Risk Management Approach

for

2H-1-Benzopyran-2-one, 7-(diethylamino)-4-methyl-

(Coumarin 1)

Chemical Abstracts Service Registry Number (CAS RN): 91-44-1

Environment and Climate Change Canada

Health Canada

May 2023

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for 2H-1-benzopyran-2-one, 7-(diethylamino)-4-methyl- (hereinafter referred to as coumarin 1), which has been concluded harmful to human health, but not to the environment in Canada at levels of exposure considered in the assessment.

In particular, the Government of Canada is considering the following risk management action:

> Measures to reduce dermal exposure of the Canadian population to coumarin 1 from specialty body makeup for ages 4 years and older, and to children ages 2-13 years old in temporary gel hair dye, by describing coumarin 1 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 options outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options or actions published for other Chemicals Management Plan (CMP) substances as required to ensure an effective, coordinated, and consistent risk management decision-making.

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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 or to human health as set out in section 64 of CEPA[1,2], and if so, to manage the associated risks.

The substance 2H-1-benzopyran-2-one, 7-(diethylamino)-4-methyl-, Chemical Abstracts Service Registry Number (CAS RN[3]) [91-44-1], hereafter referred to as coumarin 1, is included in the third phase of the Chemicals Management Plan.

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of coumarin 1 in Canada. A notice summarizing the scientific considerations of the screening assessment for this substance was published in the *Canada Gazette*, Part I (ECCC, HC 2023). For further information, refer to the screening assessment for coumarin 1.

2.1 Screening Assessment Conclusion

Based on the information available, the screening assessment concludes that coumarin 1 is toxic under section 64(*c*) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (ECCC, HC 2023).

[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 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 used by 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 a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of 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: 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.

The screening assessment also concludes that coumarin 1 meets the criteria for persistence but not for bioaccumulation as defined in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000).

It is also concluded that coumarin 1 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 (ECCC, HC 2023).

The exposure source of concern, identified in the screening assessment, is based on the potential dermal exposure from the use of certain cosmetics, specifically specialty body makeup and temporary gel hair dye (children ages 2-13 years old). The additional sentinel hair dye scenario was identified based on updated information on concentrations in hair dye products. This document focuses on the dermal exposures of greatest concern (refer to section 5).

2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment conducted pursuant to section 74 of CEPA, the ministers recommend that coumarin 1 be added to the List of Toxic Substances in Schedule 1 to the Act[4].

The ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for coumarin 1 and associated Risk Management Scope. As the ministers finalize the recommendation to add coumarin 1 to Schedule 1, risk management instruments will be proposed and finalized within the time frames described in sections 91 and 92 of CEPA.

2.3 Public comment period on the draft screening assessment and the Risk Management Scope

The draft screening assessment for coumarin 1 and its associated Risk Management Scope document summarizing the proposed risk management options under consideration at that time were published on October 31, 2020 (ECCC, HC 2020). 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.

[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 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.

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.

For coumarin 1, the proposed objective is focused on addressing the risks and exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective for this substance is to reduce exposure of the Canadian population to coumarin 1 to levels that are protective of human health.

3.2 Proposed risk management objectives

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 substances. The proposed risk management objective for coumarin 1 is to reduce dermal exposure of the Canadian population to coumarin 1 from specialty body makeup, and temporary gel hair dye, to levels that are protective of human health.

3.3 Proposed risk management actions under consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management action being considered for coumarin 1 is as follows:

> Measures to reduce dermal exposure of the Canadian population to coumarin 1 from specialty body makeup and to temporary gel hair dye, by describing coumarin 1 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*. More information on the Hotlist consultation process can be found here: https://www.canada.ca/en/health-canada/programs/consultation-proposed-updates-cosmetic-ingredients-hotlist.html.

Following the publication of this 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[5]. The risk management options outlined in this document

[5] The proposed risk management regulation, instrument or tool 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 Regulation (TBS 2018), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

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 human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance. To achieve this, the Government of Canada will review the effectiveness of the risk management action(s) for coumarin 1.

The Government of Canada plans to measure the effectiveness of the risk management action by collecting and analyzing data, including data on coumarin 1 prevalence in cosmetics, such as specialty body makeup and temporary gel hair dye, available to consumers in order to measure progress towards meeting the risk management objective.

The Government of Canada plans to collect and analyze data, such as data obtained through the Cosmetic Notification System, in order to establish a baseline status of the Canadian market, and again over time to measure progress towards meeting the human health objectives.

