



Government  
of Canada

Gouvernement  
du Canada

## PROPOSED RISK MANAGEMENT APPROACH

for

Benzene, (chloromethyl)-  
(Benzyl Chloride)

Chemical Abstracts Service Registry Number (CAS RN):  
100-44-7

Environment Canada  
Health Canada

November 2009

**Canada**

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This proposed risk management approach document builds on the previously released risk management scope document for Benzene, (chloromethyl)- 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 (the Ministers) to categorize 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 the Act.

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 information-gathering authority in section 71 of CEPA 1999 is 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 Benzene, (chloromethyl)-, Chemical Abstracts Service Registry Number (CAS RN)<sup>1</sup> 100-44-7 referred to throughout this document as “benzyl chloride” is included in Batch 6 of the Challenge under the Chemicals Management Plan.

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<sup>1</sup> CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

## 1.2 Final Screening Assessment Report Conclusion for Benzyl Chloride

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 benzyl chloride on November 28, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that benzyl chloride 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 and 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.

Based principally on the weight-of-evidence assessments of several international and other national agencies (International Agency for Research on Cancer, European Commission and United States Environmental Protection Agency), a critical effect for characterization of risk to human health for benzyl chloride is carcinogenicity. In the absence of a full evaluation of the mode of action for benzyl chloride, a mode of action for the induction of effects involving direct interaction with genetic material cannot be precluded. For substances for which the critical health effect is assumed to have no threshold of exposure for induction (e.g., a genotoxic carcinogen) it is assumed that there is a probability of harm to human health at any level of exposure, and it is therefore concluded that benzyl chloride meets the criteria in paragraph 64(c) of CEPA 1999.

The final screening assessment report also concluded that benzyl chloride meets the criteria for persistence in air, but does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999 (Canada 2000). The presence of benzyl chloride in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for benzyl chloride, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-6/index-eng.php>.

## 1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of 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 the Act. 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 Minister proposed to recommend the addition of benzyl chloride to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop an 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 benzyl chloride meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, benzyl chloride will not be subject to the virtual elimination provisions under CEPA 1999.

## 2. BACKGROUND

### 2.1 Substance Information

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

**Table 1. Identity of Benzyl Chloride**

<b>Chemical Abstracts Service Registry Number (CAS RN)</b>	<b>100-44-7</b>
<b>Domestic Substances List (DSL) name</b>	<b>Benzene, (chloromethyl)-</b>
<b>National Chemical Inventory names</b>	<i>Benzene, (chloromethyl)- Benzene, chloromethyl- Benzyl chloride (Chloromethyl)benzene <math>\alpha</math>-Chlorotoluene</i>
<b>Other names</b>	<i>1-Chloromethylbenzene; Chloromethylbenzene; Chlorophenylmethane; NSC 8043; Phenylmethyl chloride; Toluene, <math>\alpha</math>-chloro-; Tolyl chloride; UN 1738; UN 1738</i>
<b>Chemical group (DSL stream)</b>	Discrete organics
<b>Major chemical class or use</b>	Chlorinated organics
<b>Major chemical subclass</b>	Aromatic chlorinated organics
<b>Chemical formula</b>	$C_7H_7Cl$
<b>Molecular mass</b>	126.59 g/mol

## 3. WHY WE NEED ACTION

### 3.1 Characterization of Risk

Based principally on the weight-of-evidence assessments of international and other national agencies (International Agency for Research on Cancer, European Commission and the United States Environmental Protection Agency), a critical effect for characterization of risk to human health for benzyl chloride is carcinogenicity. Increased incidences of tumours of the thyroid, forestomach, lung, liver and circulatory system were observed in a 2-year oral study in rats and mice. Dermal application of benzyl chloride also induced skin tumours in one study in mice.

Also, epidemiological studies provided some limited evidence of respiratory and digestive system cancers in occupationally exposed humans. In light of the clear evidence in the in vitro genotoxicity assays and mixed results in the in vivo assays and the range of tumours observed in two species of experimental animals for which the modes of induction have not been elucidated, it cannot be precluded that benzyl chloride induces tumours via a mode of action involving direct interaction with genetic material.

