Risk Management Approach

for

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

Chemical Abstracts Service Registry Number (CAS RN):

59-50-7

Environment and Climate Change Canada

Health Canada

May 2021

Summary of Proposed Risk Management

This document outlines the proposed risk management options for phenol, 4-chloro-3-methyl, commonly known as chlorocresol. In particular, the Government of Canada is proposing the following risk management action to address human health concerns:

> Measures to reduce exposures to chlorocresol from body lotion by describing chlorocresol as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

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

Note: Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management action may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

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

The substance phenol, 4-chloro-3-methyl, Chemical Abstracts Service Registry Number (CAS RN)[3] 59-50-7, referred to throughout this document as chlorocresol (See Appendix A), is included in the CMP.

2. Issue

2.1 Screening Assessment Report Conclusion

Health Canada and Environment and Climate Change Canada conducted a screening assessment of chlorocresol in Canada. A notice summarizing the scientific considerations of the screening assessment for this substance was published in the *Canada Gazette*, Part I, on May 22, 2021 (Canada 2021).

On the basis of information available, the screening assessment concludes 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

[1] 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.*

[2] 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.

[3] 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.

constitute or may constitute a danger in Canada to human life or health (Canada 2021).

It is concluded 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 sections 64*(a)* or *(b)* of CEPA, respectively (Canada 2021).

It has also been determined that chlorocresol does not meet the persistence or bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

The exposure sources of concern for chlorocresol, as identified in the screening assessment, are dermal exposures to certain body lotions (Canada 2021). 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 2021). Compared to the natural health products or pharmaceuticals identified as containing chlorocresol, a greater potential for exposure to chlorocresol is expected to result from its use in body lotions, as they are typically applied in greater quantities per application, and are used daily (as opposed to intermittent use for treatment of a skin condition).

Please refer to the screening assessment for chlorocresol for further information.

2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment, the ministers recommend that chlorocresol be added to the List of Toxic Substances in Schedule 1 of the Act[4] as per section 77(2) of CEPA. According to section 91 of CEPA, a proposed regulation or instrument establishing “preventative control actions” must be published in the *Canada Gazette*, Part I, within 24 months of the recommendation to add the substance to Schedule I. Once proposed, the ministers have a further 18 months to finalize the regulation or instrument (Environment Canada, 2004). If needed, additional regulations or instruments can be developed within that period or afterwards.

[4] 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 substance, 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.

2.3 Public Comment Period on the Draft Screening Assessment and the Risk Management Scope

The draft screening assessment for chlorocresol and its associated Risk Management Scope document summarizing the proposed risk management options under consideration at that time were published on July 27, 2019 (Canada 2019). Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period. Comments received on the draft screening assessment and the Risk Management Scope were taken into consideration in the development of this document. A summary of responses to public comments received is available.

3. Proposed Risk Management

Section 3 presents the health and risk management objectives, as well as the proposed action to achieve them. For more information on the context and rationale for this action, please consult sections 4 and 5.

Following the publication of this Risk Management Approach document, additional information submitted during the public comment period or obtained from other sources will be considered, along with the information presented in this document, during the instrument(s) selection and development process[5]. The risk management action outlined in this document may evolve through consideration of assessments and risk management actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

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 to levels that are protective of human health.

3.2 Proposed Risk Management Objectives

[5] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's *Cabinet Directive on Regulatory Management* (TBS 2018), Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or group of substances.

In the case of chlorocresol, the proposed risk management objective is to reduce exposures to chlorocresol for the general population in certain cosmetic products, specifically body lotion, to levels which are protective of human health.

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the proposed risk management action for chlorocresol will focus on this source of exposure.

3.3 Proposed Risk Management Action under Consideration

The proposed risk management objective for chlorocresol is:

> Measures to reduce exposures to chlorocresol from body lotion by describing chlorocresol as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist. The Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* or provisions of the *Cosmetic Regulations*.

The proposed risk management objectives and proposed options are intended to address risks identified in the screening assessment for the general population.

3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[6]. The aim is to determine whether the human health objectives have been met and whether there is a need to revisit the risk management approach for that substance, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review the effectiveness of the risk management action for chlorocresol.

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[6] Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (*i.e.*, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

The Government of Canada plans to measure the effectiveness of the risk management action by collecting and analyzing data, including data on chlorocresol prevalence in cosmetics in order to measure progress towards meeting the risk management objective.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

4. Background

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

Chlorocresol was included in a survey issued pursuant to 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 a component in concrete admixture (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 a limited number of body moisturizer creams/lotions, as a non-medicinal ingredient in a limited number of natural health products and as a non-medicinal ingredient in pharmaceutical products including topical creams to treat skin irritations. Chlorocresol is a registered active ingredient in pest control products in Canada, which is formulated into concrete admixtures. Chlorocresol may also be present in Canada as an incidental component in additives (lubricants) used in food processing facilities with the potential for food contact; however, exposure is considered negligible (Canada 2021).

