



Government  
of Canada

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du Canada

## **Risk Management Scope**

**for**

## **Phenol, 4-chloro-3-methyl (Chlorocresol)**

**Chemical Abstracts Service Registry Number  
59-50-7**

Environment and Climate Change Canada

Health Canada

July 2019

**Canada**The wordmark for Canada, with a small red maple leaf icon integrated into the letter 'a'.



## Summary of Proposed Risk Management

This document outlines the risk management options under consideration for phenol, 4-chloro-3-methyl, commonly known as chlorocresol. In particular, the Government of Canada is considering:

1. Communicating measures to reduce exposures to chlorocresol from certain cosmetics by describing chlorocresol as prohibited or restricted ingredients on the Health Canada Cosmetic Ingredient Hotlist; and
2. Communicating measures to reduce exposures to chlorocresol from certain natural health products and non-prescription drug products by modifying the existing entry(ies) in the Natural Health Products Ingredients Database and impacted monographs; and
3. Applying Significant New Activity (SNAc) provisions under *Canadian Environmental Protection Act, 1999* (CEPA) to chlorocresol that would require any proposed new manufacture, import or use of natural health products and pharmaceutical products containing this substance to be subject to further assessment and potential risk management.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

**Note:** The above summary is an abridged list of options under consideration to manage this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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# 1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment, to human health or both the environment and human health as set out in section 64 of CEPA,<sup>1,2</sup> and, if so, to manage the associated risks.

The substance phenol, 4-chloro-3-methy, Chemical Abstracts Service Registry Number (CAS RN)<sup>3</sup> 59-50-7, is part of the Government of Canada's Chemicals Management Plan (CMP) (Canada 2019).

## 2. Issue

### 2.1 Draft screening assessment conclusion

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment relevant to the evaluation of chlorocresol in Canada. A notice summarizing the scientific considerations of the draft screening

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<sup>1</sup> Section 64 [of CEPA]: *For the purposes of [Parts 5 and 6 of CEPA], except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- (a) *have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- (b) *constitute or may constitute a danger to the environment on which life depends; or*
- (c) *constitute or may constitute a danger in Canada to human life or health.*

<sup>2</sup> A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

<sup>3</sup> CAS RN: 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.

assessment for this substance was published in the *Canada Gazette*, Part I, on July 27, 2019 (Canada 2019).

Based on the information available, the draft screening assessment proposes to conclude that chlorocresol is harmful to human health under section 64(c) of CEPA because it is 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 2019).

It is proposed that chlorocresol 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 under paragraphs 64(a) or 64(b) of CEPA, respectively (Canada 2019).

The exposure sources of concern for chlorocresol, as identified in the draft screening assessment, are dermal exposures to certain cosmetics such as moisturizer creams/lotions due to the greater potential for exposure to chlorocresol from these product types as they are typically applied in greater quantities per application, and used daily (Canada 2019). Dermal exposures to certain topical natural health products or pharmaceuticals were also identified, but were not considered a concern as their applications are intermittent use for treatment of skin conditions (Canada 2019).

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft screening assessment are preliminary and may be subject to change. Please refer to the [draft screening assessment for chlorocresol](#), for further information.

## **2.2 Proposed recommendation under CEPA**

Based on the findings of the draft screening assessment conducted pursuant to CEPA, the ministers will consider proposing to recommend that chlorocresol be added to the *List of Toxic Substances* in Schedule 1 of the Act.<sup>4</sup>

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and Risk Management Scope document in the preparation of the final screening assessment and Risk Management Approach document, if required. If it is concluded that chlorocresol meets one or more of the criteria under section 64 of CEPA at the time of the final screening assessment and the ministers recommend the addition of chlorocresol to Schedule 1, risk management

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<sup>4</sup> When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

instrument(s) will be proposed within 24 months of the date on which the final screening assessment is published and will be finalized within 18 months of the date on which the risk management instrument(s) are proposed.

### **3. Proposed risk management**

#### **3.1 Proposed human health objective**

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

The proposed human health objective for chlorocresol is to reduce exposures to chlorocresol for the general population as well as for identified vulnerable populations, specifically infants and children, to levels that are protective of human health.

#### **3.2 Proposed risk Management objective and options under consideration**

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances.

In the case of chlorocresol, the proposed risk management objective is to reduce exposures to chlorocresol for the general population as well as for identified vulnerable populations, specifically infants and children, in certain cosmetic products, natural health products, and pharmaceutical products to levels which are protective of human health.

