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

New Substances Notification No. 18462: 1-Propanamine, 1-(triethoxysilyl)-, reaction products with trimethyoxymethylsilane and 2-[[3-(trimethoxysilyl)propoxy]methy]oxirane

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, 1-Propanamine, 1-(triethoxysilyl)-, reaction products with trimethyoxymethylsilane and 2-[[3-(trimethoxysilyl)propoxy]methy]oxirane (Chemical Abstracts Service Registry No. 474530-85-3), of unknown or variable composition, complex reaction products or biological materials, can be classified as a complex mixture of siloxanes.

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 an adhesion promoter and curing agent for use in structural adhesives and sealants. Potential uses may include various industrial applications, and consumer use in adhesives.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, soil and sediment. It is not expected to be persistent in water, soil or sediment based on its tendency to react with water in the environment to form insoluble particles and moderate biodegradation (30-60%). The substance is not expected to bioaccumulate based on its tendency to readily react with water to form large, immobile matrices whose large molecular structures will limit their ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration (LC_{50}) and median effective concentration >100 mg/L). Using the LC_{50} from the most sensitive organism (aquatic invertebrates) 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 and potential activities is expected to be mainly from the cleaning of transportation and formulation vessels by release of the substance to waste water at low levels. The predicted environmental concentration (PEC) for notified and potential 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 on the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral, dermal and inhalation routes (oral and dermal median lethal dose >2000 mg/kg body weight, inhalation LC_{50} >20 mg/L). Based on surrogate data, the substance has a moderate subchronic toxicity by oral route (28-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/d) and inhalation (90-day NOAEL 0.2-1.0 mg/L/6 hr) routes of exposure, and a low (28-day NOAEL >1000 mg/kg-bw/day) reproductive/developmental toxicity following repeat oral doses in mammalian test animals. It is a non-sensitizer (0-8% response (guinea pig maximization test scale)). The provisional tolerable daily intake (PTDI) for the oral route was determined to be 0.1-1 mg/kg-bw/day based on the NOAEL from repeated-dose oral toxicity of 10-100 mg/kg-bw/d. The PTDI for the inhalation route was determined to be 1-10 mg/kg-bw/d based on the NOAEL from repeated-dose inhalation toxicity of 0.2-1.0 mg/L/6 hr.

Although the notified substance was not mutagenic *in vitro*, one structurally related substance is mutagenic and clastogenic *in vitro*, but not clastogenic *in vivo*. The potential for carcinogenicity was considered on this basis. The PTDI protective of carcinogenic effects was determined to be 1-10 mg/kg-bw/d based on available carcinogenic potency data. The lifetime carcinogenic risk for dermal and inhalation exposure were determined to be within the range of 10^{-5}-10^{-6} which is not considered to be significant.

When the notified substance is used as an adhesion promoter and curing agent in industrial settings, direct exposure of the general population is not expected. Members of the general population may come into contact with industrially treated end-use products, however, the substance will already be chemically reacted into a stable polymer matrix once cured and will be unavailable for uptake. Direct exposure of the general population from the use of commercial products is expected to be low. Dermal and inhalation exposures were conservatively estimated to be 0.0001 to 0.001 mg/kg-event for both routes of exposure. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. Other potential uses of the notified substance include industrial applications, and consumer use in adhesives. Direct and indirect exposure of the general population resulting from these potential

uses is expected to be similar to that of the notified industrial and commercial uses estimated above.

Based on a comparison of the PTDI to the estimated 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 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.