



Government  
of Canada

Gouvernement  
du Canada

## PROPOSED RISK MANAGEMENT APPROACH

for

Methyloxirane

(Propylene Oxide)

Chemical Abstract Service (CAS) Registry Number:  
75-56-9

Environment Canada  
Health Canada

July 2008

**Canada** 

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This proposed risk management approach document builds on the previously released risk management scope document for methyloxirane, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

## **1. ISSUE**

### **1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders**

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (Ministers) to categorize all substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms, or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of “toxic” set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the mandatory information-gathering provisions under section 71 of CEPA 1999 are being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance methyloxirane, Chemical Abstract Service (CAS) Registry Number 75-56-9, referred to throughout this document by “methyloxirane,” was included in Batch 1 of the Challenge under the Chemicals Management Plan.

### **1.2 Final Screening Assessment Report Conclusion for Methyloxirane**

A Notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for methyloxirane on July 5, 2008, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that methyloxirane is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Based principally on weight-of-evidence based assessments by several international and national agencies, a critical effect for the characterization of risk to human health posed by methyloxirane is carcinogenicity, based on the observation of nasal cavity tumours in rats and mice.

Methyloxirane was also genotoxic in several *in vitro* and *in vivo* assays. Therefore, although the mode of induction of tumours has not been fully elucidated, it cannot be precluded that the tumours observed in experimental animals resulted from direct interaction with genetic material. In addition, the upper-bounding estimate of exposure via inhalation during use of consumer products containing methyloxirane may approach or exceed the critical effect level for non-cancer effects in the nasal cavity.

On the basis of the carcinogenicity of methyloxirane, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margin between estimated exposure from products and the critical effect level for non-cancer effects, it is concluded that methyloxirane be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The final screening assessment report also concluded that methyloxirane is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends. Additionally, methyloxirane does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* (Canada 2000) made under CEPA 1999. The presence of methyloxirane in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for methyloxirane, refer to the final screening assessment report, available at [http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot\\_1\\_e.html](http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_1_e.html).

### 1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of methyloxirane to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that methyloxirane meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, methyloxirane will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a lifecycle approach, to prevent or minimize its release into the environment.

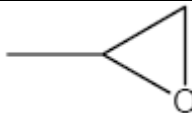
## 2. BACKGROUND

### 2.1 Substance Information

Methyloxirane is part of the chemical grouping discrete organics and the chemical sub grouping epoxides.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure, and the molecular mass for methyloxirane.

**Table 1. Identity of Methyloxirane**

CAS Registry Number	75-56-9
DSL name	Methyloxirane
Inventory names <sup>1</sup>	Oxirane, methyl-; Methyloxirane; Methyloxiranne; Propylene oxide
Other names	(±)-1,2-Epoxypropane; (±)-2-Methyloxirane; (±)-Epoxypropane; (±)-Methyloxirane; 1,2-Epoxypropane; 1,2-Propylene oxide; 2,3-Epoxypropane; AD 6; 1,2-Epoxypropane; Epihydrin; Epoxypropane; Methyl ethylene oxide; Methyloxacyclopropane; Oxypropylene; Propene oxide; Propozone; Propylene epoxide
Chemical group	Discrete organics
Chemical sub-group	Epoxides
Chemical formula	C <sub>3</sub> H <sub>6</sub> O
Chemical structure	
SMILES	O(C1C)C1
Molecular mass	58.08 g/mol

<sup>1</sup> From NCI 2007: AICS (Australian Inventory of Chemical Substances); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ELINCS (European List of Notified Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); NZIoC (The New Zealand Inventory of Chemicals).

## 3. WHY WE NEED ACTION

### 3.1 Characterization of Risk

Based principally on the weight-of-evidence based assessments of several international and national agencies (IARC, EU, US EPA and US NTP), a critical effect for characterization of risk to human health for methyloxirane is carcinogenicity, for which a mode of induction involving direct interaction with genetic material cannot be precluded.

With respect to non-cancer effects, comparison of the critical non-neoplastic effect level in chronically exposed experimental animals (i.e., 71 mg/m<sup>3</sup>) with the upper-bounding estimate of general population exposure via inhalation—the expected principal route of exposure, the estimation of which was based on detection limits in a U.S. study (i.e., 0.31 µg/m<sup>3</sup>)—results in a margin between estimated ambient exposure from the general environment and the critical effect level of approximately 229 000. However, if the conservative upper-bounding estimate of air-borne concentration during use of consumer products containing methyloxirane is considered (i.e., 200 mg/m<sup>3</sup> in paint stripper), the resulting margin between estimated exposure from this product and the critical effect level would be less than 1. If estimated exposure from products is compared to the lowest effect level for short-term repeated exposure (i.e., 362 mg/m<sup>3</sup>), which may be more appropriate in light of the infrequent use patterns for such products, the resulting margin would be approximately 2. Thus, while the margin of exposure for non-neoplastic effects is adequate for exposure in the general environment, the margin for consumer product exposure scenarios (although conservative in nature), may not be adequate to account for uncertainties in the databases on exposure and effects.

