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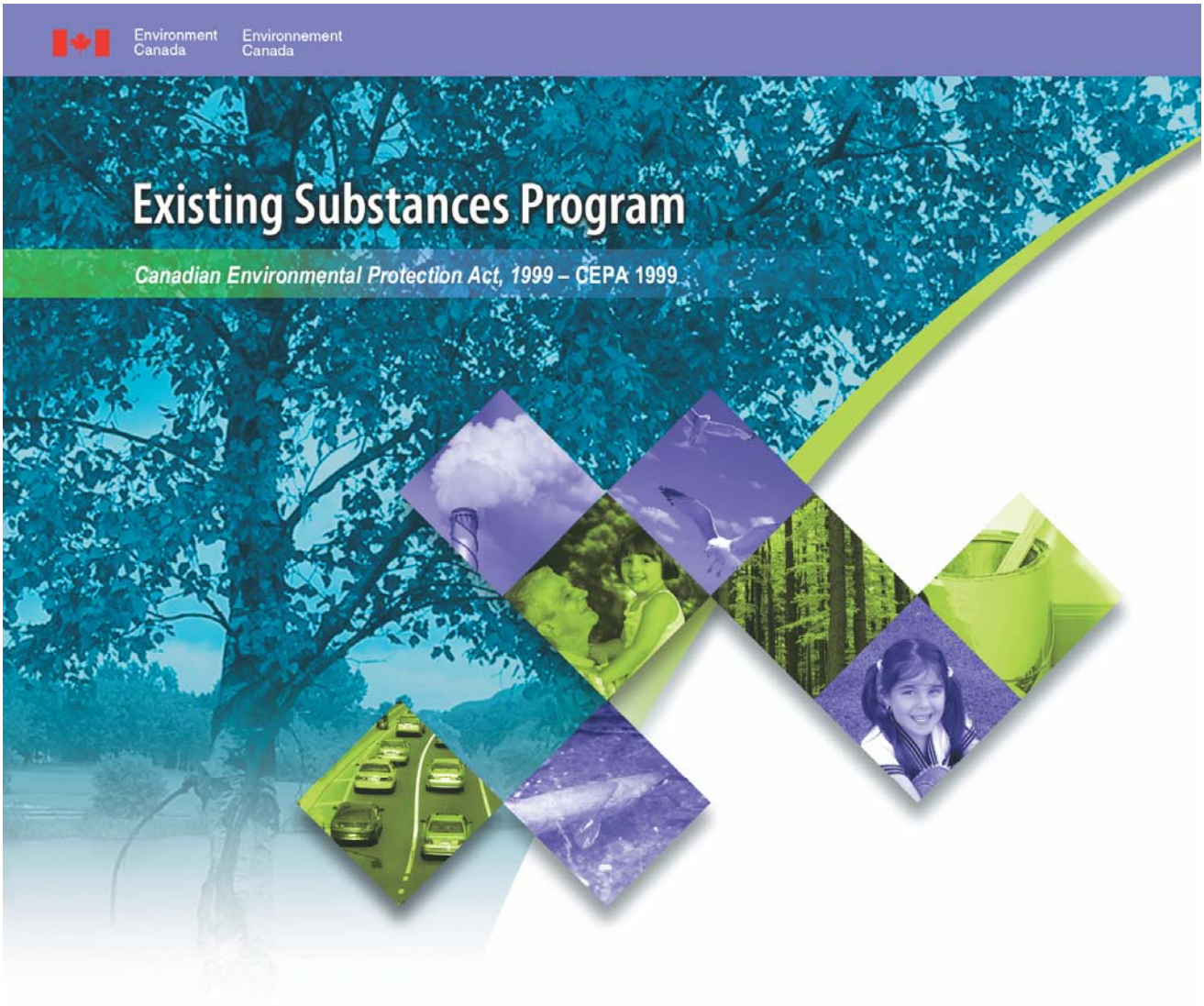

Canadian Environmental Protection Act, 1999

Draft Ecological Screening Assessment Report on 2,2'-methylenebis[6-(1,1-dimethylethyl)-4-methylphenol (MBMBP)

July 2006

Canada

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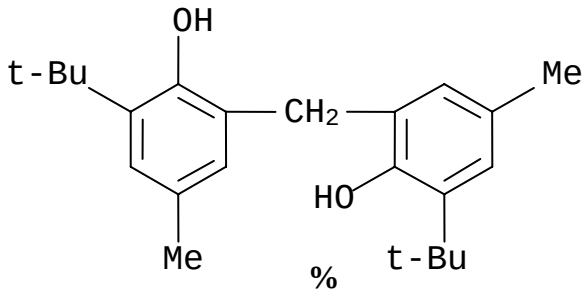

Figure 1. 2,2'-Methylenebis[6-(1,1-dimethylethyl)-4-methylphenol

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments to determine whether substances present or may present a risk to the environment or to human health. Based on the results of a screening assessment, the Ministers can propose taking no further action with respect to the substance, adding the substance to the Priority Substances List for further assessment or recommending that the substance be added to Schedule 1 and, where applicable, the implementation of virtual elimination.

