

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

New Substances Notifications 18178 and 20537: 1,2-Propanediol, 1,2-dibenzoate (Chemical Abstracts Service Registry Number 19224-26-1)

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 constitute or may constitute a danger in Canada to human life or health.

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. 18178](#) published in the *Canada Gazette* Part I, Vol. 149, No. 42, October 17, 2015, and in [Ministerial Condition No. 20537](#) published in the *Canada Gazette* Part I, Vol. 155, No. 11, March 13, 2021.

Substance identity

The notified chemical is 1,2-propanediol, 1,2-dibenzoate (Chemical Abstracts Service Registry Number¹ 19224-26-1).

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 as a plasticizer in coatings and sealants. Potential uses may include use as a plasticizer in adhesives, plastic products, putty, floor polish, plastisol flooring, cosmetics and personal care products, and as a flavour enhancer.

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 not expected to be persistent in these compartments based on high ready biodegradation (> 60-85% over 28 days). The substance is not expected to bioaccumulate based on its moderate octanol-water partition

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coefficient ($\log K_{ow} > 3-6$) and low predicted bioaccumulation and bioconcentration factors ($< 250 \text{ L/kg}$).

Environmental risk assessment

Based on the available hazard information, the substance has high acute toxicity to algae (median effective concentration (EC_{50}) $< 1 \text{ mg/L}$) and is expected to have moderate acute toxicity to aquatic invertebrates and fish (EC_{50} and median lethal concentration (LC_{50}) $1-100 \text{ mg/L}$). The substance has moderate chronic toxicity to algae (10% effective concentration [EC_{10}] $0.1-10 \text{ mg/L}$) and is expected to have moderate chronic toxicity to aquatic invertebrates (EC_{10} $0.1-10 \text{ mg/L}$) and high chronic toxicity to fish (no-observed-effect-concentration (NOEC) $< 0.1 \text{ mg/L}$). Using the NOEC from the most sensitive organism (fish) and by applying an assessment factor of 4 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of $10-100 \mu\text{g/L}$, which was used to estimate the ecological risk.

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 use by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of $0.01-0.1 \mu\text{g/L}$, and from cleaning of transportation vessels by release of the substance to water resulting in a PEC in the range of $1-10 \mu\text{g/L}$. For potential activities such as manufacturing plastic items and general replacement of other phthalate plasticizers, environmental exposure is expected to be similar to that of the notified use.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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 inhalation route ($LC_{50} > 5.0 \text{ mg/L/4hr}$) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level [NOAEL] $30-300 \text{ mg/kg body weight /day}$). The substance has a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL $30-300 \text{ mg/kg bw/day}$). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as plasticizer in coatings and sealants, direct exposure of the general population is expected to be mainly by contact with the skin at levels conservatively estimated to be in the range of $0.1-1 \text{ mg/kg bw/day}$. Potential uses of the substance are conservatively estimated to lead to the following direct exposures of the general population: $0.01-0.1 \text{ mg/kg bw/day}$ from adhesives for sealing envelopes, mainly by ingestion; $0.01-1.0$

mg/kg bw/day from plastics, mainly by contact with the skin; 10-100 mg/kg bw/day from personal care products, mainly by contact with the skin; 0.01-0.1 mg/kg bw/day from floor polish, mainly by contact with the skin; and 0.0001-0.001 mg/kg bw/day from use as a flavour enhancer, by ingestion. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.00001-0.0001 mg/kg bw/day for adults and 0.0001-0.001 mg/kg bw/day for children, for both the notified and potential uses of the substance.

The derived margin of exposure (MOE_D) for the intended use of the substance in coating and sealant products was calculated to be in the range 1000-10 000, based on the point of departure (POD) derived from reproductive/developmental toxicity in the repeated oral toxicity study in mammalian test animals. The MOE_D is greater than the acceptable margin of exposure (MOE_A) of 1000, at or above which there is not expected to be a significant risk in the exposed population. The MOE_D values for the potential uses of the substance in adhesives (1000-10 000), plastics (1000-10 000), floor polish (1×10^4 - 1×10^5) and as a flavour enhancer (1×10^6 - 1×10^7) suggest there is no significant health risk to the general population from these applications. However, potential use of the substance in personal care products yields an unacceptable MOE_D in the range of 10-100.

Based on the potential for frequent dermal exposure combined with the moderate subchronic toxicity, the substance is anticipated to be harmful to human health when used in personal care products. As a result, a Ministerial Condition was imposed to manage this risk.

The assumptions made in the assessment and the risk management measures applied are considered to be adequately protective for the general population and subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

The substance is suspected to constitute a danger to human health according to the criteria under paragraph 64 (c), but is not suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (a) or (b) of the Act.

Due to the identified risk to human health related to the subchronic toxicity, Ministerial Conditions were issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use, handling and disposal in order to mitigate these potential risks. [Ministerial Condition No. 18178](#) was published in the *Canada Gazette* Part I, Vol. 149, No. 42 on October 17, 2015, and [Ministerial Condition No. 20537](#) was published in the *Canada Gazette* Part I, Vol. 155, No. 11 on March 13, 2021.

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 the *Hazardous Products Regulations* for products intended for the workplace.