With respect to non-cancer effects, the lowest lowest-observed-effect concentration (LOEC) for inhalation exposure (the principal route of exposure for the general population) was 62 mg/m<sup>3</sup>, based on increased relative liver weight in guinea pigs in a 27-week study, whereas the lowest lowest-observed-effect level (LOEL) for orally administered benzyl chloride was 2.7 mg/kg-bw per day for liver hyperplasia in mice exposed by gavage for 26 weeks. Comparison of these effect levels with the highest concentration of benzyl chloride measured in indoor air in Canada (i.e., 0.073 µg/m<sup>3</sup>) and upper-bounding estimates of total daily intake via environmental media (i.e., 0.04 µg/kg-bw per day) results in margins of exposure of approximately 850 000 and 67 500, respectively. However, exposures could be greater during use of consumer products containing residual benzyl chloride, with potential “per event” airborne concentrations and chronic dermal exposures being conservatively predicted to be up to 1.3 µg/m<sup>3</sup> (hair conditioner) and 0.1 µg/kg-bw per day (shower gel), respectively. Comparison of these values with the lowest inhalation LOEC and oral LOEL (as a very conservative approach in light of the lack of a dermal effect level) results in margins of exposure of approximately 48 000 and 27 000, respectively. In light of the conservative nature of these estimates, these margins are likely sufficient to be protective against the induction of non-cancer effects in the general population in Canada.

On the basis of the carcinogenicity of benzyl chloride, for which there may be a probability of harm at any level of exposure, it is proposed that benzyl chloride be considered 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.

#### **4. CURRENT USES AND INDUSTRIAL SECTORS**

Based on a Canadian survey conducted under section 71 of CEPA 1999, no company manufactured benzyl chloride at quantities greater than or equal to 100 kg in the year 2006. The total quantity imported into Canada in 2006 was reported to be in the range of 100 000–1 000 000 kg and the total quantity used in Canada was also reported to be in the 100 000–1 000 000 kg range in the same calendar year.

Benzyl chloride is used in Canada mainly as a chemical intermediate for the synthesis of quaternary ammonium compounds in which benzyl chloride may be present at very low (trace) levels as residual materials (left over from the manufacturing process). Quaternary ammonium compounds are used as active ingredients in pest control products or as surfactants in numerous products (e.g., hard surface sanitizers, corrosion inhibitors, industrial and institutional cleaners, and household and personal care products). Quaternary ammonium compounds also function as bactericides in hair care products and in architectural paints and coatings for marine yachts and industrial steel.

In pharmaceuticals, quaternary ammonium compounds are active ingredients in hard surface disinfectants and skin antiseptics; they also function as preservatives in numerous drug products. In natural health products, the quaternary ammonium compound benzalkonium chloride is a known antimicrobial preservative and is listed in the Natural Health Products Ingredients Database as an acceptable non-medicinal ingredient with specific concentration limits based on the route of administration of the product in which it is a preservative, to mitigate any possible risk to health. Only trace levels of benzyl chloride are expected in the final mixture, product or manufactured item.

Literature sources that are not specific to Canadian use indicate that benzyl chloride may also be used as a chemical intermediate for the synthesis of benzyl alcohol and benzyl butyl phthalate. Benzyl alcohol is used in a wide range of applications including pharmaceuticals, natural health products, cosmetics, flavour products, solvents and textile dyes. In the United States, benzyl alcohol is no longer produced from benzyl chloride but rather is produced from the hydrogenation of benzaldehyde. Benzyl butyl phthalate is used mainly as a plasticizer in vinyl flooring and other flexible poly(vinyl chloride) uses such as food packaging. Benzyl chloride may also be used in the manufacture of photographic developer and gasoline gum inhibitors.

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

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

While significant amounts of benzyl chloride are used in the manufacture of other chemicals, industrial emissions are low. Under the National Pollutant Release Inventory, industrial facilities in Canada reported a release of 5 kg and 1 kg of benzyl chloride to air in the years 2000 and 2006, respectively. No releases to water or land have been reported (NPRI 2006).

Non-Canadian literature sources indicate that benzyl chloride may be released into the atmosphere during the burning of fossil fuels; however, Canadian studies have shown that no significant quantities of benzyl chloride were released from industrial facilities of coal-fired power plants, iron and steel facilities, landfills, and solid and hazardous waste incinerator sites. Recent Canadian measurement data of ambient (outdoor) and indoor air were also low.

### **5.2 Exposure Sources**

No monitoring data for benzyl chloride in drinking water, food, or soil were identified. Concentrations in these media are likely to be negligible. The principal route of exposure for the general population is likely through inhalation.

Benzyl chloride does not appear to be directly used as an ingredient in consumer products including cosmetics, but may be present indirectly as a residual. Exposures of the Canadian general population due to the use of products containing residual quantities of benzyl chloride (e.g., hair conditioner) are predicted to be low.

