Proposed Risk Management Strategy for 2-Methoxyethanol

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RISK MANAGEMENT STRATEGY FOR 2-METHOXYETHANOL

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1. Issue

On August 9, 2003, the Ministers of the Environment and of Health published their final decision on the assessment of 2-Methoxyethanol (2-ME) in the *Canada Gazette* and recommended that 2-ME be added to the *List of Toxic Substances* in Schedule 1 under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The final version of the assessment report concludes that 2-ME is harmful to human health. However, 2-ME is not considered harmful to the environment, or the environment on which life depends.

Under subsection 91(1) of CEPA 1999, the Minister of the Environment must propose a regulation or instrument respecting preventive or control actions to manage 2-ME no later than 2 years after the publication of final assessment report recommending its addition to Schedule 1 of CEPA. Further under subsection 92(1), the instrument must be finalized within 18 months thereafter.

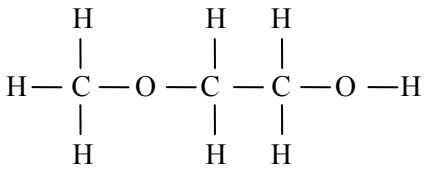
This risk management strategy outlines the risk management objectives, instruments and approaches proposed to reduce the risks associated with 2-ME. A stakeholder consultation approach is also proposed.

2. Background

2.1. Structure and Function of 2-ME

2-Methoxyethanol (2-ME) is a member of a larger group of compounds known as glycol ethers. Glycol ethers are used mainly as solvents in formulated products such as paints, inks and cleaning fluids. These compounds can be categorized as either E-series (ethylene glycol ethers) or P-series (propylene glycol ethers). 2-ME is an E-series glycol ether with the chemical formula $C_3H_8O_2$ and the following structure:

Figure 1: Structure of 2-ME



As can be seen from Figure 1, 2-ME has both hydroxyl and ether functional groups. The balance between hydrophobic and hydrophilic characteristics makes 2-ME an extremely versatile solvent and an effective coupling agent.

2.2. Production, Import and Use of 2-ME

2-ME is not produced in or exported from Canada. Currently, there is only one manufacturer of 2-ME in North America. In the last decade, the major suppliers of 2-ME to Canada have been US producers and various US chemical distributors.

In the past, 2-ME was used in a wide variety of consumer products such as paints, coatings, inks and cleaning products. However, since 2-ME has been associated with a wide range of adverse effects on health, its use in consumer products appears to have been phased-out in some countries. Recent use pattern information indicates that 2-ME is not used in consumer products except in a cleaning solvent for white boards in Canada. The quantity used is estimated to be small.

As summarized in Table 1, approximately 80% of the 2-ME used in Canada in 2002 was used in military and private jet fuel as an anti-icing agent and by the military as a component of a decontamination agent. The decontamination agent is used by the Canadian Forces to protect equipment and vehicles against chemical warfare agents by chemically modifying or removing the substances from the surface of the equipment. Canadian refineries ceased production of the jet fuel (JP4) that contains 2-ME as an anti-icing agent. The phased out of use of JP4 jet fuel was completed at the end of May 2003 by the Canadian Forces. It is expected that this phase-out should significantly reduce the volume of 2-ME used in Canada. The exact amount of 2-ME stockpiled as a decontamination agent is considered confidential information. The Canadian military is currently developing an aqueous based decontamination agent to replace the agent containing 2-ME by 2006.

2-ME is also used as a chemical intermediate in the production of specialty plasticizer (DMEP), esters (EMA-2-methoxyethyl acetate), etc., accounting for 15% of the total use in Canada. Approximately 2% of the estimated total 2-ME used in Canada is used industrially as a process solvent in the production of printed circuit board laminates (e.g. electronics manufacturing) and in the electroplating, pharmaceutical and photographic chemical industries. The use pattern information provided by ToxEcology also indicates that 2-ME is used as a solvent in pigment bases in specialty wood finishing products for wood furniture manufacturing and in specialty primer coatings for rubber manufacturing. These products are used exclusively in industrial settings and represent 3% of all 2-ME uses. Annex 1 provides a list of products containing 2-ME, their 2-ME content and reference information.

Table 1: Estimated Uses of 2-ME in 2002

Use	%	Tonnes
Anti-icing and Decontamination Agent	80	500
Chemical Intermediate	15	94
Coatings	3	19
Other industrial uses	2	12
Consumer uses	0	0
TOTAL		625

Note: The total estimated use of 2-ME in 2002 was 625 tonnes.

