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

New Substances Notification No. 18923: Siloxanes and silicones, 3-[(2-aminoalkyl)amino]alkyl, alkoxy, alkoxy alkyl, alkoxy-terminated

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 polymer is siloxanes and silicones, 3-[(2-aminoalkyl)amino]alkyl, alkoxy, alkoxy alkyl, alkoxy-terminated (Confidential Accession No. 19245-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons and because it contains alkoxysilane and cationic amine groups.

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 in industrial sealants. Potential uses may include other industrial and consumer sealants.

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 in soil and sediment because it reacts with water to form high molecular weight, insoluble complexes that are resistant to degradation. The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient (log K_{ow} 0-3) and its high cationic charge which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance and after application of a conservative mitigation factor, the substance is expected to have low acute toxicity in fish, aquatic invertebrates and algae (median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 low. In the event of release to water during cleaning of transport vessels or formulation, the substance will react with water to form higher molecular weight, insoluble complexes which will be removed during wastewater treatment, and the substance will be consumed during use and immobile once cured. A predicted environmental concentration was not estimated given the low potential for environmental exposure.

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 on the substance and surrogate data on structurally related chemicals, it is expected to have a low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight) and a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/d). It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 1-10 mg/kg-bw/d based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used as an adhesion promoter in industrial sealants, consumers may come into contact with end-use products containing the substance, however direct exposure is not expected because the substance will 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 is expected to be low. If the substance is used in other industrial applications, direct and indirect exposure of the general population is expected to be similar to that of the notified use. However, if the notified substance is used in consumer sealants, direct dermal exposure was estimated to be 0.1-1 mg/kg-bw/event.

Based on the low potential for exposure from the notified use and based on a comparison on the PTDI to the predicted exposure for potential consumer uses, 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 used as notified or for other identified potential uses, the substance 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 *Hazardous Products Regulations* for products intended for the workplace.