## 6. OVERVIEW OF EXISTING ACTIONS

### 6.1 Existing Canadian Risk Management

Benzyl chloride is subject to the following:

- the *Transport of Dangerous Goods Regulations* (Transport Canada 2008)
- the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999 (Canada 2005)
- the *Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals* (Canada 2007a)
- the *Controlled Products Regulations* established under the *Hazardous Products Act*, requiring any chemical ingredient on the Ingredient Disclosure List to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals if present above a certain prescribed concentration (Canada 1988)
- the Pest Management Regulatory Agency's List of Formulants as a List 2 formulant in pest control products (Canada 2007b)
- reporting under the National Pollutant Release Inventory (NPRI 2006)
- the *Airborne Contaminant Discharge Monitoring and Reporting Regulation* of Ontario (Ontario MOE 2006)
- provincial occupational regulations

### 6.2 Existing International Risk Management

Benzyl chloride is subject to the following

- *Transport of Dangerous Goods* (Europe) (European Commission 2004a, b)
- *Resource Conservation and Recovery Act* (U.S.): Benzyl chloride waste must be managed according to federal and/or state hazardous waste regulations (US EPA 2001)
- *Emergency Planning and Community Right-to-Know Act* (U.S.): Releases above 100 lbs require reporting to state and local governments. Emergency planning activities are required if the presence of the substance is above the threshold planning quantity of 500 lbs (US EPA 2001)
- *Comprehensive Environmental Response, Compensation, and Liability Act* (U.S.): Releases above 100 lbs require reporting to national governments (US EPA 2001)
- Air Pollution Control Law (Japan): Hazardous air pollutant (NITE 2002)
- *Controlled Substances Act* (U.S.): List II substance – chemical used in the manufacturing of a controlled substance (US DEA 2001)
- Directive 2004/93/EC amending Directive 76/768/EEC (Europe): Substance prohibited in cosmetic products due to European Commission classification as a category 2 carcinogen (European Council 1976)
- Environmental quality objective (Sweden): All newly produced articles should not contain “phase-out” substances. Benzyl chloride is a “phase-out” substance due to classification by the European Commission as a category 2 carcinogen (KEMI 2006)



## **7. CONSIDERATIONS**

### **7.1 Alternative Chemicals or Substitutes**

No information on potential substitutes for benzyl chloride was brought forward in the voluntary Challenge Questionnaire submissions or during the public comment period on the Risk Management Scope document.

### **7.2 Alternative Technologies and/or Techniques**

No alternative technologies and/or techniques were identified which would minimize or eliminate the use and/or release of the substance.

### **7.3 Socio-economic Considerations**

Socio-economic factors will 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**

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. 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, it is proposed that no 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 benzyl chloride is to minimize human exposure to the greatest extent practicable.

## 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 regulations, instrument(s) and/or tool(s).

As the current exposures of Canadians to benzyl chloride were considered to be negligible under the current use conditions, the risk management objective is to prevent increases in exposure.

## 9. PROPOSED RISK MANAGEMENT

### 9.1 Proposed Risk Management Tools

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 tools were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for benzyl chloride is the requirement for notification of the federal government regarding any potential changes in the use pattern for benzyl chloride so that the potential for exposure to the Canadian population does not substantially increase.

Additionally, the Government will add benzyl chloride to the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

The Government has also assessed benzyl chloride in the event that it were to enter the environment as a result of an environmental emergency and has concluded that the substance meets one of the criteria set out in section 200 of CEPA 1999. Therefore, the Government intends to propose adding benzyl chloride to the *Environmental Emergency Regulations* with a proposed threshold of 4500 kg set through the Risk Evaluation Framework for sections 199 and 200 of CEPA 1999 (Environment Canada 2002).

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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".

## 9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to benzyl chloride will be published in the *Canada Gazette*, Part I, no later than November 2011, as per the timelines legislated in CEPA 1999.

## 10. CONSULTATION APPROACH

The risk management scope for benzyl chloride, which summarized the proposed risk management under consideration at that time, was published on May 30, 2009. 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 document will involve publication on November 28, 2009, and a 60-day public comment period.

The primary industry stakeholders include

- the cosmetics industry
- manufacturers of benzyl chloride based quaternary ammonium compounds

## 11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Consultation on proposed risk management approach	November 28, 2009, to January 27, 2010
Response to comments on the risk management approach	At the time of publication of the proposed instrument
Consultation on the draft instrument	Fall 2010
Publication of the proposed instrument	No later than November 2011
Formal public comment period on the proposed instrument	No later than January 2012
Publication of the final instrument	No later than May 2013

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 January 27, 2010, since the risk management of benzyl chloride will be moving forward after this date. During the development of regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division  
Gatineau Quebec K1A 0H3  
Tel: 1-888-228-0530 / 819-956-9313  
Fax: 819-953-7155  
Email: [Existing.Substances.Existantes@ec.gc.ca](mailto:Existing.Substances.Existantes@ec.gc.ca)

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