Substance Profile for The Challenge

Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)-
(PBMBDP)
CAS RN 25155-25-3

Environment Canada
Health Canada

August 2007

Introduction

The *Canadian Environmental Protection Act, 1999* [CEPA 1999] (Canada 1999) required the Minister of Health and Minister of the Environment to categorize the approximately 23 000 substances on the Domestic Substances List (DSL). Categorization involved identifying those substances on the DSL that are a) considered to be persistent (P) and/or bioaccumulative (B), based on criteria set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000), and "inherently toxic" (iT) to humans or other organisms, or b) that present, to individuals in Canada, the greatest potential for exposure (GPE).

Further to this activity, the Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that meet the categorization criteria. A screening assessment involves a scientific evaluation of available information for a substance to determine whether the substance meets the criteria set out in section 64 of CEPA 1999. 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 (PSL) for further assessment or recommending the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999 and, where applicable, the implementation of virtual elimination of releases to the environment.

A number of substances have been identified by the Ministers as high priorities for action based on the information obtained through the categorization process. This includes substances:

- that were found to meet all of the ecological categorization criteria, including persistence, bioaccumulation potential and inherent toxicity to aquatic organisms (PBiT), and that are known to be in commerce, or of commercial interest, in Canada, and/or
- that were found either to meet the categorization criteria for GPE or to present an intermediate potential for exposure (IPE), and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

Based on a consideration of the ecological and/or human health concerns associated with these substances, and the requirement under section 76.1 of CEPA 1999 for the Ministers to apply a weight of evidence approach and the precautionary principle when conducting and interpreting the results of an assessment, sufficient data are currently available to conclude whether these substances meet the criteria under section 64 of CEPA 1999.

As such, the Ministers have issued a Challenge to industry and other interested stakeholders through publication in Canada Gazette Part I December 9, 2006 (Environment Canada and Health Canada 2006) to submit, within the timelines stated in the Challenge section of this document, specific information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

The substance Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)- was identified as a high priority for action as it was found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada. The technical human health and ecological information, that formed the basis for concern associated with this substance, is presented in this document.

The Challenge

Respecting direction under section 76.1 of CEPA 1999, and in the absence of additional relevant information as a result of this Challenge, the Ministers are predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic under section 64 of CEPA 1999. As such, the Ministers are prepared to then recommend to the Governor in Council that this substance be added to the List of Toxic Substances in Schedule 1 of CEPA 1999, with the intent of initiating the development of risk management measures taking into account socio-economic considerations.

If it is determined that the substance meets the virtual elimination criteria in subsection 77(4) of CEPA 1999, then subsequent risk management activities will be based on the objective of eliminating the release of any measurable quantity of the substance to the environment. In the absence of further information on existing management practices for a substance, actions will be proposed based on the assumption of worst-case practices. The management actions being considered for such substances at this time include prohibition through regulations, of the manufacture, use, sale, offer for sale and import of this substance, except for those activities controlled under the *Pest Control Products Act* (Canada 2002) and/or the *Food and Drugs Act* (Canada 1985).

Exceptionally, should no information be identified to indicate that this substance is in commerce in Canada, the Ministers will conclude, based on a screening assessment, that this substance does not satisfy the definition of toxic under section 64 of CEPA 1999. However, given the properties of this substance, there is concern that new activities for the substance that have not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore it would be recommended that this substance be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of this substance in quantities greater than 100 kg/year is notified, and that ecological and human health risk assessments are conducted as specified in section 83 of the Act prior to the substance being introduced into Canada.

Section 71 Notice

Under the Challenge, information deemed necessary for improved decision making may be gathered by the Minister of Environment using section 71 of CEPA 1999. This information may be used for the purpose of assessing whether a substance is toxic or is capable of becoming toxic as defined under section 64 of CEPA 1999, or for the purpose of assessing whether to control, or the manner in which to control a substance.

