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

New Substances Notification No. 19007: Benzoic acid, 2-benzoyl, methyl 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 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 are authorized subject to conditions as described in Ministerial Condition No. 19007 published in the *Canada Gazette* Part I, Vol. 151, No. 24, June 17, 2017.

Substance identity

The notified chemical is benzoic acid, 2-benzoyl, methyl ester (Chemical Abstracts Service No. 606-28-0).

Notified and potential activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial and consumer coating applications. Potential uses may include a variety of consumer applications, such as use in wall plasters, joint sealants, modelling clay and cosmetic or 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. The substance is expected to be persistent in this compartment based on its very low biodegradation (≤10% at 28 days), however is expected to hydrolyze over time. The environmental product of hydrolysis is also expected to be persistent in water. The substance and its product of hydrolysis are not expected to bioaccumulate based on the low bioconcentration and bioaccumulation factors (<250 L/kg) and low octanol-water partition coefficient (log K_{ow} 0-3) of the substance, and the low to moderate octanol-water partition coefficient (log K_{ow} <5) of its hydrolysis product.

Ecological assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration 1-100 mg/L) and moderate chronic toxicity in algae (no-observed-effect-concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 20 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1-1 mg/L, 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 cleaning of transportation vessels and formulation by release of the substance to water at rates of 1 to 10 kg/day-site. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use. The predicted environmental concentration (PEC) is estimated to be between 0.01 and 0.1 mg/L for notified and potential activities.

Comparing the PEC for notified and potential 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.

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 moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >250 mg/kg-bw/day with no evidence of reproductive or developmental toxicity). It is not a skin sensitizer (>10% effective concentration to induce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro*. The substance was found to have moderate clastogenic potential *in vitro* in one study, but was not clastogenic or mutagenic in two other *in vitro* studies and is not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be between 0.01 and 0.1 mg/kg-bw/day for children and between 0.1 and 1 mg/kg-bw/day for adults based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used in consumer coating applications, direct exposure of the general population is expected to be mainly by contact with the skin at levels between 0.01 and 0.1 mg/kg-event. When the notified substance is used in industrial coating applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake.

If the substance is used in cosmetics or personal care products, direct dermal exposure of the general population could be at levels between 1 and 10 mg/kg-day for children and adults. Potential use of the substance in modelling clay for children could lead to a combined oral and dermal exposure between 0.1 and 1 mg/kg-event. If the substance is used in consumer joint sealants or wall plasters, direct dermal exposure of the general population is expected to be similar to that of the notified use. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels between 0.0001 and 0.001 mg/kg-day for adults and between 0.001 and 0.01 mg/kg-day for children.

Based on a comparison of the PTDI to estimated human exposure from the notified uses, 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 when used in consumer or industrial coatings.

However, based on increased oral and dermal exposure and potential for chronic exposure from other potential consumer uses combined with the moderate subchronic oral toxicity, the substance is anticipated to become harmful to human health. These risks are associated with use of the substance in children's modelling clay and cosmetics and personal care products for children and adults.

Assessment conclusion

The substance is suspected to be harmful to human health according to the criteria under paragraph 64 (*c*) of the Act.

Due to the identified risk to human health related to the moderate subchronic toxicity noted above, a ministerial condition was issued to restrict the manner in which the notifier may manufacture and/or import the substance with conditions on its use in order to mitigate these potential risks. Ministerial Condition No. 19007 was published in the *Canada Gazette,* Part I, Vol. 151, No. 24 on June 17, 2017.

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.