

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

New Substances Notification 16278: Cyclohexane, 1,3-bis(isocyanatomethyl)-, polymer with 1,4-bis(isocyanatomethyl)cyclohexane (Chemical Abstracts Service registry number 1253391-53-5)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Order 2011-87-07-05 Amending the Domestic Substances List](#) [PDF] outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 145, No. 16 on August 3, 2011. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified polymer is cyclohexane, 1,3-bis(isocyanatomethyl)-, polymer with 1,4-bis(isocyanatomethyl)cyclohexane (Chemical Abstracts Service registry number¹ 1253391-53-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons. Additionally, it contains aliphatic isocyanates.

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 automotive and wood coatings. Potential uses may include consumer paints.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it is expected to react in the presence of moisture to form high molecular weight, insoluble compounds. These compounds are expected to partition to soil and sediment and are expected to be persistent in these compartments based on their high molecular weights and resistance to degradation. They are not

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expected to bioaccumulate based on their high molecular weights, which will limit their ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low toxicity in fish, aquatic invertebrates and 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 as no release is expected to occur during normal operating conditions, and because the substance will be chemically reacted into a stable matrix once the product is cured and unavailable for release. A predicted environmental concentration was not calculated due to the low potential for both 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 risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (oral median lethal dose (LD_{50}) >300 mg/kg body weight with no mortality at highest dose tested; dermal LD_{50} >1000 mg/kg body weight with no mortality at highest dose tested) and acute toxicity by the inhalation route in two tests (median lethal concentration (LC_{50}) >0.5 mg/L/4hr with no mortality or clinical effects; LC_{50} <0.5 mg/L/4hr with lung irritation). In the absence of adverse systemic effects other than lung irritation from a single 4 hour exposure, acute inhalation toxicity was judged moderate. The notified substance has moderate to high subchronic toxicity following repeated inhalation doses in mammalian test animals (90-day no-observed-adverse-effect concentration (NOAEC) <0.2 mg/L/6hr with lung inflammation and swelling, but no adverse systemic effects; 14-day NOAEC <0.6 mg/L/6hr with similar lung effects to the 90-day study, and no adverse systemic effects). It is a strong dermal sensitizer in two separate tests (0.1-1% concentration required to produce a stimulation index of 3 (EC3) (local lymph node assay)). It is not expected to be associated with mutagenicity or genotoxicity. Therefore, the substance is unlikely to cause genetic damage. The acceptable exposure limit (AEL) was calculated to be in the range of 0.001 to 0.01 mg/cm² based on the EC3 range of the local lymph node assay in mammalian test animals. The AEL is the level of exposure below which no skin sensitization induction is expected in exposed individuals.

When the notified substance is used in automotive and wood coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible given the low potential for release to the environment. However, if the substance is used in consumer paints and coatings, an increased level of direct exposure may exist, and is expected to be by dermal contact at levels in the range of 1-10 mg/cm². Subsequent systemic uptake may be limited by the low percent of low molecular weight components.

Based on the low potential for exposure when used as notified, 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.

However, based on the potential for increased dermal exposure combined with indications that the substance may be a strong dermal sensitizer, the potential use of the substance in consumer products such as paints and coatings could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to dermal sensitization if the substance were to be used in consumer paint applications, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2011-87-07-05 was published in the *Canada Gazette* Part II, Vol. 145, No. 16 on August 3, 2011.

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.