The information mandated through the notices may relate to, among other things; quantity of the substance imported, manufactured, used, or released, concentrations, suppliers, customers, as well as types of uses of the substance.

Copies of the section 71 notice and guidance on how to comply with it are available from the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca), or from the contact provided below.

Opportunity to Submit Additional Information to Inform Screening Assessment

The Ministers of Health and Environment are inviting the submission of additional information for consideration during screening assessment of this substance. Data of the types described in the following paragraphs are considered most relevant, although other submitted information will be considered.

Data on the persistence, bioaccumulation, and potential for toxicity of the substance to organisms in different environmental media – Through the categorization exercise, available experimental data were collected up to December 2005. Where acceptable experimental data were not available, Quantitative Structure Activity Relationships (QSARs) or read-across data were used to fill the data gaps. Since experimental data are preferred, interested parties have an opportunity to provide new or additional relevant experimental study information on the persistence, bioaccumulation, and potential for toxicity of this substance to organisms in different environmental media (air, water, sediment, soil), or on the physical/chemical properties values that were used as input into the QSAR models.). Efforts should focus on providing data for the endpoints for which good quality experimental data do not already exist, as demonstrated by the information summarized in the "Ecological Information" or "Physical/Chemical Properties" sections of this document. As submitted data will be evaluated for completeness and robustness, it is recommended that stakeholders follow the guidance for test protocols and alternative approaches for test data, as described in Section 8 of the "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers" (Government of Canada 2006).

Data on the toxicity of the substance to human health – Through the categorization exercise, the high health priorities for action were those substances identified by a Simple Hazard tool, which identified a potential high health hazard on the basis of classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity. The hazard classifications used were those developed by national or international agencies in which large numbers of substances have been classified for endpoint-specific hazard based on original review and critical evaluation of data, assessments of weight of evidence and extensive peer review. Interested parties have an opportunity to provide new or additional relevant experimental study information on the toxicity of the substance to human health which could inform the screening assessment.

Information submitted in response to the section 71 Notice or as additional information on current uses and existing control measures (see following section) will also be considered when characterizing exposure potential.

Responses to this part of the Challenge for this substance should be received at the address provided below by the date indicated on the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca).

Opportunity to Submit Additional Information on Current Uses and Existing Control Measures to Inform the Risk Management Approach for this Substance

The Ministers of Health and Environment are inviting the submission of additional information that is deemed beneficial by interested stakeholders, relating to the extent and nature of the management/stewardship of substances listed under the Challenge.

Organizations that may be interested in submitting additional information in response to this invitation include those that manufacture, import, export or use this substance whether alone, in a mixture, in a product or in a manufactured item.

Additional information is being invited in the following areas:

- Import, manufacture and use quantities
- Substance and product use details
- Releases to the environment and spill management
- Current and potential risk management and product stewardship actions
- Existing legislative or regulatory programs controlling/managing the substance
- Information to support the development of a regulatory impact assessment.

A questionnaire is available which provides a detailed template as an example for the submission of this information. Guidance on how to respond to the Challenge questionnaire is also available. Interested stakeholders are invited to provide available additional information, recognizing that not all questions in the questionnaire may be relevant to a particular substance, use, or industrial sector.

Copies of the questionnaire and associated guidance are available from the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca)**,** or from the contact provided below.

Responses to this part of the Challenge for this substance should be received at the address provided below by the date indicated on the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca).

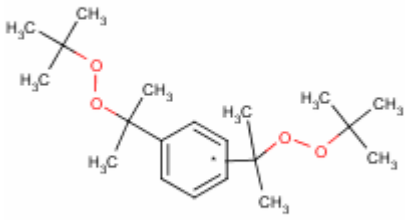
Request for Documents and Submission of Information

Documents and instructions may be requested from the following contact. Information in response to the above Challenge must be submitted to this address:

DSL Surveys Coordinator
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530/819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: DSL.surveyco@ec.gc.ca

Substance Identity

For the purposes of this document, this substance will be referred to as PBMBDP.