5. Exposure Source and Identified Risk

According to the screening assessment, in Canada, individuals may be exposed to chlorocresol via exposure to body lotions.
The critical health effect for chlorocresol was identified as decreased absolute adrenal gland weights in a chronic exposure study conducted on rats. A comparison of estimated exposure to chlorocresol from its use in 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 for the general population (Canada 2021).

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 for the general population (Canada 2021).

6. Risk Management Considerations

6.1 Alternatives

No information on chemical alternatives to chlorocresol was identified. As stated above, chlorocresol is used in cosmetics, natural health and pharmaceutical products including topical creams to treat 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 the specific need for chlorocresol is available, 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.

Natural Health Products (NHPs): NHPs are regulated under the *Natural Health Products Regulations.* Chlorocresol is listed in the Licensed Natural Health

Products Database as being present as a non-medicinal ingredient in topical creams used to treat skin irritations in Canada (Canada 2021).

Food: The safety of chemicals used in incidental additives is 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”.

Pharmaceuticals: Chlorocresol is a medicinal ingredient in a veterinary drug and non-medicinal ingredient in human and veterinary topical creams to treat skin irritations (Canada 2021).

Pesticides: Chlorocresol is an active ingredient in certain pest control products, which is formulated into concrete admixtures, registered for material preservative uses under the authority of the *Pest Control Products Act* (Canada 2021).

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.

7.2.1 United States

Food: 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).

Pest Control Products: Chlorocresol is a registered active ingredient for pesticides in the United States (USEPA 1997).

7.2.2 European Union

Pest Control Products: The European Commission has chlorocresol listed as an active pesticide substance (EC 2004).

Cosmetic Products Regulations

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).

7.2.3 Other Jurisdictions

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).

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 Approach document or other information that would help to inform decision-making (such as outlined in section 3.2). Please submit additional information and comments prior to July 21, 2021.

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

Environment and Climate Change Canada
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819-938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.ca

Companies who 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.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration during the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: May 22, 2021 to July 21, 2021.

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): At the latest, 24-months from the date on which the Ministers recommended that chlorocresol be added to Schedule 1 of CEPA.

Consultation on the proposed instrument(s): 60-day public comment period starting upon publication of the proposed instrument.

Publication of the final instrument, if required: At the latest, 18-months from the publication of the proposed instrument.

These are planned timelines, and are subject to change. Please consult the schedule of risk management activities and consultations for updated information on timelines.

9. References

Canada. 1999. *Canadian Environmental Protection Act, 1999*. S.C. 1999, c.33. Canada Gazette Part III, vol. 22, no. 3.

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ChemIDPlus [database]. 1993- . Bethesda (MD): US National Library of Medicine. Search results for CAS RN 59-50-7. [accessed: 2018 February 14].

[CIR] Cosmetic Ingredient Review. 1997. Final report on the safety assessment of p-chloro-m-cresol. International Journal of Toxicology, 16:235-268.

[CosIng] Cosmetic Ingredient Database. 2016.

[EC] European Commission. 2004. Pesticide EU-MRLs Database– 4-chloro-3-methlyphenol.

Environment Canada. 2013. DSL Inventory Update data collected under the *Canadian Environmental Protection Act, 1999*, section 71: *Notice with respect to certain substances on the Domestic Substances List.* Data prepared by: Environment Canada, Health Canada; Existing Substances Program.

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

[TBS] Treasury Board of Canada Secretariat. 2007. Assessing, Selecting, and Implementing Instruments for Government Action.

[TBS] Treasury Board of Canada Secretariat. 2012a. Cabinet Directive on Regulatory Management. Available from: http://www.tbs-sct.gc.ca/ri-qr/directive/directive00-eng.asp.

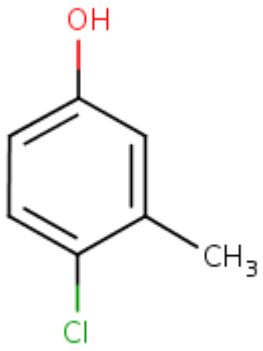
[TBS] Treasury Board of Canada Secretariat. 2012b. Red Tape Reduction Action Plan.

[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[a]	Molecular weight (g/mol)[a]
59-50-7	Phenol, 4-chloro-3-methyl	Chlorocresol	 C_7H_7ClO	142.58

[a]ChemIDPlus 2018, USEPA 1997