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

New Substances Notification 20087: 1,2-Cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester (Chemical Abstracts Service registry number 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 the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential environmental and human health impacts that could arise as a result of potential new activities. Order 2020-87-07-01 amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 154, No. 6 on March 18, 2020. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is 1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester (Chemical Abstracts Service registry number[1] 1200806-67-2).

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 the manufacture of coated fabrics. Potential uses may include consumer 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 sediment and air. The substance is not expected to be persistent in these compartments based on moderate ready biodegradation (30-60% over 28 days) and moderate atmospheric half-life (<2 days). The substance is not expected to bioaccumulate based on a low measured bioconcentration factor (<250 L/kg).

[1] The Chemical Abstracts Service registry number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity to fish (no adverse effects observed in saturated solutions), moderate acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L) and moderate chronic toxicity to aquatic invertebrates and algae (10% effective concentration 0.1-10 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying appropriate assessment factor of 250 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the ecological risk.

The environmental exposure of the notified substance was evaluated as read-across from data available for the substances that are intended to be replaced. Significant environmental monitoring is available for medium chain phthalates whose concentrations in surface waters have been reported to range between 0.13 and 3.06 µg/L, when detected.

Comparing the PEC for notified activities 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.

However, the manufacture of the substance in Canada may significantly alter environmental release and exposure, resulting in the substance becoming harmful to the environment. Consequently, more information is necessary to better characterize potential environmental risks.

Human health 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). The substance has a moderate subchronic toxicity and a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is not a dermal sensitizer (0% response (Buehler scale)). It is not mutagenic *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 0.1-1 mg/kg bw/day based on the NOAEL of the oral subchronic/reproductive/developmental toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as a plasticizer in the manufacture of coated fabrics, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given the low potential for release to the environment. However, if the substance is used in consumer products, increased levels of direct and indirect exposure is expected.

Based on the low potential for exposure when used as notified, 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.

However, based on the potential for increased dermal exposure combined with indications that the substance has a moderate reproductive/developmental toxicity following repeated exposure, the potential use of the substance in consumer products could result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment according the criteria under section 64 of the Act. However, it is suspected that a SNAc in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to the environment due to chronic ecological effects if the substance is manufactured in Canada, and the potential risk to human health related to developmental toxicity if the substance is potentially used in consumer products, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2020-87-07-01 was published in the *Canada Gazette* Part II, Vol. 154, No. 6 on March 18, 2020.

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.