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

New Substances Notification No. 18415: Carbamic acid, [(polyalkoxysilyl)alkyl]-polyalkylalkanediyl ester

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 chemical, acid, [(polyalkoxysilyl)alkyl]-polyalkylalkanediyl ester (Confidential Accession No. 19003-4), can be classified as a siloxane, carbamate.

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 cross-linker for industrial coatings. Potential activities may include manufacturing.

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 not expected to be persistent in soil and sediment based on its short hydrolysis half-life (<10 days). The substance and its hydrolysis products are not expected to bioaccumulate based on low octanol-water partition coefficient ($\log K_{ow}$ <3).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal loading and median effective loading (EL_{50}) >100 mg/L) and moderate acute toxicity in algae (EL_{50} 1-100 mg/L). Using the EL_{50} from the most sensitive organism (algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 1000-10 000 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 activity is expected to be mainly from formulation, transportation, and the final use in coatings by release of the substance to water via waste water. The predicted environmental concentrations (PEC) for notified activities are estimated to range from 1-1000 µg/L. The substance is currently expected to be imported into Canada, but could potentially be manufactured in Canada in the future. The PEC for potential future manufacturing activities is estimated to be 10-100 µg/L.

Comparing the PEC for notified and potential activities 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 has a low acute toxicity by oral, dermal and inhalation routes (oral and dermal median lethal dose >2000 mg/kg body weight, inhalation median lethal concentration >5 mg/L/4 hours). The substance has a low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). It is a non-sensitizer (effective concentration >10% (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a cross-linker for industrial coatings, direct exposure of the general population is not expected. Although the general public may have dermal contact with surfaces containing cured coatings, the substance will already be chemically reacted into a stable matrix once cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be low. No other potential uses were identified for the notified substance.

Based on the low toxicity and the low potential for public 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

When the substance is used as notified, itis 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.