Substance Profile for The Challenge

1-Propanol, 2-methoxy-
(2-Methoxy-1-propanol)
CAS RN 1589-47-5

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 1-Propanol, 2-methoxy-was identified as a high priority for action as it was determined to be of intermediate potential for exposure to individuals in Canada and is considered to present a high hazard to human health. 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.

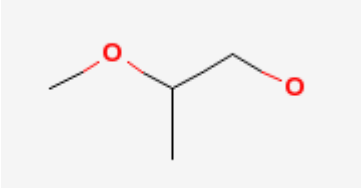
Responses to this part of the Challenge for this substance should be received at the address provided below by the date indicated on the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca).

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

Chemical Abstracts Service Registry Number (CAS RN)	1589-47-5
Inventory names	*1-Propanol, 2-methoxy-; 2-Méthoxypropanol; 2-Methoxy-1-propanol*
Other names	*Propylene Glycol Methyl Ether (PGME) beta isomer*
Chemical group	Organic
Chemical sub-group	Alcohols
Chemical formula	$C_4H_{10}O_2$
Chemical structure	
SMILES	OCC(OC)C
Molecular mass	90.12 g/mol

Physical and Chemical Properties

Table 1 contains experimental and modelled physical-chemical properties of 2-methoxy-1-propanol which are relevant to its environmental fate.

Table 1. Physical and chemical properties for 2-methoxy-1-propanol.

Property	Type	Value	Temperature (C°)	Reference
Melting point (^{o}C)	Modelled	-55.74		MPBPWIN v1.41
Boiling point (^{o}C)	Experimental	130		SRC PHYSPROP Database 2003
Boiling point (^{o}C)	Modelled	124		MPBPWIN v1.41
Vapour pressure (Pa)	Modelled	544 (4.08 mm Hg)	25	MPBPWIN v1.41
Henry's Law constant (Pa-m^3/mole)	Modelled	$1.84x10^{-3}$ to $5.63x10^{-3}$ (1.813×10^{-8} to 5.56×10^{-8} atm-m^3/mole)	25	EPIWIN v3.12
Log Kow (Octanol-water partition coefficient - dimensionless)	Modelled	-0.49	25	KOWWIN v1.67
Log Koc (Organic carbon partition coefficient - dimensionless)	Modelled	0.00		PCKOCWIN v1.66
Water solubility (mg/L)	Modelled	1000000	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 110,000 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-86 was fewer than 4.

Use Codes and Description

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

44 Solvent/carrier
80 Paint and coating

Potential Uses in Canada

Information on potential uses of 2-methoxy-1-propanol was identified through searches of the available scientific and technical literature.

2-Methoxy-1-propanol is the beta isomer of Propylene Glycol Methyl Ether (PGME) and is not produced commercially (OECD 2003). Verschueren (2001) indicates that commercial products consist of no more than 5% 2-methoxy-1-propanol and in European Union countries, labelling regulations require that commercially available 2-propanol, 1-methoxy- (PGME alpha isomer – CAS RN 107-98-2) should contain less than 0.5% of the beta isomer as an impurity (OECD 2001). Exposure to 2-methoxy-1-propanol may occur as a result of exposures to PGME, therefore, a list of the potential uses of PGME is included in this section.

PGME is mainly used as a chemical intermediate in the manufacture of propylene glycol methyl ether acetate but may also be used as a solvent in surface coatings, varnishes, paints, and agricultural pesticides (OECD 2001; Dow 2004). This substance may also be used as a solvent and/or coupling agent in various types of inks, for household and industrial cleaners (including automotive cleaners, window and oven cleaners, carpet and upholstery cleaners, etc. (OECD 2001; 3M 2002; Imperial 2004; Noveon 2001a-c)), rust removers and hard surface cleaners (Dow 2004).

2-Methoxy-1-propanol may be found as an impurity in other PGME containing products including adhesives, electronics, non-structural caulking compounds and sealants,

synthetic resins and rubber adhesives (OECD 2001); plaster (HPD 2005); for surface treatments; for wood protection; for waterproofing; for shoes and leather; in photographic chemicals; hydraulic brake fluids and lubricants; disinfectants; for metals; for galvano technique; pickling solutions, and perfumes (Dentan et al. 2000).

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

2-Methoxy-1-propanol 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 classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity (Health Canada 2005).

Results of the Application of SimHaz

2-Methoxy-1-propanol is considered to be a potentially high hazard substance based on its classification for developmental toxicity by the European Commission.

The following classification for developmental toxicity of 2-methoxy-1-propanol is available:

The European Commission has classified 2-methoxy-1-propanol as Category 2 for developmental toxicity (Substance which should be regarded as if it causes developmental toxicity to humans) (European Commission 1997, 1998; ESIS 2006).

Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL that are considered to be human health 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. However, as a result of the combination of the severe hazard properties of this substance as determined in weight of evidence evaluations of other agencies and its potential for exposure (IPE), assessment of the risk to health in Canada is considered a priority.

Ecological Information

Data relevant to an ecological screening assessment were identified in original literature, review documents and 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

No information concerning releases of 2-methoxy-1-propanol to the environment has been identified.

Fate

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 water and soil (Table 2), where the chemical is not expected to be persistent (see Table 3).

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%)	1.07	25.70	73.10	0.05
Water (100%)	0.00	99.80	0.01	0.18
Soil (100%)	0.02	22.00	77.90	0.04
Air, water, soil (33% each)	0.34	40.70	58.90	0.07

An estimated vapour pressure of 544 Pa combined with an estimated Henry's Law constant of 1.84 x 10^{-3} to 5.63 x 10^{-3} Pa-m^3/mole indicates that if 2-methoxy-1-propanol is released solely to air, a small part will remain in this compartment but most will be readily removed from the atmosphere in rainwater. In air, the chemical seems to be fairly rapidly degraded, indicated by an estimated oxidation half-life value of 0.5426 days (EPIWIN v3.12) (Table 3).