3. Exposure Sources

1. Releases due to Industrial/Commercial Uses

In Canada, 2-ME was primarily used as an anti-icing agent in jet fuel by the Canadian military. Environmental releases from this use could have occurred during the addition of 2-ME to jet fuel (either at the point of use or at fuel formulation stage) or during transport of fuel from storage tanks to aircraft. Since 2-ME is burned during fuel combustion, there were no atmospheric emissions of this chemical as a result of normal aircraft operations.

Decontamination agents containing 2-ME are designed for use as protection against chemical warfare agents by the Canadian military. Their purpose is to rapidly and effectively render harmless or remove poisonous hazardous substances from personnel and equipment. The resulting environmental releases could be to air, soil or water.

Atmospheric emissions of 2-ME from industrial sources (wood furniture, rubber, pharmaceutical manufacturers and in the photochemical and electronics industries) could result from the use of paint and solvent products containing the chemical. Based on information provided in the PSL Assessment Report, concentrations of 2-ME in ambient air are not likely to be detectable.

When used as a chemical intermediate, decontamination agent or solvent, environmental emissions to air, soil and/or water may result from spills/leaks of the chemical from storage tanks and as a result of waste/wastewater disposal.

Based on 2002 National Pollutant Release Inventory (NPRI) early data, two facilities in Canada reported releases of 2-ME. The largest emitter of 2-ME, a furniture and furniture fixture manufacturer, released 99% of reported emissions of 2-ME in Canada. This facility has also indicated it has plans to phase out its use of 2-ME and is currently working on converting 75% of its current VOC containing finishing products by the end of September 2003.

2. Human Exposure due to Commercial/Industrial use of Products Containing 2-ME

The major routes of human exposure to 2-ME due to its industrial/commercial use in jet fuel, decontamination agents, solvents and industrial coatings would be the result of contact and inhalation of 2-ME from accidental spills/leaks, during handling and use of products and as a result of waste disposal. Human exposure to 2-ME from these sources is controlled through occupational health and safety legislation in Canada.

3. Human Exposure due to Consumer use of Products Containing 2-ME

Based on the recent information in Canada, 2-ME is not used in consumer products except as a cleaning solvent for white boards. The quantity used is estimated to be small. As part of the Risk Management Strategy, Environment Canada will confirm through the consultation process that 2-ME is not currently used in other consumer products and ensure that it will not be used in the future in consumer products in Canada.

4. Why we need action on 2-ME

As 2-ME is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health, Health Canada has proposed that 2-ME be considered toxic under paragraph 64(*c*) of CEPA, 1999.

Based on a relatively extensive database in experimental animals, 2-methoxyethanol has consistently been associated with a wide range of adverse effects on health, including some considered to be severe and irreversible (e.g. teratogenicity). Some of these effects are occurring at relatively low levels of exposure, often the lowest dose or concentration tested. However, based on fugacity modeling and limited sampling results, the exposure level of the general population through environmental media is approximately three orders of magnitude lower than the lowest documented toxic effect levels. Uncontrolled handling, use, storage and disposal of products containing 2-ME could potentially result in human exposure exceeding the lowest effect levels.

2-ME is considered a "Track 2" substance as defined in the Toxic Substances Management Policy, hence life cycle management is therefore the approached to be taken to prevent or minimize its releases into the environment.

5. Considerations / Discussion

The Priority Substances List Assessment Report for 2-ME, which was published on August 2003, identifies the following considerations:

1. Follow-up to the Report

The PSL assessment report contains the following considerations for follow-up: additional information should be acquired on patterns of use of the compound in Canada and its potential presence in consumer products and, depending on results of use pattern work, conduct a fuller assessment of the potential adverse effects of 2-methoxyethanol. The updated use pattern information for 2-ME and confirmation of its apparent absence in consumer products was completed by a consultant in May 2003 and is reflected in this strategy.

2. Alternatives/substitutes

The most common replacement for 2-ME as a jet fuel additive is diethylene glycol methyl ether (DEGME). This alternative has replaced 2-ME as an additive in Canadian military fuel and private jet fuel for land-based aircrafts at the end of May 2003.

The Canadian military is currently developing a broad-spectrum aqueous based decontamination agent that would replace the product DS2 (28% 2-ME). A representative at the Department of National Defence has indicated that the use of DS2 will likely be phased out in 2006.

2-ME may be replaced in industrial solvent and coatings applications with alternative E-series glycol ethers (e.g. DEGME) or with P-series glycol ethers. Toxic effects similar to those for 2-ME have been documented for exposure to DEGME. However, with the exception of dermal contact, acceptable exposure levels for DEGME are higher than for 2-ME. DEGME may not be a suitable alternative to 2-ME in applications where significant and/or prolonged exposure could be expected. In general, the P-series glycol ethers do not appear to all of the effects associated with 2-ME (testicular atrophy, teratogenicity). Toxicity towards the liver and kidney have been observed for P-series glycol ethers, but at concentrations higher than 2-ME.

