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

New Substances Notification 20463: Propanoic acid, 2-hydroxy-, 2-(C_{10-16}-alkyloxy)-1-methyl-2-oxoethyl ester (Chemical Abstracts Service registry number 910661-93-7)

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 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 chemical is propanoic acid, 2-hydroxy-, 2-(C_{10-16}-alkyloxy)-1-methyl-2-oxoethyl ester (Chemical Abstracts Service registry number[1] 910661-93-7), 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 consumer and industrial applications. Potential uses may include liquid soaps, antiperspirants, and cosmetic 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 sediment and soil. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in these compartments based on high biodegradation (60-85% over 29 days). The substance is not expected to bioaccumulate based on low predicted bioconcentration factors (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (median lethal concentration >100 mg/L) and high acute toxicity to aquatic invertebrates and algae (median effective concentrations (EC_{50}) <1 mg/L). Using the EC_{50} from the most sensitive organisms (aquatic invertebrates and algae) and by applying an assessment factor of 100 to account for acute to chronic extrapolation, species sensitivity variation, and extrapolation from laboratory to field, the predicted no-effect

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concentration (PNEC) was calculated to be in the range of 1-10 µg/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 processing and use and from release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 0.01-10 µg/L.

Comparing the PECs 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) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). There was no evidence of sensitivity in a human repeated insult patch test. It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in consumer applications, direct exposure of the general population is expected to be mainly by contact with the skin. When the notified substance is used in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. 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. Potential uses of the substance include use in liquid soaps, antiperspirants, and cosmetic applications, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity, 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 and 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.