

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

New Substances Notification 20798: Stannane, dioctyloxo- (Chemical Abstracts Service Registry Number 870-08-6)

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 stannane, dioctyloxo- (Chemical Abstracts Service Registry Number¹ 870-08-6). The substance is a diorganotin oxide.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities up to or greater than 10 000 kg/yr for industrial, commercial and consumer uses as a catalyst for polymers in sealant applications. Potential uses may include as a catalyst in paints, coatings, plastics, and rubber products.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is expected to be persistent in these compartments based on low inherent biodegradation rates ($\leq 10\%$ over 28 days). The substance is not expected to bioaccumulate based on the low bioavailability which is due to very low water solubility (< 0.01 mg/L) and a high predicted adsorption-desorption coefficient ($\log K_{oc} > 4.5$).

Environmental risk assessment

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Based on the available hazard information, the substance did not demonstrate adverse acute effects at saturated concentrations in fish, aquatic invertebrates and algae. A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 is expected to be mainly from use 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 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 dermal route (median lethal dose > 2000 mg/kg body weight) but it is expected to have high subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level < 10 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity following repeated oral doses in mammalian test animals. It is not a dermal sensitizer (Stimulation Index < 3 (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

The substance has low systemic bioavailability via the dermal route of exposure and low acute hazard via this dermal exposure route. The target margin of exposure (MOE_T) was not calculated due to anticipated low exposure and dermal hazard potential.

When the notified substance is used as a catalyst for polymers in industrial sealant applications, direct exposure of the general population is not expected due to the industrial nature of use. When the notified substance is used as a catalyst for polymers in sealants for commercial or consumer applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be bound within a matrix once the product is cured and will be unavailable for uptake. Further to this, exposure of the general population to the substance in end-use products is expected to be limited by the frequency and duration of use, the low reported concentration in consumer products, and the limited ability of the substance to absorb through the skin. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses of the substance include as a catalyst in paints, coatings, plastics, and rubber products, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

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.

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 suspected 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 workplace use.