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

New Substances Notification 21660: Neodecanoic acid, tin(2+) salt, (Chemical Abstracts Service Registry Number 49556-16-3)

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 neodecanoic acid, tin(2+) salt (Chemical Abstracts Service Registry Number[1] 49556-16-3).

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 flexible polyurethane foams. Potential uses include adhesives, sealants, and coatings.

Environmental fate and behaviour

Based on its physical and chemical properties, if the notified substance is released to the environment, it is expected to dissociate into an organic component (neodecanoic acid) and the tin(2+) ion. Tin(2+) tends to hydrolyse and form tin hydroxides that partition to soil and sediments, and neodecanoic acid is expected to partition to water. Both dissociation products are expected to be persistent in these compartments based on the low biodegradation of neodecanoic acid (10-30% over 28 days) and because tin cannot degrade any further. The substance is not expected to bioaccumulate based on the very low bioconcentration factor (< 250 L/kg) of neodecanoic acid and limited bioavailability of tin.

Environmental risk assessment

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.

Based on the available hazard information, the substance has low to moderate acute toxicity to algae (median effective loading rate > 1 mg/L). It is expected to have low acute toxicity to fish (median lethal loading rate > 100 mg/L), low acute toxicity to aquatic invertebrates (median effective loading rate > 100 mg/L) and moderate chronic toxicity to aquatic invertebrates (lowest-observed-effect-concentration 1-100 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified and 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 is expected to be mainly by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure. No potential activities that 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose [LD_{50}] > 2000 mg/kg body weight) and is expected to have a low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg body weight). It is expected to be a weak dermal sensitizer (an estimated concentration of > 10% required to produce a stimulation index of 1.6 in a local lymph node assay). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in flexible polyurethane foams, consumers may come in contact with end-use products containing the substance, however, direct exposure is expected to be negligible because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Potential uses of the substance include consumer products such as adhesives, sealants, and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin. Exposure will be limited by the infrequent and short duration of use, as well as the low concentration of the substance in these consumer products. 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.

Based on the low toxicity of the substance as well as the 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

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 the *Hazardous Products Regulations* for products intended for the workplace.