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

New Substances Notification No. 18640: Poly(oxy-1,2-ethanediyl), α-(isoalkyl)-ω-hydroxy-

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, poly(oxy-1,2-ethanediyl), α-(isoalkyl)-ω-hydroxy- (Confidential Accession No. 19127-2), can be classified as an ethylene glycol ether.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use in mineral ore processing. Potential uses may include a variety of applications, such as paints and cleaners.

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 (from dry environments only). The substance is not expected to be persistent in water as it is expected to be susceptible to biodegradation based on its structure and available analogue data. It is not expected to be persistent in air as the substance is expected to undergo rapid oxidation resulting in a short half-life in air (≤2 days). The substance is not expected to bioaccumulate based on its high water solubility (>10 000 mg/L) and high biodegradability suggested by structural analogue data.

Ecological Assessment

Based on available surrogate data on structurally related chemicals, the substance has low to moderate acute toxicity in fish and algae (median lethal concentration and median effective concentration (EC_{50}) >1 mg/L) and low acute toxicity in aquatic invertebrates (EC_{50} >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for 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 not expected. Containers used for transport will be returned to the supplier for cleaning, treatment and disposal. There are numerous other potential uses of the substance, including several industrial uses and in paints and cleaners. A predicted environmental concentration for notified or potential activities was not estimated given the low potential for ecological risk.

Based on the low ecotoxicity and high biodegradability, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on surrogate data on structurally related chemicals, the substance is expected to have a low to moderate potential for acute toxicity by the oral route of exposure (median lethal dose (LD_{50}) >300 mg/kg body weight), a moderate to high potential for acute toxicity by the dermal route of exposure (LD_{50} 200-2000 mg/kg body weight) and a low potential for acute toxicity by the inhalation route of exposure (no effects at highest possible vapour concentration (10-100 ppm)). It is expected to have a low potential for subchronic toxicity following repeat oral doses (53-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/d) and moderate subchronic toxicity following repeat inhalation doses (90-day NOAEL 0.2-1.0 mg/L/6 hr) in mammalian test animals. The substance is expected to have a low potential for reproductive/developmental toxicity by the oral and inhalation routes of exposure (oral NOAEL >1000 mg/kg-bw/d, inhalation NOAEL >20 mg/L/d). The substance is not expected to be a skin sensitizer. It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was determined to be 10-100 mg/kg-bw/d for short-term dermal exposure based on the NOAEL of repeat-dose dermal mammalian animal studies, and the PTDI for inhalation was determined to be 1-10 mg/kg-bw/d based on the NOAEL of repeat-dose inhalation mammalian animal studies.

When the notified substance is used in mineral ore processing, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. Significant environmental releases of the substance are not expected because of the specific conditions of import, transport, processing, use and disposal.

Potential uses of the substance include consumer applications such as in paints and cleaners, which may result in an increased potential for direct exposure of the general population mainly by dermal contact and inhalation. The acute dermal and inhalation exposures to the substance from use of household cleaners were estimated to be 0.01-0.1 mg/kg-bw/d and 0.1-1 mg/kg-bw/d, respectively, and the total acute dose estimated to be 0.1-1 mg/kg-bw/d. The chronic dermal and inhalation exposures were estimated to be 0.001-0.01 mg/kg-bw/d and 0.01-0.1 mg/kg-bw/d, respectively and the total chronic dose was estimated to be 0.01-0.1 mg/kg-bw/d. The acute dermal and inhalation exposures to the substance from use of latex paints were both estimated to be 1-10 mg/kg-bw/d and the total acute dose was estimated to be 1-10 mg/kg-bw/d. As the use of latex paints by the general population is considered infrequent, a chronic exposure

was not estimated. Environmental releases of the substance from potential consumer uses is expected via the rinsing of products containing the substance down the drain. Indirect exposure with the substance in drinking water following environmental release was estimated to be <0.001 mg/kg-bw/d.

Based on a comparison of the PTDI to the estimated dermal and inhalation exposures, 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 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.