



Government  
of Canada

Gouvernement  
du Canada

# PROPOSED RISK MANAGEMENT APPROACH

for

1,2-Benzenediol

(Catechol)

Chemical Abstract Service (CAS) Registry Number:  
120-80-9

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 catechol, 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 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 1,2-benzenediol, Chemical Abstract Service (CAS) Registry Number 120-80-9, referred to throughout this document by “catechol,” was included in Batch 1 of the Challenge under the Chemicals Management Plan.

### 1.2 Final Screening Assessment Report Conclusion for Catechol

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 catechol on July 5, 2008, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that catechol 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 other agencies, a critical effect for the characterization of risk to human health is carcinogenicity, based on observation of tumours, including tumours in the glandular stomach in rats chronically exposed to the substance. Catechol was 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.

On the basis of the carcinogenicity of catechol, for which there may be a probability of harm at any level of exposure it is concluded that catechol is 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 (Canada 2008a).

The final screening assessment report also concluded that catechol 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 catechol in the environment does not result primarily from human activity.

For further information on the final screening assessment report conclusion for catechol, refer to the final screening assessment report, available at [http://www.chemicalsubstanceschemiques.gc.ca/challenge-defi/batch-lot\\_1\\_e.html](http://www.chemicalsubstanceschemiques.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 catechol 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 catechol meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, catechol 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.

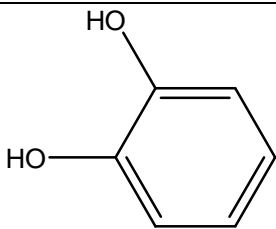
## 2. BACKGROUND

### 2.1 Substance Information

Catechol is part of the chemical grouping discrete organics and the chemical sub-grouping phenols.

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

**Table 1. Identity of Catechol**

CAS Registry Number	120-80-9
DSL name	1,2-Benzenediol
Inventory names <sup>1</sup>	1,2-Benzenediol (TSCA, DSL, ENCS, AICS, ECL, SWISS, PICCS, ASIA-PAC, NZIoC); Pyrocatechol (DSL, EINECS, PICCS); Catechol (PICCS); Pyrocatechin (PICCS)
Other names	Catechol, 1,2-Benzoldiol; 1,2-Dihydroxybenzene; 2-Hydroxyphenol; C.I. 76500; C.I. Oxidation Base 26; Durafur Developer C; Fouramine PCH; Fourrine 68; NSC 1573; o-Benzenediol; o-Dihydroxybenzene; o-Dioxybenzene; o-Hydroquinone; o-Hydroxyphenol; o-Phenylenediol; Oxyphenic acid; Pelagol Grey C; Phthalhydroquinone; Phthalic alcohol; Pyrocatechine; UN 2811
Chemical group	Discrete organics
Chemical sub-group	Phenols
Chemical formula	C <sub>6</sub> H <sub>6</sub> O <sub>2</sub>
Chemical structure	
SMILES	<chem>Oc(c(O)ccc1)c1</chem>
Molecular mass	110.11 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 on the weight-of-evidence based assessment by IARC, a critical effect for characterization of risk to human health is carcinogenicity, for which a mode of induction involving direct interaction with genetic material cannot be precluded.

With respect to non-cancer effects, the lowest dietary lowest-observed-effect level (LOEL) in the database is 33 mg/kg-bw/day based on effects in the stomach (the apparent target organ) of rats. Given that the predominant source of exposure to the general population is through the naturally occurring presence of catechol in foods and beverages, derivation of a margin of exposure between effect levels in experimental animals and upper-bounding estimates of exposure to the general population would not be meaningful. For non-cancer effects, the incremental risk associated with catechol in environmental media resulting from its industrial uses is considered to be negligible (Canada 2008a).

One consumer product use was identified (i.e., photographic developer). When air concentrations resulting from this use ( $0.023 \text{ mg/m}^3$ ) are compared to the only inhalation no-observed-effect concentration (NOEC) in the database ( $1500 \text{ mg/m}^3$ ), the margin of exposure is approximately 65 200. Dermal exposure may contribute to total exposure if gloves and/or tongs are not used as recommended on product labels. This margin is considered adequate to account for uncertainties in the databases on exposure and effects.

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

According to submissions made under section 71 of CEPA 1999, catechol is used as a photographic developer, and in various applications that would not result in exposure to the general population (Canada 2007a). Based on voluntary data submitted by industry to Environment Canada, it is also used in small quantities as a laboratory reagent for raw material testing in the pharmaceutical industry (Canada 2007b), and is used as an antioxidant in electroplating baths where it is completely destroyed (oxidized) during the process (Canada 2007c).

This substance is currently listed (as pyrocatechol) on Health Canada's Cosmetic Ingredients Hotlist prohibiting its use in all cosmetic products (Health Canada 2007). However, it may be used elsewhere, and has been used in the past as an oxidizing agent in hair colorants (Winter 2005) and as an antioxidant for perfumes and essential oils (Ash and Ash 2002).

In Canada, catechol is not registered as an active ingredient in pest control products, nor is it present as a formulant in pest control products (PMRA 2007a; PMRA 2007b).

