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

Ministerial Condition No. 18306: 1,2-Cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester, Chemical Abstracts Service Registry No. 1200806-67-2

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 have or may have an immediate or long term harmful effect on the environment or its biological diversity and 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, handling, and disposal as described in Ministerial Condition No. 18306 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 cyclohexane-dicarboxylic acid derivative.

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a plasticizer in sealants, coated textiles, and flexible tubing.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is not expected to be persistent in water, soil, or sediments based on data for structurally-related chemicals that report moderate-to-high levels of biodegradation (ready and inherent biodegradation conditions with results > 50%). The substance is not expected to be bioaccumulative based on its moderate octanol-water partition coefficient (log K_{ow} = 3-6) and the low-to-moderate predicted bioaccumulation and bioconcentration factors (BCF/BAF < 1000 L/kg).

Ecological Assessment

Based on the available hazard information on the substance, modelled data, and surrogate data on structurally-related chemicals, the substance has high (LC_{50}/EC_{50} = 0.1-1 mg/L) acute toxicity and moderate-to-high (NOEC = 0.01-1 mg/L) chronic toxicity to fish, invertebrates and algae.

The predicted no effect concentration was calculated to be 2-25 µg/L using modelled data and the chronic NOEC from the most sensitive organism (invertebrates).

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 cleaning of transport vessels and manufacturing, by release of the substance to water. The predicted environmental concentration for notified activities is estimated to be 0.1-25 µg/L.

Based on the potential for aquatic exposure in conjunction with the high chronic toxicity to fish, invertebrates, and algae, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water from cleaning transportation vessels and manufacturing.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by both the oral and dermal routes of exposure (LD_{50} > 2000 mg/kg bw). It is a slight skin irritant ($PII_{(1\text{-}72h)}$ = 0.6-1.5) but is not an eye irritant (MAS = 0-0.5). It is not a sensitizer in Guinea pigs (0-8% response). It is not mutagenic *in vitro*. Therefore the substance is unlikely to cause genetic damage. Based on data from a surrogate substance, the notified substance may have developmental and reproductive effects after repeated oral exposure.

When used as a plasticizer in sealants, coated textiles, and flexible tubing, direct exposure of the general population is expected to be mainly by contact with the skin and by inhalation at low levels. Indirect exposure of the general population from environmental media is expected to be low and mainly by ingestion of drinking water, inhalation following degassing of the substance from end-use products and via ingestion of dust containing the substance that has migrated out of end-use products and into the surrounding environment.

Based on the potential for low direct and indirect exposure in conjunction with the low acute oral and dermal toxicity of the substance and its negative *in vitro* mutagenicity and sensitization results, 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 and oral exposure in relation to the potential for effects on reproduction and development, the substance may be harmful to human health. Potential risks have been identified with the use of the substance in toys, children's articles and personal care products (that is, any cosmetic or drug as defined in section 2 of the *Food and Drugs Act* or in any natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations*). These uses may significantly alter the exposure of the general population, especially young subpopulations, resulting in the substance becoming harmful to human health.

Other Considerations

The United States Environmental Protection Agency has published a Significant New Use Rule on the substance based on adverse environmental effects [Significant New Use Rules on Certain Chemical Substances. Federal Register 77(80): 24613-24628 (2012)].

A similar substance, 1,2-benzenedicarboxylic acid, butyl phenylmethyl ester, or benzyl butyl phthalate (BBP; CAS# 85-68-7), has been assessed in Canada as a Priority Substance and will be re-examined as part of the Phthalate Substance Grouping of the Chemicals Management Plan.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(*a*) of CEPA and to have the potential to be harmful to human health according to the criteria under paragraph 64(*c*).

Environmental risk related to aquatic toxicity and the potential risk to the general population related to potential for effects on reproduction and development if the substance is used in toys, children's articles and any cosmetic or drug as defined in section 2 of the *Food and Drugs Act* or in any natural health product as defined in subsection 1(1) of the *Natural Health Products Regulation*s (personal care products) has been identified. As a result, Ministerial Condition No. 18306 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, handle and dispose of the substance in order to mitigate the risks.

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