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

Significant New Activity No. 17116: Acetamide, *N*,*N*'-(ethenylmethylsilylene)bis[*N*-ethyl-, Chemical Abstracts Service Registry No. 87855-59-2

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), and pursuant to section 83 of that 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.

However, a significant new activity (SNAc) Notice was recommended based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities, such as use in consumer products in an unreacted form. SNAc No. 17116 outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 147, No. 30 – July 27, 2013. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

Substance Identity

The substance is a chemical that can be classified as an amidosilane.

Notified Activities

The substance is proposed to be manufactured in or imported into Canada in quantities greater than 1000 kg/yr for use in commercial sealants.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment the substance is expected to hydrolyze rapidly. The substance is not expected to be persistent nor bioaccumulative based on its rapid rate of hydrolysis. The substance's hydrolysis products are not expected to be persistent based on their high biodegradation rate (60% - 85%) and would not be expected to be bioaccumulative based on predicted very low log K_{ow} (≤ 0).

Ecological Assessment

Based on the available hazard information on the substance, the substance has low acute toxicity to fish and algae (LC_{50} values >100 mg/L) and moderate acute toxicity to *daphnia magna* (EC_{50} value >1 mg/L and <100 mg/L). The predicted no effect concentration was calculated to be moderate using the EC_{50} from the most sensitive aquatic organism, 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 releases from drums to water at levels of < 10 ug/L. Exposure due to potential activities, such as manufacturing of the substance in Canada, are also expected to be low. The predicted environmental concentration for notified activities is estimated to be low.

Based on a low to moderate hazard characterization and low exposure potential, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a moderate potential for acute toxicity by the oral route of exposure (LD50 300-2000 mg/kg body weight), and a low potential for acute toxicity by the dermal route of exposure (LD50>2000 mg/kg body weight). It is irreversibly corrosive to eye and not an irritant to skin (skin – PII $\leq$ 0.1) and is negative for skin sensitization (i.e. not skin sensitization). It is not mutagenic or clastogenic in *in vitro* tests. Therefore, the substance is unlikely to cause genetic damage. The substance has moderate to high potential for subchronic toxicity following repeated oral doses in mammalian test animals (NOAEL$\leq$100 mg/kg body weight for females; $\leq$10 mg/kg for males), based on effects observed in male reproductive organs.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

When used in a commercial sealant, direct exposure of the general population to the substance is not expected. The general public may come into dermal contact with the dried sealants; however, upon application and curing, the substance will be fully reacted into a large polymer matrix from which it is not expected to be released. Indirect exposure of the general population to the substance from environmental media such as drinking water is not expected, and potential exposure through drinking water to hydrolysis products was analyzed and not found to pose a risk to consumers. However, if the substance is used in the unreacted form in consumer products, the potential exists for direct exposure by dermal contact.

Based on the low potential for direct exposure of the general population to the unreacted substance or its hydrolysis products, 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.

However, based on the potential for direct dermal exposure in relation with the moderate to high subchronic toxicity, the use of the unreacted substance in consumer products may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Assessment Conclusion

When used as notified, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA 1999. However it is suspected that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the potential risk to the general population related to the subchronic toxicity, with the use of the unreacted substance in consumer products, a SNAc Notice was issued to obtain information prior to such new uses, to ensure that the substance, in relation to these potential activities, undergoes further assessment. SNAc No. 17116 was published in the *Canada Gazette* Part I, Vol. 147, No. 30 - July 27, 2013.

A conclusion under CEPA 1999, on this substance, is not relevant to, nor does it preclude, an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.