Chemical Abstracts Service Registry Number (CAS RN)	25155-25-3
Inventory names	*Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)-* *Peroxyde de [1,3(ou et de 1,4)-phénylènebis(1-méthyléthylidène)]bis[tert-butyle]* *[1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide* *Bis (1-t-butylperoxy-1-methylethyl) benzene* *[1,3(or 1,4)-Phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl) peroxide*
Other names	*Vul-Cup* *Vul-Cup R* *Vul-Cup 40KE* *CCRIS 4588* *Bis(tert-butyldioxyisopropyl)benzene* *EINECS 246-678-3* *Bis t-butyldioxyisopropylbenzene* *(Phenylenediisopropylidene)bis(tert-butylperoxide)* *Peroxide, (phenylenediisopropylidene)bis(tert-butyl* *alpha,alpha'-Bis(tert-butylperoxy)diisopropylbenzene* *1,3-bis(3-tert-butylperoxypropyl)benzene*
Chemical group	Peroxides
Chemical sub-group	Dialkyl peroxides
Chemical formula	$C_{20}H_{34}O_4$
Chemical structure	
SMILES	CC(c1ccc(cc1)C(OOC(C)(C)C)(C)C)(OOC(C)(C)C)C
Molecular mass	*422.46 g/mol*

Physical/Chemical Properties

Table 1 contains modelled physical-chemical properties of PBMBDP which are relevant to its environmental fate. No experimental values have been identified.

Table 1. Physical and chemical properties for PBMBDP

Property	Type	Value	Temperature (°C)	Reference
Melting point (°C)	Modelled	113.26		MPBPWIN v1.41
Boiling point (°C)	Modelled	350.78		MPBPWIN v1.41
Vapour pressure (Pa)	Modelled	0.00228 (1.71×10^{-5} mm Hg)	25	MPBPWIN v1.41
Henry's Law constant ($Pa \cdot m^3/mol$)	Modelled	9.94 (9.8×10^{-5} atm-m^3/mole)	25	HENRYWIN v1.90
Log Kow (Octanol-water partition coefficient - dimensionless)	Modelled	7.34	25	KOWWIN v1.67
Log Koc (Organic carbon partition coefficient - dimensionless)	Modelled	6.273	25	PCKOCWIN v1.66
Water solubility (mg/L)	Modelled	0.0039	25	WSKOWWIN v1.41

Sources and Uses

Information from DSL Nomination (1984-1986)

Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 1,110,000 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-86 was 5.

Use Codes and Description

The following DSL use codes have been identified for the substance:

07 - Antioxidant/corrosion inhibitor/tarnish inhibitor/scavenger/antiscaling agent
29 - Oxidizing agent
37 - Polymer, crosslinking agent
76 - Organic Chemicals, Industrial
80 - Paint and Coating
86 - Plastics
92 - Rubber Products

Potential Uses in Canada

Information on potential uses of PBMBDP was identified through searches of the available scientific and technical literature.

PBMBDP can be used as a cross-linking agent and as a curing agent to manufacture items such as: hoses and profiles; rubber seals and gaskets; technical goods; wires and cables; golf balls; EPDM and EVA based shoe soles.

Human Health Information

Under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), Health Canada undertook to categorize all substances on the Domestic Substances List (DSL) to identify those representing the greatest potential for human exposure (GPE) and those among a subset of substances considered persistent (P) and/or bioaccumulative (B) that are also considered to be "inherently toxic" to humans.

