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

New Substances Notification No. 18954: Benzenepropanamide, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, *N*-C_{16-18}-alkyl derivatives

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 benzenepropanamide, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, *N*-C_{16-18}-alkyl derivatives (Chemical Abstracts Service No. 1235487-96-3).

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 additive in plastics. Potential uses may include as an additive in oils, foams or lubricants.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment based on its very low inherent biodegradation (≤10%). The substance is not expected to bioaccumulate based on its low steady-state bioconcentration factor (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 was not explored given the low water solubility (≤0.01 mg/L). For potential activities such as manufacturing and potential uses such as an additive in oils, foams or lubricants, environmental exposure is expected to be similar to that of the notified use. A

predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

Due to its poor water solubility and lack of exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for 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 >300 mg/kg-bw/day). It is not a dermal sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (EC3) (local lymph node assay)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive to plastics, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. If the substance is used as an additive in oils, foams and lubricants, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Exposure will be limited by its large molecular weight and low water solubility which limit its ability to cross biological membranes. Indirect exposure of the general population from environmental media such as drinking water is not expected.

Based on the low toxicity and low potential for human 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 used as notified or for other identified potential uses, the substance 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 *Hazardous Products Regulations* for products intended for the workplace.