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management options under consideration are:

- (1) Communicating measures to reduce exposures to chlorocresol from certain cosmetics by describing chlorocresol as prohibited or restricted ingredients on the Health Canada Cosmetic Ingredient Hotlist; and
- (2) Communicating measures to reduce exposures to chlorocresol from certain natural health products and non-prescription drug products by

- modifying the existing entry(ies) in the Natural Health Products Ingredients Database and impacted monographs; and
- (3) Apply the Significant New Activity (SNAc) provisions under CEPA to chlorocresol that would require any proposed new manufacture, import or use of certain natural health products and pharmaceutical products to be subject to further assessment and potential risk management.

The proposed risk management objectives and proposed options under consideration are intended to address risks identified in the draft screening assessment for the general population as well as for identified vulnerable populations, specifically infants and children.

Following the publication of this Risk Management Scope document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process.<sup>5</sup> The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

### **3.3 Risk management information gaps**

Interested stakeholders are invited to provide further information, to inform risk management decision-making for chlorocresol:

- 1. Changes to chlorocresol use patterns and economic impacts:**
  - Anticipated economic impacts if the import and/or use of chlorocresol is prohibited or restricted in certain applications in Canada; and
  - Ongoing or anticipated changes in use of chlorocresol.
- 2. Chemical and non-chemical alternatives to chlorocresol:**
  - Details on chemical alternatives and/or technologies to chlorocresol and their feasibility, as applicable to Canadian importers.

Should stakeholders have further information to help address these gaps, they should provide it to the contact identified in section 8 of this document on or before September 24, 2019 to inform the risk management decision-making process.

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<sup>5</sup> The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and will take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), the Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada 2015).

## **4. Background**

### **4.1 General Information on phenol, 4-chloro-3-methyl**

Chlorocresol was included in a survey issued pursuant to a notice under section 71 of CEPA (Canada 2012). In Canada, chlorocresol was not reported to be manufactured above the reporting threshold of 100 kg during the 2011 calendar year, while total import quantities were reported to be in a range of 100 to 1000 kg, for commercial uses as an admixture to concrete (Environment Canada 2013).

### **4.2 Current uses and identified sectors**

Chlorocresol is reported to be used in Canada as an ingredient in certain cosmetics like body moisturizer creams/lotions, as a non-medicinal ingredient in a limited number of natural health products and as a medicinal ingredient in pharmaceutical products including topical creams to treat temporary skin irritations. Chlorocresol is a registered active ingredient in pest control products in Canada. Chlorocresol may also be used in Canada as a component in incidental additives (lubricants) used in food processing facilities with the potential for food contact; however, exposure is considered negligible (Canada 2019).

## **5. Exposure sources and identified risk**

According to the draft screening assessment, in Canada individuals may be exposed to chlorocresol via exposure to body moisturizer creams/lotions. The critical health effect for chlorocresol was identified as decreased absolute adrenal organ weights in a chronic exposure study conducted on rats. A comparison of estimated exposure to chlorocresol from its use in cosmetics, such as body lotions, to the critical health effect level resulted in margins of exposure (MOEs) which were considered inadequate to address uncertainties in the health effects and exposure databases (Canada 2019) for the general population as well as for identified vulnerable populations, specifically infants and children.

With respect to dermal exposure to chlorocresol from the use of topical natural health products or pharmaceuticals, a comparison of the estimated exposure to the critical effect level resulted in MOEs that are considered adequate to address uncertainties in the health effects and exposure databases (Canada 2019) for the general population as well as for identified vulnerable populations, specifically infants and children.

## **6. Risk management considerations**

### **6.1 Alternatives and alternate technologies**

No information on alternatives to chlorocresol was identified. As stated above, chlorocresol is used in a variety of cosmetic, natural health and pharmaceutical products including topical creams to treat temporary skin irritations, and in body moisturizer creams/lotions. Chlorocresol is commonly used as a preservative (CIR 1997). In general, there are products available that do not contain chlorocresol for each of these product categories. If more specific information on alternatives or to specific need for chlorocresol is known, we ask that stakeholders please submit this information.

