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

Ministerial Condition No. 18554: 1,2-Cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester

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 have or may have an immediate or long term harmful effect on the environment or its biological diversity, and constitutes 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/or import is authorized subject to conditions on its use, and disposal as described in Ministerial Condition No. 18554 published in the *Canada Gazette* Part I, Vol. 150, No. 12, March 19, 2016.

Substance Identity

The chemical, 1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester (Chemical Abstracts Service Registry No. 1200806-67-2), can be classified as a carboxylic acid ester.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 1 000 kg/yr for use as a dispersant in industrial cement flooring. Potential uses may include other industrial, commercial and consumer applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to air, soil and sediment. The substance is not expected to be persistent in air based on a predicted atmospheric half-life of 0.5 days. The substance, based on data for structurally related chemicals, is not expected to be persistent in soil and sediment based on biodegradation half-lives of <182 days for water and soil and <365 days for sediment. The substance is not expected to bioaccumulate based on predicted bioaccumulation and bioconcentration factors (<250 L/kg^2) and a moderate octanol-water partition coefficient (3-6)

Ecological Assessment

Based on the available hazard information on the substance, no adverse effects on acute toxicity in fish were observed. However, hazard information for a structurally related chemical indicates

a moderate to high acute and chronic toxicity to pelagic organisms (acute median lethal concentration and median effective concentration <1 mg/L; chronic no-observed-effect concentration (NOEC) <10 mg/L), and low toxicity to sediment-dwelling organisms. The predicted no effect concentration was calculated to be 1-100 µg/L using the 28-day reproductive NOEC of 0.01-0.1 mg/L from the most sensitive organism (invertebrates), 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 low and mainly from formulation operations, disposal of wastes, and leaching from cement flooring by release of the substance to water during cleaning. The predicted environmentalal concentration (PEC) from potential activities by release of the substance to water is expected to be mainly from formulation in textiles processing and adhesive sealants (0.1 to 1 µg/L) or vinyl plastics (1 to 10 µg/L), cleaning of transport vessels (10-100 µg/L), manufacture (10-100 µg/L), and formulation into paints, lacquers and varnishes (1-10 µg/L). The PEC for potential activities is predicted to range from 0.1-100 µg/L.

Based on the predicted range of environmental concentrations in conjunction with the moderate to high acute and chronic toxicity, the substance is anticipated to cause ecological harm in Canada. The risks identified relate to releases of the substance to water when used in paints, lacquers and varnishes.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight). Based on the hazard information for an analogue substance, the substance is associated with subchronic toxicity and developmental reproductive toxicity. It is a slight skin irritant (primary irritation index 0.6-1.5), but neither an eye irritant (maximum average score 0-0.5) nor a skin sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a dispersant in industrial cement flooring, direct exposure of the general population is expected to be mainly by dermal contact at low levels because the substance will be entrapped within the hardened cement matrix. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. However, if potential uses of the substance were to include children's toys and articles, cosmetics, drugs or natural health products, it is anticipated that there would be increased potential for direct exposure.

Based on the potential for oral, dermal and inhalation exposure associated with potential uses in conjunction with the unknown toxicity due to subchronic exposures via these routes, the substance is anticipated to be harmful to human health. These risks are associated with use of the substance in children's toys and articles, and in cosmetics, drugs and natural health products.

Other Considerations

A structurally related substance, benzyl butyl phthalate (BBP; CAS# 85-68-7), is listed on the Domestic substances list. Product restrictions for BBP are included in the *Canadian Phthalate Regulations*. The substance BBP has been associated with both subchronic toxicity and developmental/reproductive toxicity; however, there is uncertainty with the toxicity of these endpoints for the notified substance.

Assessment Conclusion

The substance is suspected to have a ~~be~~ harmful effect on ~~to~~ the environment according to the criteria under paragraph 64 (*a*) of CEPA and to ~~have the~~ potentially constitute ~~to be harmful~~ a danger to human health according to the criteria under paragraph 64 (*c*).

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Due to the identified and potential risks to the environment and human health if the substance were released to water or used in children's toys or articles, in cosmetics, drugs or natural health products, Ministerial Condition No. 18554 was published in the *Canada Gazette* Part I, Vol. 150, No. 12 on March 19, 2016. The Ministerial Condition restricts the manner in which the notifier may manufacture ~~and/~~or import the substance, as well as imposes restrictions on use ~~and/~~or disposal in order to mitigate the risks that have been identified.