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

New Substances Notification No. 19252: Alkyltrimethoxysilyl-1-butanamine (Confidential Accession No. 16880-5)

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 chemical is alkyltrimethoxysilyl-1-butanamine (Confidential Accession No. 16880-5).

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 consumer sealants, adhesives and coatings. No other activities are anticipated in Canada.

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 water. The substance is not expected to be persistent in this compartments based on its very high rate of hydrolysis (half-life <1 day). The products of hydrolysis may further react to form high molecular weight, insoluble complexes, which will tend to partition to soil and sediment. The products of hydrolysis are not expected to be persistent in soil or sediment based on their expected biodegradability. The substance and its products of hydrolysis are not expected to bioaccumulate based on expected low bioconcentration and bioaccumulation factors (<250 L/kg), and the high molecular weight of the products of hydrolysis which will limit their ability to cross biological membranes.

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in aquatic invertebrates (no-observed-effect concentration >100 mg/L) and is expected to have low chronic toxicity in algae (10% effective concentration >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified 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

because the substance will not be released during its lifecycle and any released substance will react with water to form high molecular weight, insoluble materials. A predicted environmental concentration was not calculated due to the low potential for environmental exposure. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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 moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an ingredient in consumer sealants, adhesives and coatings, direct exposure of the general population is expected to be mainly by contact with the skin and inhalation at low levels. The substance hydrolyses rapidly in the presence of moisture to form high molecular weight, insoluble materials which will have limited ability to cross biological membranes. Once end-use products are dried/cured, direct exposure is not expected because the substance will be chemically reacted into a stable matrix and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for 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, 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.