

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

New Substances Notification 20548: Poly(oxy-1,2-ethanediyl),  $\alpha$ -undecyl- $\omega$ -hydroxy-branched and linear, ethers with 1,2-decanediol (1:1) (Chemical Abstracts Service Registry Number 501019-90-5)

### **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 polymer is poly(oxy-1,2-ethanediyl),  $\alpha$ -undecyl- $\omega$ -hydroxy-branched and linear, ethers with 1,2-decanediol (1:1) (Chemical Abstracts Service Registry Number<sup>1</sup> 501019-90-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it degrades substantially.

### **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 as an ingredient in household applications. Potential uses may include applications in industrial, commercial or consumer settings.

### **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 in water because it is readily biodegradable under both aerobic and anaerobic conditions. The substance is not expected to bioaccumulate based on its large molecular structure and high molecular weight, which will limit its ability to cross biological membranes.

### **Environmental risk assessment**

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Based on the available hazard information on the substance and structurally related chemicals, the substance has low to moderate acute ecotoxicity to algae (median effective concentration (EC<sub>50</sub>) 1-100 mg/L), moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration and EC<sub>50</sub> 1-10 mg/L), and low to moderate chronic toxicity to aquatic invertebrates (no observed effect concentration 0.1-10 mg/L). Using the EC<sub>50</sub> from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

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. For potential activities such as cleaning of transportation vessels, environmental exposure is expected to be mainly from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-100 µg/L, with the exact value being below the PNEC value. For potential activities such as personal/domestic products, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 1-10 µg/L. For potential activities such as formulation, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC <1 µg/L.

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 harm to the environment in Canada.

### **Human health risk assessment**

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight with no deaths observed at the highest dose tested) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level 10-100 mg/kg-bw/day). It is not expected to be mutagenic. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in household applications, direct exposure of the general population is expected to be by contact with the skin at levels in the range of 0.1-1 µg/cm<sup>2</sup>, by inhalation at levels in the range of 1-10 µg/kg bw/day, and by ingestion at levels in the range of 0.1-1 µg/kg bw/day. 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 environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity and 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

### **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 the *Hazardous Products Regulations* for products intended for the workplace.