#### 4. CURRENT USES AND INDUSTRIAL SECTORS

Methyloxirane is not known to occur as a natural product. Peroxidation and chlorohydrination are the two major processes used to manufacture methyloxirane from propylene in large quantities.

According to submissions made under section 71 of CEPA 1999, from the Challenge questionnaire submission and other data voluntarily submitted (Canada 2007), as well as from other available scientific and technical literature, methyloxirane is used mainly as a monomer in polymer production of polyether polyols. Polyether polyols are used in the production of polyurethane foams for the furniture and automotive industries. Methyloxirane may also be used in the manufacture of propylene glycol, as a starch modifying agent in food, in potential food contact applications, resins, ink, synthetic lubricants and in the automotive industry as a detergent additive and corrosion inhibitor in motor fuels, gasket removers, cleaners, petroleum defoamers, fuel additives and adhesives (Dow 1981; Sack et al. 1992; Trent 2001; European Union 2002; Dow 2007). Methyloxirane has no reported uses in Health Canada's Cosmetic Notification Database (Health Canada, Cosmetics Division, Healthy Environments and Consumer Safety Branch, pers. comm., 2008 June 9, unreferenced).

Propylene glycol manufactured from methyloxirane can also be used in the production of unsaturated polyester resin especially in the textile and plastic industries, in pharmaceuticals, and aircraft de-icers (Dow 1981; Trent 2001; European Union 2002; Dow 2007). Propylene glycol is also used in the manufacture of glycol ethers, for use as solvents in paints and varnish (Trent 2001). Methyloxirane itself is also found in paint stripper (Henkel 2008).

Methyloxirane is used for fumigation of dried fruit products and as a fumigant for bulk quantities of several food products such as cocoa, spices, processed nutmeats, starch and gum in the United States (European Union 2002; US EPA 2005). However, the substance is not a registered pesticide in Canada and methyloxirane-treated food products imported into Canada are currently subject to the General Maximum Residue Limit (MRL) of 0.1 ppm under Division 15(B.15.002(1)) of Health Canada's *Food and Drug Regulations* (PMRA 2006).

Methyloxirane is an approved food additive under Health Canada's *Food and Drugs Regulations* and is subject to conditions which ensure limited use, precluding human exposure through food consumption. It is included as a preservative substance (antimicrobial) on Health Canada's Natural Health Products non-medicinal ingredient list (HPFB 2007).

## **5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES**

### **5.1 Releases to the Environment**

Methyloxirane is not manufactured for commercial purposes in quantities greater than 100 kg in Canada (Canada 2007). Domestic supply is met by imports from the United States. The Canadian National Pollutant Release Inventory reported only one emitter in Ontario in 2005. Reported releases are exclusively to air and the volume has declined from 10.4 tonnes in 1999 to 0.059 tonnes in 2005 (NPRI 2006). In recent information gathered under the *Canadian Environmental Protection Act, 1999* through a section 71 notice with respect to methyloxirane, companies reported the release of this substance in 2006 in a quantity less than 50 kg, the cut-off quantity for reporting (Canada 2007; Canada 2008).

The major source of release to the environment is through evaporation and vented gases during production of substances where methyloxirane is used as a chemical intermediate, storage, handling, transport and use. Process vents appear to be the most important sources of atmospheric pollution. Methyloxirane release may also originate from automobile exhaust and combustion exhaust from stationary sources that burn hydrocarbons. Emissions from waste gas are often removed by air scrubbing, with liquid waste being controlled by incineration (IPCS 1985; Ontario MOE 2001).

### **5.2 Exposure Sources**

No data were available for concentrations of methyloxirane in environmental media or food in Canada and little or none from other jurisdictions. However, approved use of methyloxirane as a food additive under the requirements of the *Food and Drug Regulations* precludes human exposure to methyloxirane in finished foods. The Final Screening Assessment Report predicts, based on a detection limit used as a surrogate for levels in air in the absence of measured data, that air would be the primary medium of exposure for methyloxirane. This would pertain to possible releases related to industrial facilities and exposure from certain consumer cleaning and paint products.

