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

New Substances Notification Number 21496: Urea, *N*,*N*'-bis(trimethylsilyl)- (Chemical Abstracts Service Registry Number 18297-63-7)

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 urea, *N*,*N*'-bis(trimethylsilyl)- (Chemical Abstracts Service Registry Number[1] 18297-63-7).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 1000 kg/yr for the notified use as an additive in sealants. Potential uses may include use as an additive in paints, adhesives and fillers, and as a chemical intermediate in the synthesis of other substances.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will rapidly degrade based on its short hydrolysis half-life in water, soil, and air (< 10 minutes). Therefore, the substance is not expected to be persistent. However, the environmental product of hydrolysis is expected to be persistent in water. The substance and its product of hydrolysis are not expected to bioaccumulate based on low octanol-water partition coefficients (log K_{ow} 0-3).

Environmental risk assessment

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Based on the available hazard information, the substance and its hydrolysis by-product have low acute toxicity to fish, aquatic invertebrates, and algae (no adverse effects observed in saturated solutions) and low chronic toxicity to algae (no adverse effects observed in saturated solution). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 minimal and mainly from the release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and low ecotoxicity. No potential activities that 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight) and low acute toxicity by the inhalation route (median lethal concentration > 5 mg/L/4 hours). The substance has moderate subchronic toxicity following repeated oral doses in mammalian test animals (repeated dose no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The substance is not considered to be a reproductive or developmental toxicant following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not a dermal sensitizer (estimated concentration required to produce a stimulation index of 3 is > 10% in a local lymph node assay). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. In addition, the substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as an additive in sealants for consumer use, direct exposure of the general population is expected to be mainly by contact with the skin at levels that do not pose a concern for human health. Dermal exposure to the substance would be infrequent, of short duration, and limited by the low concentration of the substance in these products. Once the sealant is cured, the substance will be chemically reacted into a stable matrix and will be unavailable for uptake. When the notified substance is used as an additive in sealants for industrial or commercial use, direct exposure of the general population is not expected due to the industrial or commercial nature of the use. Indirect exposure of the general population from environmental media such as drinking water or air is not expected given the low potential for environmental release. Potential uses of the substance include paints, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-0.1 mg/kg-bw/event. For potential use in adhesives and fillers, direct exposure of the general population is expected to be similar to or lower than that from use of the substance in paints. For potential uses, indirect exposure of the general

population from environmental media such as drinking water or air is expected to be at levels that do not pose a concern, similar to that of the notified use.

The target margin of exposure (MOE_T) was calculated to be 1000 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk to the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the estimated exposure levels and is compared to the MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities 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 for 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 the workplace.