

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

New Substances Notification 20588: D-Glucitol, 1-deoxy-1-(dimethylamino)- (Chemical Abstracts Service registry number 76326-99-3)

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 D-glucitol, 1-deoxy-1-(dimethylamino)- (Chemical Abstracts Service registry number¹ 76326-99-3).

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 paints. Potential uses may include personal care products and other products such as inks.

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 because it is readily biodegradable. The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient ($\log K_{ow} < 0$) and its low predicted bioaccumulation and bioconcentration factors (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (median lethal concentration and median effective concentration > 100 mg/L) and low chronic toxicity to aquatic invertebrates and algae (no-observed-effect-concentration > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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

¹ The Chemical Abstracts Service registry number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

activities is expected to be mainly from formulation and cleaning of transportation vessels from release of the substance to water. For potential activities such as use in personal care products, environmental exposure is expected to be similar to that of the notified use. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

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 a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL >300 mg/kg-bw/day). It is not a dermal sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in consumer paints, direct exposure of the general population is expected to be mainly by incidental contact with the skin at low levels. When the notified substance is used in industrial paints, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within 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 at low levels given the low potential for environmental release and high potential for biodegradation. Potential uses of the substance include personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin. Formulation into consumer products such as inks would lead to low levels of exposure by contact with the skin. Indirect exposure of the general population from environmental media is expected to be at levels that do not pose a concern, similar to that of the notified use.

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 or for other identified potential activities, 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.