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

New Substances Notification 16773: Alkanediol, reaction products with phosphorus oxide (P_2O_5), polyfluoro-1-alkanol, ammonium salts (Confidential Accession No. 18475-7)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. Order 2012-87-10-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 147, No. 1 on January 2, 2013. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is alkanediol, reaction products with phosphorus oxide (P_2O_5), polyfluoro-1-alkanol, ammonium salts (Confidential Accession No. 18475-7), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in paints, coatings, floor waxes and finishes. Potential uses may include consumer sealants and aerosol/spray surface and textile treatments.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent based on its expected inherent biodegradation (>10% over 28 days). However, the environmental products of degradation are expected to be persistent in water. The substance and its products of degradation are not expected to bioaccumulate based on low biomagnification factors (<250 L/kg) for structurally similar substances and low bioaccumulation potential for the degradation products.

Environmental risk assessment

Based on the available hazard information, the substance has low to moderate acute toxicity in fish (median lethal concentration (LC_{50}) >1 mg/L) and moderate acute toxicity in aquatic invertebrates and algae (median effective concentration (EC_{50}) 1-100 mg/L). The degradation products have low acute toxicity in fish and aquatic invertebrates (LC_{50} and EC_{50} >100 mg/L) and moderate acute toxicity in algae (EC_{50} 1-100 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying appropriate assessment factor of 100 to account for acute to chronic extrapolation and extrapolation from a chronic maximum acceptable toxicant concentration to a predicted no-effect concentration (PNEC), PNEC was calculated to be in the range of 0.1-1 mg/L, 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 activities is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in predicted environmental concentration (PEC) in the range of 0.01 to 0.1 mg/L (with the exact value being below the PNEC value) and from formulation of end-use products by release of the substance to water resulting in a PEC in the range of 0.001 to 0.01 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.01 to 0.1 mg/L, also below the PNEC value.

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 risk assessment

Based on the available hazard information, the substance has a low to moderate acute toxicity by the oral route (median lethal dose >300 mg/kg body weight with no mortality or systemic effects observed). It has high toxicity by the inhalation route (acute lethal concentration ≤0.5 mg/L/4 hour; 14-day no-observed-adverse-effect level (NOAEL) <0.06 mg/L/6 hour). The substance is expected to have high subchronic toxicity by the oral route (90-day no-observed-effect level (NOEL) <100 mg/kg-bw/day) and high subchronic toxicity by the dermal route (28-day NOAEL <30 mg/kg-bw/day) following repeated doses in mammalian test animals. The substance is expected to have a low to moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOEL 50-250 mg/kg-bw/day with no significant reproductive/developmental effects). It is not a dermal sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) for dermal exposure was calculated to be in the range of 0.01-0.1 mg/kg/day based on the NOAEL of the dermal subchronic toxicity study in mammalian test animals. The PTDI for inhalation exposure was calculated to be 0.0001-0.001 mg/kg/exposure based on the NOAEL of the repeated-dose inhalation toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used in consumer paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.001-0.01 mg/kg-bw/event. When the notified substance is used in industrial and commercial paints and coatings, consumers may also come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for

release to the environment. However, potential uses of the substance include consumer sealants, where direct exposure of the general population may be conservatively estimated to be in the range of 0.01-0.1 mg/kg-event and mainly by contact with the skin. Other potential uses include aerosol/spray surface or textile treatments, where direct exposure may be conservatively estimated to be in the range of 1-10 mg/kg-bw/event and mainly by inhalation.

Because the estimated human exposure when used as notified is less than the dermal PTDI, meaning at levels that do not pose a concern, 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 increased dermal and inhalation exposure combined with indications that the substance has suspected high acute and subchronic inhalation and dermal toxicity, the potential use of the substance in consumer sealants or aerosol/spray surface or textile treatments could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

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

Due to the potential risk to human health related to suspected high acute and subchronic inhalation and dermal toxicity if the substance were to be used in consumer sealants or aerosol/spray surface or textile treatments, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2012-87-10-01 was published in the *Canada Gazette* Part II, Vol. 147, No. 1 on January 2, 2013.

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.