

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

New Substances Notification No. 19067: Bisphenol dicyanate (Confidential Accession No. 10841-5)

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 determined that the substance is 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.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in [Ministerial Condition No. 19067](#) published in the *Canada Gazette* Part I, Vol. 151, No. 30, July 29, 2017.

Substance identity

The notified chemical is bisphenyl dicyanate (Confidential Accession No. 10841-5).

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 the production of various industrial and commercial composites. No other activities are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediment. The substance is expected to be persistent in these compartments based on its low rate of biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its moderate octanol-water partition coefficient ($\log K_{ow} < 5$) and its low bioconcentration and bioaccumulation factors (< 250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate to high acute toxicity in aquatic invertebrates (median effective concentration (EC_{50}) < 100 mg/L) and high acute toxicity in algae ($EC_{50} < 1$ mg/L). Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 100 to address acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be between 0.01 and 0.1 $\mu\text{g/L}$, which was used to estimate the ecological risk.

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 expected to be mainly from formulation by release of the substance to water at rates of 1 to 10 kg/day-site. The predicted environmental concentration (PEC) is estimated to be between 1 and 10 µg/L for notified activities. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Comparing the PEC with the PNEC, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water combined with the high toxicity to aquatic life.

Human health assessment

Based on the available hazard information for the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). It is an extreme skin sensitizer (<0.1% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in the production of various industrial and commercial composites, 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 is expected to be low. No other potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for human exposure, and considering other available lines of evidence, 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

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64 (a) of the Act.

Due to the identified risk to the environment related to the aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture and/or import the substance with conditions on its use and handling in order to mitigate these potential risks. Ministerial Condition No. 19067 was published in the *Canada Gazette* Part I, Vol. 151, No. 30, July 29, 2017.

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.