance down the drain during consumer use, resulting in release of the substance to the aquatic environment. The predicted environmental concentration (PEC) for this notified activity is estimated to be 0.01-1 µg/L. Some release of the substance from the cleaning of transport and formulation vessels is also possible. The PEC for this industrial release scenario was estimated to be 1-10 µg/L. The substance may potentially be used as a component for coatings compositions; however, this potential use is expected to result in environmental exposure similar to or less than the notified use.

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, the substance did not cause systemic toxicity at the highest repeat inhalation doses tested. It is not a skin sensitizer (0-8% [v[1]response (guinea pig maximization test)).

When the notified substance is used as a component of consumer products, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation at low levels. The high molecular weight of the substance mitigates inhalation exposure by rendering it non-volatile, and mitigates dermal exposure by limiting its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. Potential use of the substance as a component of printing products is expected to result in lower exposure than the notified use.

Based on the low potential for systemic exposure ~~of the general population~~ and the low inhalation toxicity, 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 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.