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

New Substances Notification No. 19046: 1,1'-Bisphenyl, bis(1-methylethyl) (Chemical Abstracts Service No. 69009-90-1)

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.

A significant new activity (SNAc) order was issued based on uncertainties regarding potential new activities, and the potential human health impacts that could arise as a result. Order 2018-87-07-01 amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 152, No. 26 on December 26, 2018. 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 1,1'-bisphenyl, bis(1-methylethyl) (Chemical Abstracts Service No. 69009-90-1).

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 closed industrial systems. The potential use of the substance in consumer paint, sealant and adhesive products has also been considered and it was determined that the available information is insufficient to assess the risks associated with these potential activities. Other potential uses may include printing inks, resins, agricultural applications, plastics, and solvents.

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 soil and sediment. The substance is not expected to be persistent in these compartments based on its susceptibility to biodegradation (30-60% over 28 days). The substance is expected to bioaccumulate based on its moderate to high expected log octanol-water coefficient (log K_{ow} >5) and very high expected bioconcentration factor (>5000 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish (no adverse effects observed in saturated solutions), aquatic invertebrates (median effective concentration (EC_{50}) >100 mg/L) and algae (no adverse effects observed in saturated solutions) and high chronic toxicity in aquatic invertebrates (no-observed-effect-concentration (NOEC) <0.1 mg/L). The substance is also expected to have high subchronic toxicity following repeat oral doses in wildlife mammals (no-observed-adverse-effect-level (NOAEL) <10 mg/kg-bw/day). Using the NOEC from the most sensitive aquatic organism (aquatic invertebrates) and by applying an assessment factor of 2 to address species sensitivity variation, the predicted no-effect concentration (PNEC) for aquatic life was calculated to be between 1 and 10 µg/L, which was used to estimate the ecological risk. Using the NOAEL from the sentinel wildlife species (mink) and by applying an assessment factor of 500 to address species sensitivity and acute to chronic extrapolation, the PNEC for wildlife was calculated to be between 10 and 100 µg/kg-bw/d.

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 use in industrial systems by release of the substance to water at rates of 0.01 to 0.1 kg/day. For potential activities such as manufacturing and formulation, environmental exposure is expected to be mainly by release of the substance to water at rates of 0.01 to 1 kg/day. The predicted environmental concentration (PEC) is estimated to be between 0.01 and 0.1 µg/L (aquatic life, wildlife exposure not anticipated) for notified activities and between 0.1 and 1 µg/L (aquatic life) and between 0.1 and 1 µg/kg-bw/d (wildlife) for other potential activities.

Comparing the PEC with the PNEC, and considering other lines of evidence, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information for the substance and surrogate data on structurally related chemicals, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and high subchronic toxicity following repeat oral doses in mammalian test animals (28-day NOAEL <300 mg/kg-bw/day with adverse effects in lowest dose tested). It is not expected to be a skin sensitizer (0-8% response (guinea pig maximization test)). It is not expected to be mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be between 10 and 100 µg/kg-bw/d based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used in closed industrial systems, direct exposure of the general population is not expected due to the industrial nature of the 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 µg/kg-bw/d. However, if the substance is used in consumer paint products, an increased level of direct exposure may exist, and is expected to be by dermal contact and inhalation at a combined level between 100 and 1000 µg/kg-event.

Based on a comparison of the PTDI to estimated human exposure when used as notified, and considering other available lines of evidence, 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 and inhalation exposure combined with

indications that the substance has high subchronic toxicity, the potential use of the substance in consumer paint, sealant and adhesive products could significantly alter the exposure and/or conditions of use resulting 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 environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to subchronic toxicity if the substance is potentially used in consumer paint, sealant and adhesive products, a SNAc Order was issued to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2018-87-07-01 was published in the *Canada Gazette* Part II, Vol. 152, No. 26 on December 26, 2018.

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.