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

New Substances Notification No. 19120: Hexanoic acid, 3,5,5-trimethyl-, 2,2,6,6-tetramethyl-1-[2-(3,5,5-trimethyl-1-oxohexyl)oxy]ethyl]-4-piperidinyl ester (Chemical Abstracts Service No. 1445870-18-7)

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 hexanoic acid, 3,5,5-trimethyl-, 2,2,6,6-tetramethyl-1-[2-(3,5,5-trimethyl-1-oxohexyl)oxy]ethyl]-4-piperidinyl ester (Chemical Abstracts Service No. 1445870-18-7).

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 in exterior coating formulations. Potential uses may include use in consumer paints and coatings.

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 biodegradability (≤10% over 28 days). The substance is not expected to bioaccumulate based on its low bioconcentration factor (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (median lethal loading rate >100 mg/L) 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.

The notified 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 not expected due to its very low water solubility (≤0.01 mg/L). A predicted environmental concentration was not calculated due to the low potential for ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity, 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 of exposure (median lethal dose >2000 mg/kg body weight) and moderate subchronic toxicity following repeat oral doses in mammalian test animals (56-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The notified substance has a moderate potential for reproductive/developmental toxicity by the oral route of exposure (NOAEL 50-250 mg/kg-bw/d with no significant adverse effects). It is a weak to mild skin sensitizer (>10% estimated concentration to induce stimulation index of 3 (local lymph node assay); 8-28% response (Buehler scale)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be between 1 and 10 mg/kg-bw/d based on the NOAEL of the oral subchronic toxicity study mammalian test animals.

When the notified substance is used for exterior coating formulations, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within the stable polymer matrix once the products is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels between 10^{-4} and 10^{-3} mg/kg-bw/d for children and adults. If the substance is used as in consumer paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin at levels between 0.1 and 1 mg/kg-bw/event. Indirect exposure of the general population from environmental media such as drinking water is expected to be quantitatively similar to that of the notified use, meaning at levels that do not pose a concern. The calculated direct and indirect exposures of the general population to the substance from the notified and potential uses are significantly lower than the PTDI, which is the estimated level of long-term exposure without risk of adverse health effects.

Based on a comparison of the PTDI to the estimated human exposure, 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.