

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

New Substances Notification 20487: α -Cyclodextrin (Chemical Abstracts Service registry number 10016-20-3)

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 α -cyclodextrin (Chemical Abstracts Service registry number¹ 10016-20-3).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 50 000 kg/yr for the notified use in formulated industrial and household products, food, personal care products and pharmaceuticals. No other uses 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 water. The substance is not expected to be persistent in this compartment based on ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate as the substance will be degraded in the gut by microbial fermentation processes and will also be limited in the ability to cross biological membranes due to high molecular weight.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish, aquatic invertebrates, and algae (median lethal concentration and median effective concentration >100 mg/L) and low chronic toxicity to aquatic invertebrates (no-observed-effect-concentration >10 mg/L). 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 expected to be mainly from processing, use, and disposal from release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity. No

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potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance has low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg body weight/day). The substance has low developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >300 mg/kg body weight/day). It is not a dermal sensitizer. It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in formulated household products, food, personal care products and pharmaceuticals, direct exposure of the general population is expected to be mainly by ingestion and contact with the skin. When the notified substance is used in formulated industrial products, direct exposure of the general population is not expected due to the industrial nature of the use. 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. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity, 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, 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 *Hazardous Products Regulations* for products intended for the workplace.