A screening assessment involves an analysis of a substance using available information to determine whether the substance meets the criteria set out under Section 64 of CEPA 1999. The approach taken in this ecological screening assessment is to examine various supporting information and develop conclusions based on a weight of evidence approach as required under Section 76.1 of CEPA 1999. The screening assessment does not present an exhaustive review of all available data. Instead, it presents the critical studies and lines of evidence supporting the conclusions. One line of evidence includes consideration of risk quotients to identify potential for ecological effects. However, other concerns that affect current or potential risk, such as persistence and bioaccumulation, are also considered in this report.

An ecological screening assessment was undertaken on 2,2'-methylenebis[6-(1,1-dimethylethyl)-4- (CAS No. 119-47-1) because it was identified in a pilot project list of 123 substances on the Domestic Substances List (DSL) requiring a screening assessment under CEPA 1999. Substances included in the pilot project were considered likely to meet the CEPA 1999 Section 73 categorization criteria of 1) persistent and/or bioaccumulative and inherently toxic to non-human organisms; or 2) having a high potential for exposure of Canadians.

Data relevant to the ecological screening assessment of this substance were identified in original literature, review documents and industry research reports. Online literature database searches were conducted. Data obtained as of November 2003 were considered in this document. In addition, an industry survey was conducted in 2000 through a Canada Gazette Notice issued under authority of Section 71 of CEPA 1999. This survey collected data on the Canadian manufacture and import of the DSL pilot project substances (Environment Canada, 2001).

This ecological screening assessment report and the associated unpublished supporting working documentation were written by a team of Environment Canada evaluators within the Existing Substances Division in Gatineau, Quebec. The substance matter in this report has been subjected to external review by experts, including S. Dungey (United Kingdom Environment Agency), M. Hewitt, V. Balakrishnan and J.V. Headley (National Water Research Institute, Environment Canada), T. Fletcher (Ontario Ministry of the Environment) and M. Bonnell (New Substances Branch, Environment Canada). The interpretations and conclusions presented in this report are those of Environment Canada and do not necessarily reflect the opinions of the external reviewers.

The ecological and human health screening assessment reports were approved by the joint Environment Canada/Health Canada CEPA Management Committee. The supporting working documentation for the ecological assessment is available upon request by e-mail from existing.substances.existantes@ec.gc.ca. Information on ecological screening assessments under CEPA 1999 is available at http://www.ec.gc.ca/substances/ese.

Identity, Properties, Uses and Sources of Release

This substance is named 2,2'-methylenebis[6-(1,1-dimethylethyl)-4-methylphenol on Canada's DSL. Its Chemical Abstracts Service (CAS) Registry Number is 119-47-1. It has a number of other names, including 6,6-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol and 2,2'-**m**ethylene-**b**is(4-**m**ethyl-6-*tert*-**b**utyl-**p**henol), from which the acronym MBMBP is derived. MBMBP is a phenolic antioxidant with a relative molecular weight of 340.51. It has a low vapour pressure (calculated as 4.7×10^{-11} Pa; OECD, 2001), low water solubility (0.02 mg/L; OECD, 2001) and a high octanol/water partition coefficient (log K_{ow} = 6.25; OECD, 2001).

Although MBMBP is considered a high production volume substance globally (OECD, 2004), a survey conducted pursuant to Section 71 of CEPA 1999 indicated that during the year 2000, between 10 and 100 tonnes of MBMBP at a concentration higher than 1% were imported into Canada. In addition, companies reported either importing or manufacturing MBMBP at a concentration lower than 1% and in a quantity meeting the reporting threshold of 100 kg. MBMBP was not reported as being manufactured at a concentration higher than 1% in Canada (Environment Canada, 2001). The

principal use of MBMBP is as an antioxidant in plastics such as acrylonitrile–butadiene–styrene copolymer, polypropylene and polyacetal. It is also used in industry as a stabilizer in styrenic and olefin polymers and polyoxymethylene homopolymers and copolymers and as an antioxidant in rubber, latex and adhesives (HSDB, 1999).

Fate, Exposure and Effects

The direct release of MBMBP to surface water could occur in sewage treatment plant (STP) effluent, at STPs that receive influent from the processing facilities. Releases to air are expected to be negligible, because MBMBP's vapour pressure is very low. Releases to soil could occur from the application of STP sludge that contains MBMBP. MBMBP could partition to sediment from surface water that contains MBMBP.

