

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

New Substances Notification No. 19544: Poly(oxy-1,2-ethanediyl),  $\alpha$ -(carboxymethyl)- $\omega$ -hydroxy-, C<sub>12-16</sub>-alkyl ethers (Chemical Abstracts Service No. 2242034-97-3)

### 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 polymer is poly(oxy-1,2-ethanediyl),  $\alpha$ -(carboxymethyl)- $\omega$ -hydroxy-, C<sub>12-16</sub>-alkyl ethers (Chemical Abstracts Service No. 2242034-97-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)*.

### 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 as an additive for industrial lubricants. Potential uses may include cosmetics, personal care products and consumer cleaning applications.

### 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 based on ready biodegradation (>85% at 19 days). The substance is not expected to bioaccumulate based on its ionic nature which will limit its ability to cross biological membranes.

### Ecological assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC<sub>50</sub>) and median effective concentration in the range of 1-100 mg/L). Using the LC<sub>50</sub> from the most sensitive organism (fish) and by applying an assessment factor of 200 to account for acute to chronic extrapolation, mode of action, and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100  $\mu$ g/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

activity is expected to be mainly from cleaning of transport vessels by release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 1-10 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in PECs in the range of 1-10 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 ecological harm in Canada.

### **Human health assessment**

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. Based on test data available for structurally similar substances, the substance is expected to be negative for skin sensitization.

When the notified substance is used as an additive for industrial lubricants, direct exposure of the general population is not expected due to the industrial nature of the use. Potential uses of the substance such as cosmetics, personal care products and consumer cleaning applications would lead to direct exposure of the general population. However, based on the low toxicity identified, these levels of direct exposure would not pose a significant health concern. Indirect exposure of the general population from environmental media such as air or drinking water is expected to be low from its notified and potential uses. Thus, 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.