Other potential or historical uses of catechol include its use as a developer in fur dyes (HSDB 2006), as an intermediate for antioxidants in rubber and lubricating oils, in polymerization inhibitors, and in pharmaceuticals (US EPA 2000). Catechol may also be used as a reagent, in the synthesis of adhesives, in fax papers, and in specialty inks (IARC 1999; Ash and Ash 2002).

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

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

Information reported under section 71 of CEPA 1999 indicated that 100 to 1 000 kg of catechol were released into the environment in 2006. The U.S. Toxic Release Inventory reports that most of their catechol releases are mainly to water. The section 71 respondents reported that various kraft paper production mills across Canada had a combined catechol production of over nearly 1 500 tonnes. Polyphenolic compounds such as catechol are a natural component of wood and are extracted as part of the black liquor during the kraft pulping process. This quantity was not released into the environment but was consumed with the black liquor stream in heat recovery boilers.

Catechol is reportable under the National Pollutant Release Inventory (NPRI). Since 1994 there have been few releases of catechol—on-site air emissions in 2001 as a result of a spill, and in 2003, 150 kg were sent to an off-site landfill (NPRI 2006).

### **5.2 Exposure Sources**

The draft screening assessment report for catechol notes that oral intake is the primary route of catechol exposure for the general population. The primary oral intake source for the general public would be from consuming naturally occurring catechol in fruits, vegetables and beverages, which accounts for the vast majority of all potential exposure to catechol. It is also produced endogenously and is naturally released from certain trees such as Douglas-fir, oak and willow (Canada 2008b).

The upper-bounding estimate of daily intake for the general Canadian population ranges from 0.02 µg/kg-bw per day for formula-fed infants (0 to 6 months old) to 847 µg/kg-bw per day for adults (20–59 years of age), with intakes from food and beverages representing the highest source of exposure. Other than the presence of catechol in meats and poultry (from smoke condensate), the sources of catechol in food and beverages are considered to be naturally occurring (Canada 2008b).

Contributions to general population exposure from other media (air, water and soil) from manufacturing and industrial uses of catechol are considered to be negligible in comparison to intake from food and beverages. Inhalation and dermal exposure to catechol may occur during careless handling of specialized developer chemicals used for processing black-and-white film in hobby darkrooms. Catechol has also been detected in cigarette smoke and wood smoke (Canada 2008b).

Catechol is found to occur naturally in the tannin layer of mycorrhiza of the Douglas-fir; in the leaves and branches of oak and willow; and in various food items such as apples, potatoes and refined olive oil (Brenes et al. 2004; Sternitzke et al. 1992; McDonald et al. 2001).

Based on a survey made under section 71 of CEPA 1999, the total quantity of catechol that was manufactured and/or imported into Canada in 2006 ranged between 1 000 000 and 10 000 000 kg (Canada 2007a). Most of the catechol manufactured in Canada is generated as a

by-product of kraft pulp production and is present in black liquor, an internal process stream (Canada 2007a). According to the National Council for Air and Stream Improvement (NCASI 2007), catechol is virtually destroyed during the recovery process (i.e., through combustion). Catechol has been identified in cigarette smoke (Roemer et al. 2004) and wood smoke (Fine et al. 2001; Fine et al. 2002). Another source of catechol in humans is from the metabolism of benzene (Medeiros and Bird 1997).

## **6. OVERVIEW OF EXISTING ACTIONS**

### **6.1 Existing Canadian Risk Management**

Catechol is subject to

- reporting under the *National Pollutant Release Inventory*;
- 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 Regulations* – Cosmetics Ingredients Hotlist; and
- the *Tobacco Reporting Regulations* – Determination of Phenolic Compounds in Tobacco Smoke.

### **6.2 Existing International Risk Management**

Catechol is listed on the U.S. *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory. Catechol is designated as a hazardous air pollutant (HAP) by the U.S. Environmental Protection Agency (EPA). It is also listed on California's Known Carcinogens and Reproductive Toxicants list. There are currently no international risk management measures in place to control for catechol.

## **7. CONSIDERATIONS**

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

There are alternative chemicals to the use of catechol for black-and-white photographic development. However, these alternatives may not provide the same desired artistic effects as the catechol-based developer solutions for particular uses. As this specialized discretionary market is artistic in nature and highly technical, it is uncertain as to what impact control measures would have on this community.

For certain industrial uses, a major alternative replacement chemical for catechol is hydroquinone. As hydroquinone is also being managed under the Chemicals Management Plan, it would not be considered a suitable replacement. Due to the complex nature of some of the



industrial uses for catechol, it is unknown whether there are suitable replacements for all applications.

It is important to note that these substitutes have not undergone an assessment to determine whether they meet the section 64 criteria under CEPA 1999.

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

The rise of digital photography, Web publishing and home printing is quickly replacing the home darkroom for photographers wishing to do custom black-and-white photography in Canada. However, there is a very small segment of the artistic photographic community which occasionally desires certain effects for black-and-white photographs. These effects are not yet possible with digital technology. The market for do-it-yourself darkroom photochemicals is gradually shrinking and this trend is expected to reduce what little exposure to these chemicals there may currently be.