In order to efficiently identify substances that represent the highest priorities for screening assessment [from a human health perspective], Health Canada developed and applied a Simple Exposure Tool (SimET) to the DSL to identify those substances that meet the criteria for GPE, Intermediate Potential for Exposure (IPE) or Lowest Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

Exposure Information from Health Related Components of DSL Categorization

SimET was developed and used to identify substances on the DSL considered to represent GPE. This approach was based on three lines of evidence: 1) the quantity in commerce in Canada, 2) the number of companies involved in commercial activities in Canada (i.e., number of notifiers), and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an IPE or LPE, based on criteria for quantity and nature of use (Health Canada 2003).

Results of the Application of SimET

PBMBDP has been determined to be IPE based on a consideration of the DSL nomination information listed in the section on Sources and Uses.

Hazard Information from Health Related Components of DSL Categorization

Simple Hazard Tool (SimHaz)

SimHaz is a tool that has been used to identify, among all of the approximately 23 000 substances on the DSL, those considered to present either high or low hazard to human health based on formalized weight of evidence criteria and/or peer review/consensus of experts. This tool has been developed through extensive compilation of hazard classifications of Health Canada and other agencies and consideration of their robustness based on availability of transparent documentation of both process and criteria. Those substances identified as a potential high health hazard were based on hazard classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity (Health Canada 2005).

Results of the Application of SimHaz

PBMBDPE has not been classified for hazard by any of the agencies considered under the SimHaz tool and therefore does not meet the criteria for high hazard under SimHaz.

Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL that are considered to be human health related priorities for further consideration. It is recognized that they do not include a number of elements normally considered in a human health risk assessment such as a comprehensive characterization of exposure and hazard, a comparison of exposure metrics to hazard metrics and a detailed analysis of uncertainties.

Ecological Information

Data relevant to an ecological screening assessment were identified in original literature, review documents, commercial and government databases prior to December 2005. Properties and characteristics may also have been estimated using Quantitative Structure Activity Relationship (QSAR) models.

Releases, Fate and Presence in the Environment

Releases

PBMBDP is not naturally produced in the environment. Releases from anthropogenic sources have not been reported. However, due to the potentially explosive nature of peroxides when dry, it is anticipated that waste material and container residues may be commonly rinsed down the drain.

Fate

The high log Kow and log Koc values (Table 1) indicate that this substance will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicates that if the chemical is released equally to the three major environmental compartments (air, water, and soil), it will mainly partition to soil and sediments (Table 2). If it is released only to water, the substance is expected to partition almost completely to sediments and only a small amount will remain in water.

Table 2. Results of the Level III fugacity modelling (EPIWIN v3.12)

	Fraction of Substance Partitioning to Each Medium (%)			
Substance Released to:	**Air**	**Water**	**Soil**	**Sediment**
Air (100%)	9.10	0.85	26.20	63.80
Water (100%)	0.00	1.32	0.01	98.70
Soil (100%)	0.00	0.00	99.80	0.19
Air, water, soil (33% each)	0.11	0.79	39.70	59.40

An estimated vapour pressure of 0.00228 Pa and Henry's Law constant of 9.94 Pa-m^3/mol indicates that PBMBDP has fairly low volatility.

If released to soil, PBMBDP is expected to have high adsorptivity to soil (i.e. expected to be immobile) based upon an estimated Log K_{oc} of 6.273. Volatilization from moist soil surfaces seems to be an unimportant fate process based upon an estimated Henry's Law constant of 9.94 Pa-m^3/mol.

If released into water, 98.70% of PBMBDP is expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is expected to be an unimportant fate process based upon this compound's estimated Henry's Law constant. Based on its low estimated

potential for biodegradation (Table 3b), PBMBDP is expected to persist in both water and sediments.

Presence in the Environment

No monitoring data relating to the presence of this substance in environmental media (air, water, soil, sediment) have yet been identified.

Evaluation of P, B and iT Properties

Environmental Persistence

No experimental persistence data were available for this substance.

