

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

New Substances Notification 20389: 1,4-Benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear (Chemical Abstracts Service registry number 2097734-13-7)

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 1,4-benzenedicarboxylic acid, 1,4-dipentyl ester, branched and linear (Chemical Abstracts Service registry number¹ 2097734-13-7), and is considered a substance of unknown or variable composition, complex reaction products or biological materials (UVCB).

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 PVC articles such as vinyl flooring, wall paper, and coated fabrics. Potential uses may include use in adhesives and sealants for the construction and/or automotive and transportation sector, electrical and electronics applications (primarily cabling), children's toys, paints and coatings, printing inks, various plastic and rubber articles and in personal care products.

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 air, soil and sediment. The substance is not expected to be persistent in these compartments based on short atmospheric half-life (2-12 hours) and high biodegradability (>60% in 28 days). The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (<250 L/kg), and bioconcentration factors for analogue substances (<1000 L/kg) and model estimates.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute and chronic toxicity to fish, aquatic invertebrates, and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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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 use as a plasticizer in PVC articles such as vinyl flooring, wall paper and coated fabrics. Release of the substance to water resulting from these activities is expected to be negligible. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities which 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 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 (90-day no-observed-adverse-effect level (NOAEL) >100 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 with no toxicity observed at the highest dose). 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. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 1-10 mg/kg bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without adverse health effects

When the notified substance is used as a plasticizer in PVC articles, the substance will be initially encapsulated within a stable matrix. However, long-term low-level migration and release from the PVC or abrasion of articles containing the substance may lead to exposure of both adults and children at levels in the range 0.1-1 mg/kg-bw/day. This estimate is considered to encompass all sources of exposure, including air, soil, dust and drinking water, along with any potential uses.

Because the total estimated human exposures is less than the PTDI, meaning at levels that do not pose a concern, 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.