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

New Substances Notification 19536: Silane, ethoxytrimethyl- (Chemical Abstracts Service Registry Number 1825-62-3)

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 silane, ethoxytrimethyl- (Chemical Abstracts Service Registry Number[1] 1825-62-3).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in the oil and gas industry. Potential uses are also expected to be industrial in nature.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and air. The substance is not expected to be persistent in air based on its half-life (<2 days) due to oxidation, or in water based on its rapid hydrolysis rate (≤10 days). However, one of its hydrolysis products, trimethylsilanol, is expected to be persistent in water based on its very low biodegradability (≤10% over 28 days). The substance and its hydrolysis products are not expected to bioaccumulate based on the rapid hydrolysis of the substance and the low bioconcentration and bioaccumulation factors of trimethylsilanol (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration >100 mg/L) and low chronic toxicity in algae (no-observed-adverse-effect concentration (NOAEC) >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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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 activities is not expected given the conditions of use, the low concentrations of the substance in end-use products and the expected rapid hydrolysis if released to water. For potential activities such as manufacturing, environmental exposure is not expected, similar to the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

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 low potential for acute toxicity by the oral and inhalation routes of exposure (oral median lethal dose (LD_{50}) >2000 mg/kg body weight; inhalation LC_{50} >20 mg/L). 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.

Based on the available hazard information on the hydrolysis product, trimethylsilanol has a moderate potential for acute toxicity by the inhalation route of exposure (LC_{50} 10-20 mg/L) and low potential for acute toxicity by the oral route of exposure (LD_{50} >2000 mg/kg body weight). It has 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/day) and a low potential for subchronic toxicity following repeat inhalation doses in mammalian test animals (28-day NOAEC >0.6 mg/L with no adverse effects at highest concentration tested). Trimethylsilanol has a low potential for reproductive/developmental toxicity following repeat inhalation doses in mammalian test animals (NOAEC >0.5 mg/L with no adverse effects at highest concentration tested), and a moderate potential for developmental toxicity following repeat oral doses in mammalian test animals (NOAEL 250-1000 mg/kg-bw/day). It is not mutagenic or clastogenic *in vitro* or *in vivo*. Therefore, it is unlikely to cause genetic damage.

When the notified substance is used in the oil and gas industry, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If the substance is used for other industrial applications, direct and indirect exposure of the general population is not expected, similar to the notified use, given that potential uses are also industrial in nature.

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 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, 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.