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

New Substances Notification 19454: Bis(2-ethylhexyl) cyclohexane-1,4-dicarboxylate (Chemical Abstracts Service Registry Number 84731-70-4)

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 bis(2-ethylhexyl) cyclohexane-1,4-dicarboxylate (Chemical Abstracts Service Registry Number[1] 84731-70-4).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in polyvinyl chloride (PVC) products. Potential uses may include use in other types of plastics or cosmetics and 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 water, soil and sediment. The substance is not expected to be persistent in these compartments based on its moderate biodegradability (30-60% over 28 days). The substance is not expected to bioaccumulate based on its low predicted and experimental bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish and aquatic invertebrates (no adverse effects observed in saturated solutions) and low chronic toxicity in 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 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 transportation vessels, PVC manufacturing and rinsing down the drain during consumer use of PVC products by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.01-0.1 mg/L. For potential activities such as use in other products, environmental exposure is expected to be similar to that of the notified use.

Based on the low potential for ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

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) and low subchronic toxicity following repeat 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 repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/day). It is not a skin sensitizer (0% response (guinea pig maximization test)). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 100-1000 µg/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 risk of adverse health effects.

When the notified substance is used as a plasticizer, direct exposure of the general population from all sources is estimated to be at levels in the range of 100-1000 µg/kg-bw/day for children and adults. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 0.1-1 µg/kg-day for children and adults. Potential uses of the substance include cosmetics and personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 10-100 µg/kg-bw/day for children and adults. Indirect exposure of the general population from environmental media such as drinking water for adults and children is conservatively estimated to be at levels in the range of 0.1-1 µg/kg-bw/day for children and adults.

Because all estimated human exposures are 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.