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

New Substances Notification No. 19718: Amines, bis(hydrogenated palm-oil alkyl)hydroxy (Chemical Abstracts Service No. 1374859-51-4)

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 amines, bis(hydrogenated palm-oil alkyl)hydroxy (Chemical Abstracts Service Registry Number[1] 1374859-51-4), 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 imported into Canada in quantities greater than 10 000 kg/yr for the notified use in plastic manufacturing. Potential uses may include in plastics intended for a variety of applications, including food packaging materials, children's toys and disposable diapers.

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 sediments. The substance is expected to be persistent in these compartments based on its very low biodegradation (≤10% over 28 days). The substance is not expected to bioaccumulate based on its limited bioavailability and its low predicted bioaccumulation and bioconcentration factors (<250 kg/L).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solutions) and low chronic toxicity in algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

[1] The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposures from the notified activities are not expected, as the substance is a powder that is incorporated into a solid plastic matrix. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information on a structurally related chemical, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low to moderate subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >10 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >50 mg/kg-bw/day with no signs of reproductive/developmental toxicity at highest dose tested). It is expected to be a moderate dermal sensitizer (29-64% response in the guinea pig maximization test but inconclusive in the Buehler test). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.1-10 mg/kg-bw/day based on the NOAELs of the oral subchronic toxicity study in two species of mammalian test animals.

When the notified substance is used in plastics for industrial uses, 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 and air is not expected given the low potential for environmental release.

If the substance is used in plastics for food packaging materials, direct exposure of the general population is possible and is conservatively estimated to be at levels in the range of 0.1-1 mg/kg-bw/day. If the substance is used in other plastic products such as toys and diapers, migration levels are expected to be low. As such, direct and indirect exposure of the general population is expected to be low from these uses.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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.