3. Existing Environmental Controls

- Federal Government:

  Consumer Chemicals and Containers Regulations, 2001 (under Hazardous Products Act): Any consumer products that contained 2-ME would be subject to this regulation which classifies products as very toxic, toxic or harmful based on toxicity to humans. By requiring precautionary labeling, the intent of the regulation is to inform consumers of the hazards posed by toxic and harmful products during normal use. In addition, a prohibition requirement based on the toxicological properties of products eliminates consumer exposure to very toxic chemicals. Classification is completed on a whole product basis, so 2-ME content alone would not necessarily be indicative of the hazard rating. Based on published acute toxicity values, products containing 2-ME would not be classified as "harmful" for oral and dermal exposure. Since published values for acute toxicity for inhalation vary widely, it is not possible to estimate the categorization of products containing 2-ME considering the inhalation pathway. This classification does not consider chronic toxic effects of products.

  Volatile Organic Compounds (VOCs) Guidelines: Since 2-ME is a VOC, it is covered by the various CCME and Environment Canada Guidelines which specify VOC content of products and best practices for industry.

  Federal OHS Regulation: The Canada Occupational Health and Safety Regulations (under the Canada Labour Code - Part II) specifies an allowable ambient air concentration for 2-ME of 5 ppm (16 mg/m^3) (no expected change in pulmonary ventilation or heart rates) in the workplace.

- Provinces / Territories:

  VOC Initiatives: Some provinces have VOC initiatives which could result in reductions in 2-ME use or emissions in commercial applications.

  OHSA Regulations: Each province and territory has an Occupational Health and Safety Act or Regulation which specifies the allowable ambient air concentration of 2-ME in the workplace. The 8-hour threshold levels specified by the various jurisdictions ranged from 5 ppm (16 mg/m^3) to 25 ppm (80 mg/m^3).

- United States:

  Hazardous Air Pollutants (HAPs): Glycol ethers are listed as a group of chemicals in the US EPA hazardous air pollutant (HAP) list. EPA regulations developed for industrial sectors set emission control requirements for total HAPs from facilities qualifying as major and area sources.

  Volatile Organic Compounds (VOCs): Three EPA rules were promulgated in 1998 that set specific limits for VOCs (including 2-ME) in 24 consumer product categories, architectural and industrial maintenance paints and auto-refinish paints.

  US Occupational Safety and Health Administration: Regulates occupational exposure to 2-ME and has set a permissible exposure limit of 25 ppm (based on an 8-hour time weighted average exposure).

  American Conference of Governmental Industrial Hygienists (ACGIH): The threshold level value for 2-ME specified by this organization is an 8 hour TWA of 5 ppm. This threshold level is referenced in many Canadian provincial OHSA regulations.

  Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): Under the FIFRA, information on formulants including 2-ME is collected when pesticide products are registered (or re-registered). In an EPA notice published in June, 1998 "Inert Ingredients No Longer Used in Pesticide Products" 2-ME was removed from List 1 - Inerts of Toxicological Concern since it was no longer found to be used in pesticide products. Future use in pesticides of substances removed from this list is not

permitted without determination that the substance will not pose unreasonable risk to human health or the environment.

Food and Drug Act (FDA): 2-ME is approved for use under the FDA as a solvent for use in pharmaceutical products provided the permitted daily exposure would not exceed 0.5 mg/day or an exceed a concentration limit of 50 ppm.

6. Proposed Objectives

6.1. Proposed Environmental Objective (EO)

2-ME is associated with a range of adverse health effects, including teratogenicity (for which there may not be a threshold of exposure for induction). As concluded in the CEPA PSL assessment report, it cannot be precluded that there is some probability of occurrence of effects at any level of exposure and the environmental objective is to reduce uncontrolled human exposure to 2-ME to the greatest extent possible.

6.2. Proposed Risk Management Objectives (RMO)

Since the only potential uncontrolled sources of exposure to 2-ME are products used by consumers and, since it cannot be precluded that there is some probability of occurrence of effects at any level of exposure to 2-ME, the proposed RMO is:

To eliminate the potential for human exposure to 2-ME, particularly consumer exposure from the use of products containing 2-ME.

7. Proposed Risk Management Tools / Instruments to be developed

The selected risk management instrument must satisfy the requirements of section 91 and 92 of CEPA 1999. Instruments which satisfy these requirements include CEPA regulations, environmental objectives or guidelines, environmental release guidelines, codes of practice, pollution prevention plans, environmental emergency plans and agreements respecting environmental data and research.

The following risk management tools may be suitable for managing the risks associated with consumer products containing 2-ME:

- **Performance Standard (Regulations)**
  Add 2-ME to the *Prohibition of Certain Toxic Substances Regulations, 2003* (Environment Canada) which would prevent the manufacture, import and use of 2-ME in Canada (this would also prohibit use of 2-ME in industrial applications).