### **6.2 Socio-economic and technical considerations**

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(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 Regulatory Management* (TBS 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

## **7. Overview of existing risk management**

### **7.1 Related Canadian risk management context**

Existing risk management for chlorocresol in Canada relates to its presence in natural health products, food, pharmaceuticals, and pesticides, and is summarized below:

- Chlorocresol is in the Licensed Natural Health Products Database being present as a non-medicinal ingredient in topical creams used to treat temporary skin irritations in Canada (Canada 2019).
- Incidental additives are subject to section 4(1)(a) of the *Food and Drugs Act*, which stipulates that “No person shall sell an article of food that has in or on it any poisonous or harmful substance”.
- Medicinal ingredient in a veterinary drug and non-medicinal ingredient in topical creams to treat temporary skin irritations (Canada 2019)

- Chlorocresol is an active ingredient in certain pest control products registered for material preservative uses under the authority of the *Pest Control Products Act* (Canada 2019).

## **7.2 Pertinent international risk management context**

Internationally, there are risk management measures in place for chlorocresol in cosmetics, food, and pesticides as summarized below:

- In Japan, chlorocresol is restricted to a maximum amount of 0.50g/100g in all types of cosmetics as per Japan's Standards for Cosmetics (Japan 2000).
- The European Commission has a restriction in place for chlorocresol in cosmetics. The ingredient is not to be used in products applied on mucous membranes and is restricted to a maximum concentration in ready for use preparation of 0.2% in other cosmetic products (CosIng 2016).
- The European Commission has chlorocresol listed as an active pesticide substance (EC 2004).
- Chlorocresol is a registered active ingredient for pesticides in the United States (USEPA 1997).
- Chlorocresol is subject to the U.S. Food and Drug Administration (FDA) Code of Federal Regulations Title 21, Indirect Additives used in Food Contact Substances under section 175.105 (Adhesives), section 176.200 (Defoaming agents used in coatings), section 176.210 (Defoaming agents used in the manufacture of paper and paperboard), and section 178.3120 (Animal glue) (U.S. FDA 2018a).
- Chlorocresol is also listed in the US FDA Inventory of Effective Food Contact Substance (FCS) Notifications for use as an antimicrobial preservative in lubricants with incidental food contact (U.S. FDA 2018b).

## **8. Next Steps**

### **8.1 Public comment period**

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (such as outlined in sections 3.2). Please submit additional information and comments prior to September 24, 2019. The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as

the final screening assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada  
 Chemicals Management Division  
 Gatineau Quebec K1A 0H3  
 Tel: 1-800-567-1999 | 819- 938-3232  
 Fax: 819-938-5212  
 Email: [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca)

Companies that have a business interest in chlorocresol are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding chlorocresol and may be contacted for further information.

## 8.2 Timing of actions

<b>Action</b>	<b>Date</b>
Electronic consultation on the Risk Management Scope	July 27, 2019 to September 24, 2019
Submission of additional studies or information on chlorocresol	on or before September 24, 2019
Publication of responses to public comments on the draft screening assessment and Risk Management Scope	on or before Fall 2020
Publication of the final screening assessment and, if required, the Risk Management Approach document	on or before Fall 2020
Publication of responses to public comments on the Risk Management Approach, if applicable, and publication if required, of the proposed instrument(s)	24-months from the publication of the final screening assessment
Consultation on the proposed instrument(s), if required	60-day public comment period starting upon publication of the proposed instrument(s)
Publication of the final instrument(s), if required	18-months from the publication of the proposed instrument(s)

## References

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[Japan] Ministry of Health and Welfare. 2000. [Standards for Cosmetics](#).

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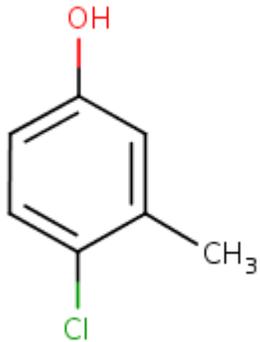
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[USEPA] United States Environmental Protection Agency. 1997. [Reregistration Eligibility Decision \(RED\) \[PDF\]](#). P-chloro-m-cresol. Prevention, Pesticides and Toxic Substances (7508W). EPA-738-R-96-008.

[U.S. FDA]. U.S. Food and Drug Administration. 2018a. [CFR – Code of Federal Regulations Title 21](#).

US FDA] US Food and Drug Administration. 2018b. [revised as of 2018 Jun 20]. [Inventory of Effective Food Contact Substance \(FCS\) Notifications](#).

## Appendix A. Substance targeted for risk management

CAS RN	DSL name	Common Name	Chemical structure and molecular formula <sup>a</sup>	Molecular weight (g/mol) <sup>a</sup>
59-50-7	Phenol, 4-chloro-3-methyl	Chlorocresol	 C <sub>7</sub> H <sub>7</sub> ClO	142.58

<sup>a</sup>ChemIDPlus 2018, USEPA 1997