Estimates of exposure to consumers resulting from the use of paint stripper and acrylic aerosol spray paint were identified, as these products represent important product uses in which methyloxirane may be present as a residual. Methyloxirane is not known to occur as a natural product.

## 6. OVERVIEW OF EXISTING ACTIONS

### 6.1 Existing Canadian Risk Management

Methyloxirane is subject to

- the *Controlled Products Regulations* established under the *Hazardous Products Act*, requiring any ingredient on the Ingredient Disclosure List to be disclosed on the Material Safety Data Sheet;
- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, requiring that products be classified against criteria based on short-term exposure situations, with the results determining the appropriate product labeling and packaging requirements;
- the *Food and Drug Act* and *Food and Drugs Regulations* toward the objective of precluding human exposure in finished foods; and
- CEPA 1999's *Environmental Emergency Regulations*.

Ontario has set a 24-hour ambient air quality guideline of 1.5 µg/m<sup>3</sup> (Ontario MOE 2001).

### 6.2 Existing International Risk Management

Various U.S. states have set 24-hour guidelines for methyloxirane ranging from 6 to 30 µg/m<sup>3</sup> (Ontario MOE 2001). Austria has an occupational daily average (8-hour) guideline of 6 mg/m<sup>3</sup> in place (Austria 2001). Methyloxirane is allowed for use as a starch modifier by other international food regulatory agencies such as the United States Food and Drug Administration (U.S. FDA) (European Union 2002).

## 7. CONSIDERATIONS

### 7.1 Alternative Chemicals or Substitutes

No information is available on alternative chemicals or substitutes. Note that methyloxirane is designated as a “phase-out substance” in Sweden whereby all new products should not contain this substance (KEMI 2008).

### 7.2 Alternative Technologies and/or Techniques

No information is available on alternative technologies and/or techniques.

### 7.3 Socio-economic Considerations

Where information was available, socio-economic factors have been considered, at least in a qualitative manner, in the selection process for an instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.



## 7.4 Children's Exposure

In screening assessments, potential exposure of the general population, including infants and children, is estimated. To the extent possible, based on available data, exposure to methyloxirane from multiple routes (i.e., inhalation, ingestion and contact on the skin) and possible sources (e.g., ambient air, indoor air, drinking water, food, beverages—including breast milk and formula for infants—soil, and in some instances consumer products) is estimated. Infants and children's exposure is characterized by their unique physiology (e.g., intake of air, food and water relative to body size) and generally known behaviour characteristics (e.g., crawling versus walking, mouthing activity).

As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, and other data considered, it is proposed that no additional risk management actions to specifically protect children are required for this substance at this time.

## 8. PROPOSED OBJECTIVES

### 8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment. The proposed human health objective for methyloxirane is to minimize, to the extent practicable, exposure to methyloxirane, and hence risk to human health associated with this substance.

### 8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management tool(s) and/or instrument(s). The risk management objective is to reduce exposure to methyloxirane.

## 9. PROPOSED RISK MANAGEMENT

### 9.1 Proposed Risk Management Instrument(s) and/or Tool(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,<sup>2</sup> and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations, instrument(s) and/or tools(s) were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

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<sup>2</sup> Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for methyloxirane pertains to minimization of methyloxirane releases from consumer products, specifically paint strippers and aerosol paints. Additional actions are focused on food fumigation, food additives, food packaging, sanitizers, cleaners and disinfectants, therapeutic products, and cosmetics.

### **9.1.1 Methyloxirane in Consumer Products**

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management instrument being considered for methyloxirane involves minimization of methyloxirane releases from paint strippers, aerosol paints and similar consumer products.

### **9.1.2 Methyloxirane in Imported Nuts and Fruits**

Issues pertaining to imported fumigated nuts and fruits fall under the regulatory area of the Pest Management Regulatory Agency (PMRA) and the Canadian Food Inspection Agency (CFIA). Methyloxirane is a formulant impurity in approximately 30 pesticide products. There is currently no maximum residue limit (MRL) in Canada, but imported food should not contain more than 0.1 ppm, as per section B15.002(1) of the *Food and Drug Regulations* (PMRA 2006).

### **9.1.3 Methyloxirane as a Food Additive**

Issues pertaining to methyloxirane in food starches fall under the *Food and Drugs Act*. Health Canada's Food Laboratory Network has investigated developing a method to detect methyloxirane in food, and has confirmed that, when combined with water in the food production process, methyloxirane breaks down into non-toxic substances.