The Level III fugacity model (CEMC, 2002) has been used to predict the environmental fate of MBMBP. According to Level III fugacity modelling, MBMBP is expected to partition mainly to soil (65.3%) and sediment (25.7%), assuming equal release to all media. If released to water, most (74.3%) of the substance would tend to partition to the sediment phase, while release only to soil or only to air would result in partitioning mostly (>90%) into the soil.

Experimental results indicate that MBMBP is persistent in water (CITI, 1992). Predicted results indicate that MBMBP is not persistent in air (SRC, 2001). No experimental data were found for half-lives in soil or sediment.

Data concerning measured levels of this substance in air, water, soil and sediment in Canada were not found. The Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) (OECD, 2001) reports that no quantitative monitoring data are available globally, including Canada. No data could be found for concentrations of MBMBP in wildlife in Canada or worldwide.

Environmental concentrations were calculated given potential losses during plastic processing. Plant effluents were assumed to be treated by municipal STPs before discharge to the environment. The local concentration in STP effluent is calculated using ChemSim, which is a modelling program developed for Environment Canada that predicts aquatic concentrations downstream from point sources of a substance's release (Canadian Hydraulics Centre, 2003). In order to run ChemSim, inputs, including the loading rate, are required. In this case, the loading rate is the mass of MBMBP in STP effluent released in one day. To calculate the loading rate, the following conservative assumptions were made:

- The upper range of the quantity of MBMBP imported in 2000 is 100 tonnes (100 000 kg). For the conservative exposure scenario, we have assumed that this quantity is imported by one distributor who sells to one customer who:
  - uses the total quantity of MBMBP as a plastic additive,
  - uses the total quantity at one processing facility in one calendar year, and
  - discharges plant effluent into a municipal sewage treatment system.
- For calculating the amount of MBMBP released from the processing facility into the

municipal sewage system, the Organisation for Economic Co-operation and Development (OECD) emission release scenario for plastic additives was used, with a release percentage of 0.65% (OECD, 2003). For determining the number of operating days (300 per year), the European Union Technical Guidance Document was used (European Chemicals Bureau, 2003).

- The 92.2% removal rate for MBMBP at the STP was calculated using the STP fugacity model within the EPI Suite of models, version 3.10 (SRC, 2001).

The ChemSim model run assumed a standard river in Southern Ontario with a flow rate of 5 m^3/s and predicted a maximum concentration of MBMBP of 7.46×10^{-3} mg/L, 50 m from the point of impingement (release). Further assumptions required to run ChemSim (pertaining to river flow and channel geometry) are listed in the ChemSim report for this substance (Environment Canada, 2004). The estimated exposure value for the aquatic medium (EEV_{aq}) is therefore 7.46×10^{-3} mg/L.

Most of the MBMBP in STP influent is removed (92.2%) and ends up in the sewage sludge. Since application of sewage sludge to agricultural land is a possibility, we have considered an exposure scenario involving sewage sludge–amended soil. No data on MBMBP concentrations in Canadian sewage sludge or soil were found. For the conservative soil exposure scenario, we calculate a concentration of MBMBP in sewage sludge to be 257 mg/kg dry weight, based on standard calculations, adapted to MBMBP, for estimating the concentration of a substance in sewage sludge (Droste, 1997). Using this MBMBP concentration in sewage sludge and assuming that MBMBP-containing sludge is applied to the land for 10 years (OMOE, 1996) and that no or little biodegradation of the MBMBP occurs, this would result in a soil concentration of 1.64 mg/kg dry weight. The estimated exposure value for soil (EEV_{soil}) is therefore 1.64 mg/kg dry weight.

MBMBP is not likely to be bioaccumulative, according to experimental results (OECD, 2001). The highest reported bioconcentration factor in this study was 125, significantly below the criterion for bioaccumulation of 5000 in the Persistence and Bioaccumulation Regulations of CEPA 1999 (Government of Canada, 2000). Caution should be exercised in the interpretation of these results, however, because the study used a solubilizer to achieve MBMBP concentrations above its aqueous solubility limit, so the actual bioconcentration factor might be higher than reported.

Experimental toxicity data exist for effects in aquatic organisms (green algae, water flea and fish; OECD, 2001). There is some uncertainty connected to these data, because the toxicity values are all above the water solubility limit. The critical toxicity value (CTV) selected is the lowest acceptable chronic value of 0.89 mg/L, the lowest-observed-effect concentration (LOEC) for immobility in *Daphnia magna* (water flea). No toxicity data were found for effects on soil or sediment-dwelling organisms, terrestrial plants or wildlife. A study found that MBMBP has a predicted relative binding affinity of 0.0034, which indicates that MBMBP is a low priority for further studies to determine its endocrine modulating activity (Klopman and Chakravarti, 2003).