The Level III Fugacity model indicates negligible partitioning of the substance into air. Accordingly, the long-range transport potential (LRTP) of PBMBDP from its point of release in air is estimated to be low according to the model prediction presented in Table 3a. The Transport and Persistence Level III Model (TaPL3) (CEMC, 2000) was used to estimate Characteristic Travel Distance (CTD), defined as the maximum distance traveled by 63% of the substance; or in other words, the distance that 37% of the substance may travel beyond. Beyer et al (2000) have proposed CTD's of >2000 km as representing high LRTP, 700-2000 km as moderate LRTP, and <700 km as low LRTP. Based on its low LRTP, PBMBDP is expected to remain primarily in the areas close to its emission sources.

Table 3a. Model Predicted Characteristic Travel Distance (CTD) for PBMBDP

Characteristic Travel Distance	Model (Reference)
390 km	TaPL3 (CEMC, 2000)

Once released into the environment, PBMBDP appears to be persistent in water, soil and sediments. Since no experimental data on biological degradation of PBMBDP are available, a QSAR-based weight-of-evidence approach (Environment Canada, 2007) was applied using the biodegradation models shown in Table 3b. Based on these results, the estimated timeframe and probability for biodegradation indicates that PBMBDP can be considered as persistent in water.

Table 3b. Modelled data for persistence

Medium	Fate Process	Degradation Value	Endpoint/Units	Reference
Water	Biodegradation	182	Half-life, days	BIOWIN v4.02 (Ultimate survey)
Water	Biodegradation	0.0069	Probability	BIOWIN v4.02 (MITI Non-linear)
Water	Biodegradation	0.023	Probability	TOPKAT v6.2

To extrapolate half-life in water to half-lives in soils and sediments, Boethling's extrapolation factors $t_{1/2\ water} : t_{1/2\ soil} : t_{1/2\ sediment} = 1: 1: 4$ (Boethling *et al.*, 1995) can be used. Using these factors and the biodegradation model results, it may be concluded that PBMBDP is expected to be persistent in soil and sediments.

The modelled data (Tables 3b) demonstrate that the PBMBDP meets the persistence criteria (half-lives in soil and water greater or equal to 182 days and/or half-lives in sediment greater or equal to 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000).

Potential for Bioaccumulation

No experimental bioaccumulation data for PBMBDP were identified. Modelled log Kow value for this substance indicates that it has the potential to bioaccumulate in the environment (Table 1).

The Modified GOBAS BAF middle trophic level model for fish produced a Bioaccumulation Factor (BAF) of 3 758 374 L/kg, indicating that PBMBDP has the potential to bioconcentrate and biomagnify in the environment. The other Bioconcentration Factor (BCF) models provide a weight-of-evidence that supports the high bioaccumulation potential of this substance.

Table 4. Modelled data for bioaccumulation

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	3 758 374 L/kg	GOBAS BAF T2MTL (Arnot & Gobas (2003)
Fish	BCF	23 988 L/kg	Gobas BCF T2LTL (Arnot & Gobas 2003)
Fish	BCF	36 308 L/kg	OASIS Forecast v1.20
Fish	BCF	22 336 L/kg	BCFWIN v2.15

The modelled bioaccumulation values do not take into account the metabolic potential of the substance. However, the experimental BCF value is high enough to indicate that this is not likely significant.

The weight of evidence indicates that the substance meets the bioaccumulation criterion (BCF, BAF $\geq$ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000).

Ecological Effects

A - In the Aquatic Compartment

No experimental toxicity data for PBMBDP were found. A range of aquatic toxicity predictions were obtained from the various QSAR models considered (refer to

Environment Canada 2003). Table 5 includes those predictions that were considered reliable and were used in the QSAR weight-of-evidence approach for aquatic toxicity (Environment Canada 2007). These estimations indicate that the substance is highly hazardous to aquatic organisms (i.e. acute LC/EC50≤1.0 mg/L**).**

Table 5. Modelled data for aquatic toxicity

Test Organism	Type of Test	Endpoint	Value (mg/L)	Reference
Fathead minnow	96-h (acute)	LC50	0.96283	Artificial Intelligence Expert System v1.25, Basic PNN
Fish	14-d (acute)	LC50	0.01	ECOSAR v.0.99h

LC50 – Lethal concentration affecting 50% of the test population

B - In Other Media

No effects studies for non-aquatic organisms were found for this compound.