### **9.1.4 Methyloxirane in Food Packaging**

Issues pertaining to methyloxirane in food packaging fall under the *Food and Drugs Act* and *Food and Drugs Regulations*. Methyloxirane usually originates from components used in the manufacture of inks, adhesives or exterior coatings used in food packaging. After adhesives and coatings are applied and cured, only residual amounts of methyloxirane, if any, are expected to be present on the exterior surface of the finished packaging materials. Future submissions on the use of methyloxirane in packaging will be reviewed, with the goal of ensuring that residual levels in finished materials are as low as possible and therefore that potential migration of methyloxirane into food is negligible.

### **9.1.5 Methyloxirane as a Non-Active Ingredient in Sanitizers, Cleaners and Disinfectants**

Issues pertaining to sanitizers, cleaners and disinfectants that contain methyloxirane as a non-active ingredient fall under the *Food and Drugs Act*. Should an application for a Drug Identification Number for a hard surface disinfectant be filed, the sponsor will be requested to replace the substance with a suitable alternative. This substance will be removed from the list of non-medicinal ingredients in the Disinfectant Drugs Guidance Document at its next posting.

### **9.1.6 Methyloxirane as a Preservative in Natural Health Products and Drugs**

Issues pertaining to methyloxirane used as a preservative in therapeutic products fall under the *Food and Drugs Act* and *Food and Drugs Regulations*. At this time, there are no licensed or in-process natural health products containing methyloxirane. Health Canada will remove methyloxirane from the Natural Health Products Directorate database of acceptable non-medicinal ingredients. Any new products containing this ingredient will require an assessment.

### **9.1.7 Methyloxirane in Cosmetics**

Issues pertaining to methyloxirane in cosmetics fall under the *Cosmetics Regulations* of the *Food and Drugs Act*. Section 16 of the Act states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. To help cosmetic manufacturers satisfy this requirement, Health Canada has developed the Cosmetic Ingredient Hotlist—a list of substances which are restricted and prohibited in cosmetics. Methyloxirane is a monomer that is not used directly in the manufacture of cosmetics, but instead is used as a precursor for a polymer used in cosmetics. Accordingly, if present at all, it would be as residual unreacted monomers in the polymer raw materials and it is assumed that the amounts would be minimal. These polymers will therefore continue to be allowed in cosmetics. Nonetheless, Health Canada will recommend that methyloxirane, as a monomer, be added to the Cosmetic Ingredient Hotlist, which will prohibit its deliberate use in cosmetics.

## **9.2 Implementation Plan**

The proposed regulation or instrument will be published in the *Canada Gazette*, Part I, no later than July 2010, as per the timelines legislated in CEPA 1999.

Releases of methyloxirane will continue to be monitored under the National Pollutant Release Inventory. Other monitoring will be considered in order to assess the performance of the risk management instrument and to determine whether further action needs to be taken with respect to methyloxirane.

## **10. CONSULTATION APPROACH**

The risk management scope for methyloxirane, which summarized the proposed risk management under consideration at that time, was published on January 19, 2008, and is available at [www.ec.gc.ca/TOXICS/EN/detail.cfm?par\\_substanceID=236&par\\_actn=s1](http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1). Industry and other interested stakeholders were invited to submit comments on the risk

management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the risk management approach will involve publication on July 5, 2008 and a 60-day public comment period.

The primary stakeholders include

- manufacturers of foods, food packaging, cosmetics and personal care products, pharmaceuticals, natural health products, resins, latexes, inks, synthetic lubricants, adhesives, paints and coatings, textiles, plastics, automotive products, petroleum defoamers, fuel additives, and of glycol ethers for paints and varnishes; and
- Health Canada and Environment Canada.

## 11. NEXT STEPS / PROPOSED TIMELINE

<b>Actions</b>	<b>Date</b>
Electronic consultation on Proposed Risk Management Approach	July 5, 2008 to September 3, 2008
Response to comments on the Risk Management Approach	At time of publication of proposed instrument
Consultation on the draft instrument	Winter 2008–2009
Publication of the proposed instrument	No later than July 2010
Formal public comment period on the proposed instrument	No later than summer 2010
Publication of the final instrument	No later than January 2012

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to September 3, 2008, since the Government of Canada will be moving forward with the risk management of methyloxirane after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management instrument(s) and/or tool(s), there will be opportunity for further consultation on the proposed instrument(s). Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Existing Substances Division  
 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: [Existing.Substances.Existantes@ec.gc.ca](mailto:Existing.Substances.Existantes@ec.gc.ca)

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