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

New Substances Notification No. 19329: Amides, tallow, *N*,*N*-bis(2-hydroxypropyl) (Chemical Abstract Services No. 1454803-04-3)

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 chemical is amides, tallow, *N*,*N*-bis(2-hydroxypropyl) (Chemical Abstract Services Registry Number [1]1454803-04-3), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an oil additive. Potential uses may include use in detergents, papermaking, metal finishing, personal care products, lubricants and fuels.

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 soil and sediment. The substance is not expected to be persistent in these compartments based on its moderate to high ready biodegradability (30-85% at 28 days) and inherent biodegradability. The substance is not expected to bioaccumulate based on its expected rapid biotransformation and low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate to high acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) <100 mg/L), moderate chronic toxicity in algae (10% effective concentration in the range of 0.1-10 mg/L), and low chronic toxicity in fish and aquatic invertebrates (no-observed-effect-concentration >10 mg/L). The substance has low acute toxicity in terrestrial invertebrates (LC_{50} >100 mg/kg dry soil). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 10 to

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account for acute to chronic extrapolation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 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 formulation by release of the substance to water resulting in a predicted environmental concentrations (PEC) in the range of 0.01-0.1 µg/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 0.1-1 µg/L. For potential activities such as cleaning of transportation vessels and use in cleaning products or papermaking, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC 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 for the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance is expected to have a low subchronic toxicity following repeat dermal doses in mammalian test animals (14-week NOAEL >200 mg/kg-bw/day). It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic or clastogenic *in vitro* and is not expected to be clastogenic *in vivo*. It is expected to have a low potential for carcinogenicity following repeat dermal doses in mammalian test animals. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an oil additive, direct exposure of the general population is expected to be infrequent, and mainly by contact with the skin at low levels based on the low concentration of the substance in end-use products (≤3%). As well, systemic exposure will be limited by its high octanol-water partition coefficient (log K_{ow} 6-8) and low water solubility (0.01-10 mg/L). Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels as significant environmental release of the substance is not expected. If potential uses of the substance were to include personal care products, direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation at low levels based on the limited ability of the substance to cross biological membranes via dermal contact, and the substance would not be respirable due to size of aerosol droplets/particles.

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.

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.