Potential to Cause Ecological Harm

Evidence that a substance is highly persistent and bioaccumulative as defined in the *Persistence and Bioaccumulation Regulations* of CEPA 1999 (Government of Canada 2000), when taken together with potential for environmental release or formation and potential for toxicity to organisms, provides a significant indication that it may be entering the environment under conditions that may have harmful long-term ecological effects (Environment Canada 2006). Substances that are persistent remain in the environment for a long time after being released, increasing the potential magnitude and duration of exposure. Substances that have long half-lives in mobile media (air and water) and partition into these media in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially for top predators. Evidence that a substance is both highly persistent and bioaccumulative, when taken together with other information such as evidence of toxicity at relatively low concentrations, and evidence of uses and releases may, therefore, be sufficient to indicate that the substance has the potential to cause ecological harm.

Based on the available information, PBMBDP will persist in soil, water and sediment and is bioaccumulative, based on criteria defined in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000). Once released in the environment, because of its resistance to degradation it will remain in water, sediment and soil for long times. As it persists in the environment, and because of its lipophilic character, it will likely bioaccumulate and may be biomagnified in trophic food chains. It also is predicted to have

relatively high toxicity to aquatic organisms. This information suggests that PBMBDP has the potential to cause ecological harm in Canada.

Uncertainties

Information and data on concentrations of the substance in the Canadian environment is currently lacking. In 1986, greater than 1,000,000 kg of PBMBDP were imported or manufactured in Canada, but there is no recent information about its importation or manufacture. However, according to US EPA TSCA quantity data, it is used in the US in amounts between one million and ten million pounds per year (US EPA 2007).

Experimental data for ecotoxicity, degradation, and bioaccumulation were not identified during categorization activities, and QSAR's were used to estimate them. There are uncertainties associated with the use of QSAR models to estimate these characteristics. Additionally, values for some key physical/chemical properties (Kow, Koc, water solubility, Henry's Law constant), which are used as input to the QSAR models, have also had to be estimated.

Uncertainties exist in the conclusions reached in this document because the evaluations of persistence, bioaccumulation and toxicity of PBMBDP are based solely on modelled data, due to the lack of empirical studies.

Regarding toxicity, based on the predicted partitioning behaviour of this chemical, the significance of soil and sediments as important media of exposure is not well addressed by the effects data available. Indeed, the only effects data identified apply primarily to pelagic aquatic exposures, although the water column may not be the medium of primary concern based on partitioning estimates.

The experimental or predicted concentrations, associated with inherent toxicity for aquatic organisms, may have an additional source of uncertainty in some situations, e.g. where these concentrations exceed the solubility of the chemical in water (either experimental or predicted). Given that concentrations for both the toxicity and water solubility are often uncertain, toxicity values that exceed solubility estimates by up to a factor of 1000 were accepted during categorization.

There is also uncertainty associated with basing the overall conclusion that PBMBDP may be causing ecological harm, solely on information relating to its persistence, bioaccumulation, relative toxicity and use pattern. Typically quantitative risk estimates (i.e., risk quotients or probabilistic analyses) are important lines of evidence when evaluating a substances potential to cause environmental harm. However when risks for persistent and bioaccumulative substances such as PBMBDP are estimated using such quantitative methods, they are highly uncertain and are likely to be underestimated (Environment Canada 2006). Given that long term risks associated with persistent and bioaccumulative substances cannot at present be reliably predicted, quantitative risk estimates have limited relevance. Furthermore since accumulations of such substances may

be widespread and are difficult to reverse, a conservative response to uncertainty (that avoids underestimation of risks) is justified.

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