## **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*.

As no additional risk management actions are proposed under CEPA 1999, socio-economic considerations are considered to be negligible.

## **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 catechol from multiple routes (i.e., inhalation, ingestion and contact on the skin) and possible sources (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.

As the primary source of exposure for the general public would be from consuming naturally occurring catechol in fruits, vegetables and beverages, the proposed human health objective for catechol is to minimize exposure to and hence risk to human health associated with exposure to catechol to the extent practicable from other, non-naturally occurring sources.

### **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 proposed risk management objective is to prevent increases in exposure to catechol from non-naturally occurring sources.

## **9. PROPOSED RISK MANAGEMENT**

### **9.1 Proposed Risk Management Instrument(s) and/or 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 regulations, instrument(s) and/or tools 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.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for catechol pertains to a requirement for notification of the federal government regarding any proposed future uses.

#### **9.1.1 Future Uses of Catechol**

It is proposed to create a provision whereby any proposed future uses of catechol would be subject to federal government notification.

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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".

### 9.1.2 Pulp and Paper Sector

Many tonnes of catechol are produced each year by pulp and paper mills in Canada as part of the black liquor extracted from wood pulp. Black liquor is an internal process stream that is not released to the environment, but rather is burned in special boilers to recover energy and certain chemicals used in the pulping process. While some catechol does enter the pulp and paper mill sewers through losses of pulping liquor, this catechol is typically removed in the wastewater treatment system. The release of pulp and paper mill effluent is governed by several previously existing acts (i.e., CEPA 1999, the *Fisheries Act*). This sector will therefore not be a candidate for risk management of catechol under CEPA 1999.

### 9.1.3 Industrial Use Sector

Industrial chemical uses are governed under provincial health and safety regulations and all workplace chemicals must comply with the *Controlled Products Regulations*, which include Workplace Hazardous Materials Information System (WHMIS) labelling, supply of Material Safety Data Sheets (MSDS). In addition, it is proposed to create a provision whereby any proposed use of catechol above a specific level in a manufacturing application would require that the federal government be notified.

### 9.1.4 Cosmetics Sector

Issues pertaining to catechol in cosmetics fall under the regulatory area 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. Catechol is on the Hotlist as a prohibited ingredient (listed as pyrocatechol) and is not to be used in cosmetics sold in Canada. As Health Canada already prohibits the use of catechol in cosmetics, this sector will not be a candidate for risk management of catechol under CEPA 1999.

### 9.1.5 Adhesives Sector

The minute concentrations of catechol as currently employed in the adhesives industry in specialty adhesives are trapped in the cured adhesive matrix and are not readily absorbed through the skin based on modelled exposure studies (Canada 2008). As there is negligible exposure to catechol through adhesives, this sector will not be a candidate for risk management of catechol.

### 9.1.6 Photographic Sector

Photographic chemicals are used by professional, artistic and hobby photographers and when purchased at retail, would be required to have appropriate short-term exposure labelling in accordance with the *Consumer Chemicals and Containers Regulations, 2001*. This labelling helps to reduce unintentional short-term incidents, but will have an impact on long-term exposure as well if the user follows the safety warnings and uses the appropriate protective equipment. Therefore the Government of Canada considers that the risks posed by catechol in photographic chemicals are already appropriately regulated under the *Hazardous Products Act*.

### 9.1.7 Foods and Beverages

The screening assessment report for catechol notes that oral intake is the primary route of exposure for the general population. The primary oral intake source for the general public is from the consumption of foods such as apples, potatoes, refined olive oil and smoked meats. Food and beverages are identified as the major source of exposure to catechol for the general population of Canada, making up over 99% of the total intake for all age groups. Catechol has also been detected in cigarette smoke and wood smoke. There is currently no evidence to indicate that the natural occurrence of catechol in staple food such as fruits and vegetables poses a risk to Canadian consumers. Fruits and vegetables are known to contain various naturally occurring substances which have been linked to important health benefits. Consumers are encouraged to continue to eat fruits and vegetables as recommended in Canada's Food Guide. Catechol may also be present as a naturally occurring substance in natural health products. As catechol is a normal constituent in whole foods and is present in low concentrations, foods and beverages will not be a candidate for risk management under CEPA 1999.

### 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 catechol will continue to be monitored under the National Pollutant Release Inventory.

## 10. CONSULTATION APPROACH

The risk management scope for catechol, which summarized the proposed risk management under consideration at that time, was published on January 19, 2008, and is available at [http://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

- the chemical manufacturing industry
- Fisheries and Oceans Canada

## 11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Risk Management Approach published on-line	July 5, 2008
60-day public comment period	July 5, 2008 to Sept. 3, 2008
Response to comments on the Risk Management Approach	Winter 2008–2009
Consultation on the draft instrument	Winter 2009–2009
Publication of the proposed instrument	No later than July 2010
Formal public comment period on the proposed instrument	No later than July–August 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 catechol 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 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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