Assessment of Risk

Risk to Aquatic Organisms

The conservative exposure scenario considered release of MBMBP to the aquatic medium following industrial processing of the imported substance entirely at one site and the subsequent treatment and release from an STP. The EEV for the aquatic medium is 0.00746 mg/L.

The CTV for this assessment is the lowest acceptable chronic value (21-day LOEC) of 0.89 mg/L for immobility in *Daphnia magna*. An application factor of 10 is applied to account for uncertainty in extrapolating from laboratory to field conditions and for intraspecies and interspecies variations in sensitivity, giving an estimated no-effect value (ENEV) of 0.089 mg/L.

Therefore, the quotient for risk to aquatic species is calculated as follows:

$$\text{Risk quotient} = \frac{EEV_{aq}}{ENEV_{aq}}$$

$$= \frac{0.00746 \text{ mg/L}}{0.089 \text{ mg/L}}$$

$$= 0.0838$$

As this calculated risk quotient is much less than 1, it is predicted that MBMBP is unlikely to cause harmful effects to pelagic organisms.

Risk to Soil-dwelling Organisms

The soil CTV for MBMBP is 2670 mg/kg dry weight, which is the LOEC calculated using an equilibrium partitioning approach. The ENEV is determined by dividing the CTV by an application factor of 10 to account for extrapolation from laboratory to field conditions and intraspecies and interspecies variations in sensitivity. Therefore, the ENEV for soil-dwelling organisms is 267 mg/kg dry weight.

A risk quotient can thus be calculated as follows:

$$\text{Risk quotient} = \frac{EEV_{soil}}{ENEV_{soil}}$$

$$= \frac{1.64 \text{ mg/kg dry weight soil}}{267 \text{ mg/kg dry weight soil}}$$

$$= 0.00614$$

Since this quotient is significantly less than 1, it is predicted that MBMBP is unlikely to cause harmful effects to soil-dwelling invertebrate organisms exposed to sewage sludge–amended agricultural land.

Proposed Conclusion

The approach taken in this ecological screening assessment was to examine relevant supporting information and develop conclusions based on a risk quotient analysis in conjunction with the weight of evidence.

The quotients for risk to aquatic and soil-dwelling organisms from exposure to MBMBP are less than 1. MBMBP does not exceed the criterion for persistence in air as defined in the Persistence and Bioaccumulation Regulations of CEPA 1999 (Government of Canada, 2000), and the potential for long-range transport is also low. MBMBP is persistent in water according to the results of OECD biodegradation protocol 301C, but it has low water solubility. No monitoring data were found for current levels or trends in environmental concentrations.

The available information suggests that MBMBP does not contribute to stratospheric ozone depletion and that its contributions to ground-level ozone formation and global warming are negligible.

It is therefore concluded that 2,2'-methylenebis[6-(1,1-dimethylethyl)-4-methylphenol is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Uncertainty

Uncertainties associated with the ecological screening assessment of MBMBP are discussed below.

Exposure Characterization

There is some uncertainty associated with the exposure characterization. There is a lack of monitoring data for MBMBP, so environmental concentrations had to be estimated using models. The use of models to predict actual concentrations based on current releases introduces uncertainties that are not easily quantifiable. Model selection, model inputs, release scenarios, site-specific information and meteorology are all factors that will affect the predicted exposure values.

Because of a lack of current information, conservative scenarios had to be developed. These scenarios also included some assumptions, such as the percentage of MBMBP released in STP effluent. Additionally, some sources might not be included in the assessment and may account for a certain volume of MBMBP released to the environment, such as small companies not meeting the reporting threshold of the Section 71 survey. Current monitoring data from sites where MBMBP could be released, as well as from sites located far from point sources, would be very useful to

support the assumptions in this assessment. However, given the available information, the scenarios developed are considered conservative (e.g. high release amounts were assumed for these sources). Even if the uncertainty on each actual exposure value is high, the confidence in our resulting conclusion is good.

Effects Characterization

Some uncertainty is associated with the ENEV determination. Due to MBMBP's low water solubility, homogeneous solutions could be reached in the toxicity studies only by using the maximum allowable dispersant (castor oil) concentration. Although effects were observed, concentrations of MBMBP in the environment are unlikely to reach the toxicity thresholds reported in the studies. Nevertheless, the studies were robustly summarized, and toxicity data can be used to select a conservative toxicity value for the assessment of risk to aquatic organisms.

There are no experimental toxicity data for soil-dwelling organisms. Equilibrium partitioning was used to estimate the toxicity of MBMBP to soil-dwelling organisms based on data for aquatic species. Also, the soil exposure concentration was estimated using conservative assumptions, such as lack of biodegradation.

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