

Existing Substances Evaluation

Screening Assessment for The Challenge Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A) Chemical Abstracts Service Registry Number 80-05-7

Environment Canada
Health Canada

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SYNOPSIS

Pursuant to section 74 of the Canadian Environmental Protection Act, 1999 (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment of phenol, 4,4' -(1-methylethylidene)bis- or bisphenol A, Chemical Abstracts Service Registry Number 80-05-7. This substance was identified as a result of the categorization of the Domestic Substances List as a high priority for action under the Ministerial Challenge, since it was considered to pose the greatest potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of reproductive toxicity. Bisphenol A also met the ecological categorization criterion for inherent toxicity to aquatic organisms, but it did not meet the ecological categorization criteria for persistence or bioaccumulation potential.

Bisphenol A is a high volume chemical, with global production at 4 billion kg in 2006. In the United States, production quantities increased from 521 million kg in 1990 to 736 million kg in 1995. Estimated production in the U.S. in 2007 was 1 billion kg. Canadian market values may be lower than those for the U.S; however, approximately 12 million kg of bisphenol A were reported as manufactured, imported or in commerce in Canada during the calendar year 1986. In 2006, no bisphenol A was manufactured in Canada at quantities equal to or greater than a reporting threshold of 100 kg. However, bisphenol A was used in Canada in the range of 100 000 to 1 000 000 kg and approximately half a million kg was imported into Canada either alone, in a product, in a mixture or in a manufactured item.

The available data indicate that bisphenol A does not persist significantly under aerobic conditions. However, the substance has been found not to degrade or to degrade only slowly under conditions of low or no oxygen. Bisphenol A has been detected in Canadian and U.S. surface waters, sediment, groundwater and soil, as well as in municipal and industrial waste treatment products. Studies from North America, Europe and Japan document detectable levels in several species of aquatic biota. The data demonstrate that bisphenol A is present in a wide range of environmental media.

Most data indicate relatively low bioaccumulation potential and a capacity for metabolism in various species. Most measured bioaccumulation and bioconcentration factors range only up to about 150 L/kg, with one study reporting a bioaccumulation factor of 650 L/kg in lower trophic levels. These studies confirm that bisphenol A is bioavailable and can accumulate in tissues to some degree. Bisphenol

A is acutely toxic to aquatic organisms and has been shown to adversely affect growth and development in both aquatic and terrestrial species. There is evidence that low-level exposure to bisphenol A, particularly at sensitive life cycle stages, may lead to permanent alterations in hormonal, developmental or reproductive capacity. In laboratory testing, these effects have occurred within the range of concentrations measured in Canada, indicating that there is potential for adverse effects in populations, particularly close to point sources.

On the basis of expected continued or increasing exposure of biota, and information indicating the potential for long-term adverse effects to organisms within the range of concentrations currently measured in the environment, it is considered appropriate to apply a precautionary approach when characterizing risk. As such, it is concluded that bisphenol A is entering 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.

Human exposure to bisphenol A in Canada can result from dietary intake (e.g., migration from food packaging, migration from repeat-use polycarbonate containers), from environmental media (i.e., ambient air, indoor air, drinking water, soil and dust), from use of consumer products and other sources. Dietary intake is the primary source of exposure. Exposure estimates for the general population of Canada range from 0.08 µg/kg body weight/day to 4.30 µg/kg-bw per day. Specific exposure estimates for the most highly exposed subpopulation (i.e., infants) range from an average of 0.50 µg/kg body weight/day (maximum 4.30 µg/kg-bw per day) for infants aged 0 to 1 month to an average of 0.27 µg/kg body weight/day (maximum 1.75 µg/kg body weight/day) for infants aged 12 to 18 months. A critical effect for characterization of risk to human health is reproductive and developmental toxicity. The neurodevelopmental and behavioural dataset for rodents, though highly uncertain, is suggestive of potential effects at doses the same order of magnitude to 1-2 orders of magnitude higher than exposures. Given that toxicokinetics and metabolism data from experimental animal and limited human studies indicate potential sensitivity to the maternal-fetal unit and infant, and that animal studies suggest a trend towards heightened susceptibility during stages of development in rodents, it is considered appropriate to apply a precautionary approach when characterizing risk. As such, it is concluded that bisphenol A be considered as a substance that may be entering 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 addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment and, where appropriate, the performance of potential control measures identified during the risk management phase.

Based on the information available, bisphenol A meets one or more of the criteria set out in section 64 of the Canadian Environmental Protection Act, 1999.

To see the complete study and other information about Bisphenol A and the regulation in Canada, please, visit <http://www.ec.gc.ca>