

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

New Substances Notification No. 19199: 1,2-Hexanediol (Chemical Abstracts Service No. 6920-22-5)

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 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 1,2-hexanediol (Chemical Abstracts Service No. 6920-22-5).

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 personal care products. Potential uses may include use in adhesives, inks and toners.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water based on its high ready biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient ($\log K_{ow}$ 0-3) and low bioconcentration factor (<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 low acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration >100 mg/L) and low chronic toxicity in 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 activities is expected to be mainly from formulation and consumer use by release of the substance to water at rates of 0.01 to 1 kg/site-day. For potential activities such as manufacturing or formulation and blending of inks and toners, environmental exposure is expected to be similar to that of the notified use. The predicted environmental concentration is estimated to be 0.1 to 10 µg/L for notified and potential activities.

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

Human health assessment

Based on the hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have a low potential for acute toxicity by the oral, dermal and inhalation routes of exposure (oral and dermal median lethal dose >2000 mg/kg body weight; inhalation LC₅₀ >5 mg/L/4hr) and has low subchronic toxicity following repeat dermal doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) >200 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >250 mg/kg-bw/day with no observed adverse effects). It is not a skin sensitizer (>10% effective concentration to induce a stimulation index of 3 (local lymph node assay)). It is not mutagenic nor clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as in personal care products, direct exposure of the general population is expected to be mainly by contact with the skin at levels between 10 and 100 mg/kg bw/d for adults and between 100 and 1000 mg/kg bw/d for children. Indirect exposure of the general population from environmental media through ingestion of drinking water is expected to be at levels between 10⁻⁶ and 10⁻⁵ mg/kg bw/d for adults and children.

If the substance is used in inks and toners, direct exposure of the general population is not expected given that the substance will be sealed within the product. Indirect exposure of the general population from environmental media such as drinking water is expected to be similar to the notified use. If the substance is used in consumer adhesives, direct and indirect exposure of the general population is expected to be negligible in comparison to 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.

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.