8. Proposed Consultation Approach

Since the focus of this RMS is on products used by consumers, stakeholders in the consultation process will likely include associations representing manufacturers of products including: Canadian Paints and Coatings Associations (CPCA), Canadian Cosmetics, Toiletries and Fragrances Association (CCTFA) and Canadian Consumer Specialty Products Association (CCSPA). As one proposed instrument is the addition of 2-ME to the *Prohibition of Certain Toxic Substances Regulations, 2003*, industrial users of products containing 2-ME would be included in the consultation. These industries include: users of 2-

ME as a chemical intermediate (manufacturers of specialty plasticizer DMEP, esters and dimethyl ethers of ethylene glycol); solvent manufacturers; manufacturers of printed circuit board laminates; electroplaters; pharmaceutical and photographic chemical manufacturers, importers, suppliers and users; wood furniture and rubber coatings manufacturers, importers and suppliers; wood furniture manufacturers; and rubber manufacturers. Representatives of the Department of National Defence will also be consulted regarding their use of decontamination agents containing 2-ME. Other stakeholders will include environmental non-governmental organizations (ENGOs).

A multi-stakeholder consultation will be held during Winter 2004. The consultations will cover the risk assessment results, the risk management process, the proposed instruments and 2-ME alternatives. Environment Canada will seek advice on the proposed risk management objectives and risk management instruments. Consultation on 2-ME instruments will likely be held in conjunction with consultation meetings on management measures for 2-BE.

9. Next steps

Technical and Socio-economic background study to be completed	completed
Use Pattern and Feasibility Study for Exposure Modeling	completed
Qualitative screening of management options	completed
Publication of Final Assessment Report and Recommendation to add 2-ME to Schedule 1 (start of 2-year timeclock)	August 9, 2003
Approval of Draft Risk management strategy	completed
Consultations with stakeholders	Winter 2004
Draft the proposed instrument	Winter to Fall 2004
Publication of Proposed Instrument	End of 2004

10. References

Environment Canada/Health Canada, 2003. Priority Substances List Assessment Report, 2-Methoxyethanol, August 2003.

ToxEcology, 2001. Inventory of and Technical/Socio-Economic Study for 2-Butoxyethanol and 2-Methoxyethanol. Prepared by ToxEcology-Environmental Consulting Ltd., Final Report, June 2001. pp242

ToxEcology, 2003. 2-Butoxyethanol and 2-Methoxyethanol - Current Use Patterns in Canada, Toxicology Profiles of Alternatives, and the Feasibility of Performing an Exposure Assessment Study. Prepared by ToxEcology-Environmental Consulting Ltd., Final Report, 23 May 2003. pp174

11. ANNEX 1 - Inventory of Products Containing 2-ME

The following table summarizes the use and 2-ME content of selected commercial/industrial products.

Product	Average % 2-ME	Comment
Industrial Uses		
Equistar EM solvent Lyondell Glycol Ether DM Industrial Grade and Fuel Grade	100%	Equistar is the only 2-ME producing company in the US currently (ACC Panel). Uses include process solvent, chemical intermediate,
Dow Corning A-4040 Prime Coating	0.1-1.0%	Used by rubber manufacturing company as a primer to achieve a chemical bond between rubber and metal inserts in the manufacturing of parts.
Pigment bases for coatings including wood stains	Variable 5-30%	Supplied by Polyval Coatings Inc. (Quebec). Parent company is Xymax Coating Inc. (US based)
HFDA - 1544/6522 wire and cable compounds	0.006%	Data from Union Carbide (Dow), 2001 - 2-ME is a contaminant
"UCARTHERM" Heat transfer fluid PM-6141	0.0009%	Data from Union Carbide (Dow), 2001 - product still current (CCOHS MSDS database February 2003) - 2-ME is a contaminant
Commercial or Consumer Uses		
Cleaning solvent "Dual Purpose Cleaner" for white boards	60-100%	Supplied by Visual Planning Corp. (Quebec).
Military and Private Jet Use		
Fuel system anti-icing additive for jet fuel (FSII)	90-100%	Aviation fuel for private jets/some military aircraft except Hi-Flash PRIST that contains DEGME in place of 2-ME (manufactured by PPG), Quell Aviation fuel. JP4 and JP5 specs allow 2-ME uses.
JP4 (Jet B) and JP5 jet fuels	0.1-0.2%	Specifications allow for 2-ME or DEGME. JP8 specs allow for use of DEGME only.
Other Military Uses		
Decontamination Agent DS2 Specification: MIL-D-50030H(EA)	28%	Produced by DalDen (US), Karcher (US) and All-Bann Enterprises (US).