If released to soil, 2-methoxy-1-propanol is expected to be quite mobile, based upon an estimated Log K_{oc} of 0. Very little volatilization from moist soil surfaces is expected to occur based upon an estimated Henry's Law constant in the range of 1.84 x 10^{-3} to 5.63 x 10^{-3} Pa-m^3/mole. This chemical would volatilize from dry soil surfaces to some extent based upon its moderate to high vapour pressure of 544 Pa. The substance would not be expected to persist in soil as its estimated biodegradation half-life is 15 days (Table 3).

If released into water, 2-methoxy-1-propanol is expected to occur mostly in a dissolved form, based on its very low estimated Log K_{oc} of 0 and its high water solubility (Table 1). Volatilization from water would not be significant based upon this compound's estimated Henry's Law constant. Thus, if water is a receiving medium, 2-methoxy-1-propanol is expected to remain mainly in the aqueous phase. The substance is not expected to persist in this phase, however, with an estimated biodegradation half-life of 15 days (Table 3).

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 have yet been identified for 2-methoxy-1-propanol.

The Level III Fugacity model indicates negligible partitioning of the substance into air. Hence, once released into the environment, 2-methoxy-1-propanol is not predicted to be persistent in air, water, soil or sediment. Since no experimental data on biological degradation of 2-methoxy-1-propanol are available, a QSAR-based weight-of-evidence approach (Environment Canada, 2007) was applied using the biodegradation models shown in Table 3. Based on these results, the estimated timeframe and probability for biodegradation indicates that 2-methoxy-1-propanol cannot be considered as persistent in water.

Table 3. Modelled data for persistence

Medium	Fate Process	Degradation Value	Endpoint/Units	Reference
Water	Biodegradation	15	Half-life, days	BIOWIN v4.02; Ultimate Survey Model
Water	Biodegradation	0.7667	Probability	BIOWIN v4.02; MITI Non-Linear

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 2-methoxy-1-propanol is not expected to be persistent in soil and sediments.

The modelled data (Table 3) demonstrate that 2-methoxy-1-propanol does not meet the persistence criteria (half-lives in soil or water $\geq$ 182 days; half-life in sediment $\geq$ 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000).

Potential for Bioaccumulation

Modelled data for the bioaccumulation potential of 2-methoxy-1-propanol presented in Table 4 indicate that this chemical is not expected to bioaccumulate in the environment.

The Modified GOBAS BAF middle trophic level model for fish produced a Bioaccumulation Factor (BAF) value of 0.96 L/kg wet weight, indicating that this substance is not likely to bioconcentrate or biomagnify in the environment. The Bioconcentration Factor (BCF) models also provide a weight-of-evidence to support the low bioconcentration potential of the substance (Table 4).

Metabolism information for this substance was not available, nor was it considered in the BAF models.

Table 4. Modelled data for bioaccumulation

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	0.96 L/kg	Gobas BAF T2MTL (Arnot and Gobas, 2003)
Fish	BCF	1.001 L/kg	Gobas BCF 5% T2LTL (Arnot and Gobas, 2003)
Fish	BCF	10.06 L/kg	OASIS Forecast v1.20
Fish	BCF	3.16 L/kg	BCFWIN v2.15

The weight of evidence indicates that the substance does not meet the bioaccumulation criterion (BCF, BAF ≥ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000).

Ecological Effects

A - In the Aquatic Compartment

There is modelled evidence that the substance does not cause harm to aquatic organisms at relatively low concentrations (e.g., does not exhibit acute LC/EC50s ≤1.0 mg/L) [Table 5].

Table 5 Modelled data for aquatic toxicity

Test Organism	Type of Test	Endpoint	Value (mg/L)	Reference
Fish	Acute	LC50	4997.69 – 16500	ECOSAR v0.99h; TOPKAT v6.2; Artificial Intelligence Expert System v1.25; ASTER
Daphnia	Acute	EC50	19000	TOPKAT v6.2
Daphnia	Chronic	EC50	227.843	ECOSAR v0.99h
Algae	Acute	EC50	7152.973	ECOSAR v0.99h

LC50 – Lethal concentration affecting 50% of the test population
EC50 – Concentration effecting 50% of the test population

A range of aquatic toxicity predictions were obtained from the various QSAR models considered. Table 5 lists those estimates that were considered reliable and were used in the QSAR weight-of-evidence approach for aquatic toxicity (Environment Canada 2007). These results indicate that the substance is not highly hazardous to aquatic organisms (i.e. does not exhibit acute LC/EC50s ≤1.0 mg/L or chronic NOEC ≤0.1 mg/L) but rather has low toxicity.

B - In Other Media

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

Potential to Cause Ecological Harm

Based on the available information, 2-methoxy-1-propanol does not persist in the environment and is not bioaccumulative based on criteria defined in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000). Information on concentrations of 2-methoxy-1-propanol in the environment has not been identified at this time. However, the estimated ecotoxicological data indicates that the substance has low toxicity to aquatic organisms. Information on potential impacts in other environmental compartments has not been identified.

Uncertainties

QSAR models were used to estimate persistence and bioaccumulation. There are uncertainties associated with the use of QSAR models to estimate these characteristics. In addition, values for some key physical/chemical properties such as vapour pressure, Kow, Koc and Henry's law constant, which are used as input to the QSAR models, have also had to be estimated.

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