

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

Significant New Activity No. 17420: Dodecanoic acid, 3-[[3-[[[2,2-dimethyl-3-[(1-oxododecyl)oxy]propylidene]amino]methyl]-3,5,5-trimethylcyclohexyl]imino]-2,2-dimethylpropyl ester; Chemical Abstracts Service Registry No. 932742-30-8

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), and pursuant to section 83 of that 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.

However, a significant new activity (SNAc) Notice was recommended based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities, such as use in consumer products in an unreacted form. [SNAc No. 17420](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 148, No. 8, February 22, 2014. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

Substance Identity

The substance is a chemical that can be classified as an imine (blocked cycloaliphatic diamine).

Notified Activities

The substance is proposed to be imported into Canada in quantities up to 10,000 kg/yr for use as a curing agent in industrial/commercial polyurethane sealants.

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 suspended solids/sediments in water. The substance is not expected to be persistent in these compartments because it is subject to hydrolysis and biodegradation. The substance is not expected to be bioaccumulative based on the expected low bioaccumulation and bioconcentration factor values.

Ecological Assessment

Based on the available hazard information on the substance, the substance has moderate acute toxicity in fish (LC₅₀ 10 - 100 mg/L) and low toxicity to daphnia and algae (EC₅₀ >100 mg/L). The predicted no effect concentration was based on modeled data for the hydrolysis product of the substances and was calculated to range between 10 and 100 mg/L using the 48h-EC₅₀ from the most sensitive organism (daphnia), which was used to estimate the environmental risk.

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 formulation by release of the substance to surface water at levels of < 1 kg/day. The predicted environmental concentration for notified activities is estimated to be < 1 µg/L.

Based on the fate and use of the notified substance and the fate and hazard of its hydrolysis product, the substance is not anticipated to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (LD₅₀ > 2000 mg/kg) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (NOAEL=1000 mg/kg/day). It is a mild eye irritant (MMS between 2.3-15) and a strong dermal sensitizer (EC₃ between 0.1-1.0%). It is not mutagenic *in vitro* in multiple assays and is considered unlikely to cause genetic damage.

Hazards related to substances used in the workplace should be classified accordingly under the Workplace Hazardous Materials Information System (WHMIS).

When used as a curing agent in industrial/commercial polyurethane sealants, direct exposure of the general population to the unreacted form of the substance is not expected. Indirect exposure of the general population from environmental media such as drinking water is also not expected. However, if the substance is used as a curing agent in a consumer product, an increased potential for direct exposure of the skin to the unreacted form of the substance may exist.

Based on low potential for direct and indirect exposure to the unreacted form of the substance when used as notified, it is unlikely to be harmful to human health. However, the use of the substance in its unreacted form in consumer products may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Assessment Conclusion

When used as notified, the substance is not suspected to be harmful to human health or environment according to the criteria under section 64 of CEPA 1999. However it is suspected

that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the potential risk to the general population related to skin sensitization if the substance is used in a consumer product in its unreacted form, a SNAC was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment. SNAC No. 17420 was published in the Canada Gazette Part I, Vol. 148, No. 8 on February 22, 2014.

A conclusion under CEPA 1999, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for WHMIS that are specified in the *Controlled Products Regulations* for products intended for workplace use.