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

New Substances Notification No. 18363: Substituted polyalkane tetra-alkyl amine

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 chemical, substituted polyalkane tetra-alkyl amine (Confidential Accession No. 18942-6), can be classified as an aliphatic amine.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use in polyurethane foams. Potential activities may include manufacturing, and similar industrial uses.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, soil and sediment. The substance is expected to be persistent in water, sediment and soil based on its very low biodegradability (<10%) and expected half-life (>182 days in water and soil, >365 days in sediment). The substance has the potential to partition to air based on a moderate vapour pressure (10^{-4}-1 mmHg), but would be readily oxidized (half-life $\leq$2 hours) and therefore is not persistent in air. The substance is not expected to bioaccumulate based on its ionic nature within environmental conditions (pH 4-9) and low modelled bioconcentration factors and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance has low acute toxicity in fish (median lethal concentration >100 mg/L) and low to moderate acute toxicity in aquatic invertebrates and algae (median effective concentration >1 mg/L). The substance has low to moderate chronic toxicity in aquatic invertebrates (no-observed-effect concentration (NOEC) and LOEC >0.1 mg/L). Using the chronic NOEC from the most sensitive organism (aquatic invertebrate) and by applying an appropriate assessment factor, the predicted

no-effect concentration (PNEC) was calculated to be 100-1000 µg/L and 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 cleaning of transportation vehicles and formulation of the substance by release of the substance to water. The predicted environmental concentration (PEC) for notified activities is estimated to be 10-100 µg/L. Potential activities may include manufacturing. The aquatic PEC from manufacturing is estimated to be 100-1000 µg/L. As the substance is an aliphatic amine, there are a variety of other potential uses beyond the notified activity such as application as a curing agent, fuel/oil lubricant, and petroleum production and refining. Potential environmental releases from these potential uses are expected to result in a similar PEC as the notified activity with the exception of manufacturing.

Comparing the PEC with the PNEC, the ratio is less than 1. This along with other lines of evidence including environmental fate, hazard, and exposure indicates that 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, the substance is expected to have a moderate acute toxicity by oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and low acute toxicity by dermal route (LD_{50} >2000 mg/kg body weight). The substance is expected to have a low to moderate r subchronic and reproductive toxicity following repeat oral doses in mammalian test animals (no-observed-adverse-effect level >10 mg/kg-bw/d). It is a moderate skin sensitizer (effective concentration 1-10% (local lymph node assay)). It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance has low potential to cause genetic damage.

When the notified substance is used in polyurethane foams, direct exposure of the general population is expected to be low because the application of the substance is confined to industrial settings with no anticipated commercial or consumer uses. Once foams are formed and cured, the substance will be encapsulated within the foam matrix and is not expected to be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. Other potential uses of the substance are expected to be limited to industrial applications with similarly low potential for direct and indirect exposure as the notified use.

Based on the low potential for exposure of the general population, 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 he substance is used as notified or for other identified potential uses, it 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 the *Hazardous Products Regulations* for products intended for workplace use.