

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

Ministerial Condition No: 18178, 1,2-Propanediol, 1,2-dibenzoate, Chemical Abstracts Service Registry No. 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 that 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 is authorized subject to conditions on its use as described in [Ministerial Condition No. 18178](#) published in the *Canada Gazette* Part I, Vol. 149, No. 42, October 17, 2015.

### **Substance Identity**

The substance is a chemical that can be classified as a dibenzoate ester.

### **Notified Activities**

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a plasticizer in plastics, coatings, adhesives and caulks/sealants.

### **Environmental Fate and Behaviour**

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in water, soil and sediments based on its ready biodegradability. The substance is not expected to be bioaccumulative based on its moderate octanol-water partition coefficient ( $\log K_{ow} = 3-6$ ) and low predicted bioaccumulation and bioconcentration factors ( $BAF/BCF < 250$ ).

### **Ecological Assessment**

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate ( $LC_{50}/EC_{50} = 1-100$  mg/L) acute toxicity in fish, daphnia and algae. The predicted no effect concentration was calculated to be 10-100 µg/L using the  $EC_{50}$  from the most sensitive organism (algae), 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 manufacturing and compounding into plastics and from cleaning of transport vessels, by release of the substance to water. The predicted environmental concentration for notified activities is estimated to be  $< 10 \mu\text{g/L}$ .

Based on the environmental fate and use of the substance, the substance is unlikely to cause ecological harm in Canada.

### **Human Health Assessment**

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral, dermal ( $\text{LD}_{50} > 2000 \text{ mg/kg}$ ) and inhalation routes of exposure ( $\text{LC}_{50} > 5.0 \text{ mg/L}$ ) and a moderate potential for subchronic toxicity following repeated oral doses in mammalian test animals ( $\text{NOAEL} = 30\text{-}300 \text{ mg/kg bw/day}$ ). It is a mild eye and skin irritant and a weak dermal sensitizer ( $\text{EC}_3 > 10\%$ ) based on European Chemicals Agency (ECHA) data summaries. It is not mutagenic or clastogenic *in vitro*. Therefore the substance is unlikely to cause genetic damage.

When used as a plasticizer in plastics, coatings, adhesives and caulks/sealants, direct exposure of the general population is expected to be mainly by contact with the skin, by inhalation and by ingestion at levels of 0.1 to 0.25 mg/kg bw/day by dermal contact,  $3 \text{ to } 9 \times 10^{-4} \text{ mg/kg bw/day}$  by inhalation and 0.1 to 0.3 mg/kg bw/day by ingestion. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of  $2 \text{ to } 5 \times 10^{-4} \text{ mg/kg bw/day}$  and mainly by ingestion. However, if the substance is used in cosmetics, drugs and natural health products (personal care products), an increased direct exposure potential via frequent, sustained, dermal contact may exist.

Based on the low estimates of direct and indirect exposure in conjunction with the moderate subchronic toxicity ( $\text{NOAEL} = 30\text{-}300 \text{ mg/kg bw/day}$ , skeletal muscle degeneration effects), 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 for the notified use.

However, based on the potential for increased direct dermal exposure in conjunction with the moderate subchronic toxicity ( $\text{NOAEL} = 30\text{-}300 \text{ mg/kg bw/day}$ , skeletal muscle degeneration effects), the substance is anticipated to be harmful to human health when used in personal care products. Thus, risks have been identified with dermal exposure when used in personal care products.

### **Assessment Conclusion**

The substance is suspected to have the potential to be harmful to human health when used in potential applications according to the criteria under paragraph 64 (c) of CEPA.

Due to the identified risk to the general population related to the potential use of the substance in personal care products, [Ministerial Condition No. 18178](#) was published in the *Canada Gazette Part I*, Vol. 149, No. 42, October 17, 2015 to restrict the manner in which the notifier may use

the substance in order to mitigate these potential risks. The Ministerial Condition specifies a list of applications that do not pose a concern to the environment or human health and as such are permitted uses under the Ministerial Condition; personal care products are not included on this list and are therefore not permitted uses under this Condition.

A conclusion under CEPA on this substance, does not concern, 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 workplace use.