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 coumarin 1

Coumarin 1 is an organic substance included in the third phase of the CMP. There is a lack of empirical data on the physical-chemical properties and the potential health effects of coumarin 1; therefore, modelled values and a read-across approach using data from analogues were used to inform the screening assessment. Analogues were selected based on structural and/or functional similarities to the substance and that they had relevant empirical data that could be used to read-across to endpoints of potential concern. 6-Methylcoumarin (CAS

[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).

RN 92-48-8) was found to be the closest analogue to coumarin 1 and was used to inform genotoxicity and carcinogenicity. Coumarin (CAS RN 91-64-5) was used to inform reproductive and developmental toxicity.

4.2 Current uses and identified sectors

Coumarin 1 was included in a survey issued pursuant to section 71 of CEPA (Environment Canada 2013). Total reported imports of coumarin 1 for 2011 were in the range of 1000 kg to 10 000 kg, and no manufacturing activities above the reporting threshold of 100 kg were reported. According to information submitted in response to the CEPA section 71 survey, coumarin 1 was reported to be used as a dye in commercial fabric, textile and leather articles in Canada (Environment Canada 2013). In addition, information received as part of the public comment period on the draft screening assessment indicates that coumarin 1 is used in the manufacture of engine components and as a fragrance ingredient in cleaning products.

Coumarin 1 is present in cosmetics in Canada, based on notifications submitted under the *Cosmetic Regulations* (personal communication, emails from Consumer and Hazardous Products Safety Directorate, Health Canada (HC) to Existing Substances Risk Assessment Bureau (ESRAB), HC, October 2018; unreferenced). Coumarin 1 may be used as a marker ingredient in an adhesive for meat packaging with no potential for direct food contact (personal communication, email from the Food Directorate, HC, to the ESRAB, HC, July 2021; unreferenced). Coumarin 1 was also identified as a stabilizer in a carpet cleaner available in Canada (SDS 2015).

Internationally, coumarin 1 has also been identified in tattoo ink (Piccinini et al. 2015; Landeg et al. 2016), in cleaning products (HCPA 2019; CPID c2001-2019; RB c2012-2019), as well as in leather and textile treatment products, paper chemicals and dyes (ECHA c2007-2021).

5. Exposure sources and identified risks

Direct exposures from use of cosmetics and other products available to consumers, as well as exposure from environmental media, were evaluated. Product scenarios that result in the highest levels of potential exposure for the substance by the dermal routes were presented in the screening assessment. Inhalation exposure was also considered, but was not found to be a concern to human health at current levels of exposure.

The critical human health effect associated with coumarin 1 identified in the assessment (ECCC, HC 2023) is developmental toxicity based on read-across data for 2H-1-benzopyran-2-one (coumarin [CAS RN 91-64-5]).

In the assessment, dermal exposure to coumarin 1 from certain cosmetics, specifically occasional use of specialty body makeup and temporary gel hair dye, were identified as potential concerns. The margins of exposure for specialty body makeup (4 years and older) and temporary gel hair dye (2 to 13 years old) were determined to be inadequate to address uncertainties in the health effects and exposure databases.

The margins of exposure for environmental media, nail polish, temporary powder hair dye, facial makeup (including eye makeup), lipstick/lip gloss, carpet cleaner and multi-purpose spray cleaner were considered adequate to address uncertainties in the health effects and exposure databases. Therefore, no current sources of exposure other than cosmetics were identified as a concern in the screening assessment (ECCC, HC 2023).

6. Risk management considerations

6.1 Alternatives and alternate technologies

No information on alternatives to coumarin 1 was identified, and it is not known whether there are safe alternatives available to replace coumarin 1 in cosmetics.

Coumarin 1 is expected to function as a stabilizer and may also be used for its fluorescent properties (Landeg et al. 2016).

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 Regulation* (TBS 2018) 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

Domestic risk management actions specifically addressing coumarin 1 were not identified.

7.2 Pertinent international risk management context

International risk management actions specifically addressing coumarin 1 were not identified.

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 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 14, 2023.

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

Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: substances@ec.gc.ca

Companies who have a business interest in coumarin 1 are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding coumarin 1 and may be contacted for further information.

8.2 Timing of actions

Electronic consultation on the Risk Management Scope: May 20, 2023 to July 14, 2023

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): no later than 24 months from the publication of the screening assessment report

Consultation on the proposed instrument if required: 60-day public comment period starting upon publication of the proposed instrument

Publication of the final instrument(s), if required: no later than 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

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