Government of Canada / Gouvernement du Canada

Risk Management Scope

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

October 2020

Canada

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for 2H-1-benzopyran-2-one, 7-(diethylamino)-4-methyl- (herein referred to as coumarin 1), which has been proposed to be harmful to human health, but not to the environment in Canada.

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

> Communicating measures to reduce exposures of Canadians to coumarin 1 from certain cosmetics, specifically body makeup, by describing coumarin 1 as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist.

The risk management options outlined in this Risk Management Scope 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], herein 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 draft screening assessment for these substances was published in the *Canada Gazette*, Part I, on October 31, 2020 (ECCC, HC 2020). For further information, refer to the draft screening assessment report for coumarin 1.

2.1 Draft Screening Assessment Conclusion

Based on the information available, the draft screening assessment proposes that coumarin 1 is toxic under section 64(*c*) of CEPA because 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 2020).

It is proposed to conclude that coumarin 1 does not meet the criteria under paragraphs 64(*a*) or 64(*b*) of CEPA as it is not entering the environment in a

[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.

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.

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

The exposure source of concern, identified in the draft screening assessment, is based on the potential dermal exposure from the use of certain cosmetics, specifically specialty body makeup. This document focuses on the dermal exposures of greatest concern (refer to section 5).

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. For further information, refer to the draft coumarin 1 screening assessment.

2.2 Proposed Recommendation under CEPA

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

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment report for coumarin 1 and the associated Risk Management Scope document.

If the ministers finalize the recommendation to add coumarin 1 to Schedule 1, risk management instrument(s) must be proposed and finalized within a set period of time, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this substance).

[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 general 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 from certain cosmetics, specifically body makeup, to levels that are protective of human health.

Should the final screening assessment confirm that coumarin 1 is harmful to human health, the proposed risk management objective may be revised in the Risk Management Approach document. This document would be published concurrently with the final screening assessment for this substance.

3.3 Proposed Risk Management Options under Consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management option under consideration for coumarin 1 is as follows:

> Communicating measures to reduce exposures of Canadians to coumarin 1 from certain cosmetics, specifically body makeup, by describing coumarin 1 as a prohibited or restricted ingredient on the Health Canada Cosmetic Ingredient Hotlist.

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 may also evolve through consideration of assessments and risk management

[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).

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(s) by collecting and analyzing data to measure progress towards meeting the risk management objective(s).

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.

3.5 Risk Management Information

Should stakeholders have relevant information on coumarin 1, they should provide it on or before December 29, 2020 to the contact identified in section 8 of this document. Such information can help inform the risk management decision-making process.

[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).

4. Background

4.1 General Information on Coumarin 1

2H-1-Benzopyran-2-one, 7-(diethylamino)-4-methyl- is an organic substance included in the third phase of the CMP. The substance has the common name coumarin 1. 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 draft screening assessment. Analogues were selected that were structurally and/or functionally similar to the substance and that had relevant empirical data that could be used to read-across to endpoints of potential concern. 6-Methylcoumarin (CAS 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 human health reproductive and developmental toxicity.

4.2 Current Uses and Identified Sectors

Coumarin 1 was included in a mandatory survey conducted under section 71 of CEPA (Environment Canada 2013). Total reported imports of coumarin 1 for 2011 were in the range of 1000 to 10 000 kg, and no manufacturing activities above the reporting threshold of 100 kg were reported. According to information reported in response to a 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).

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 to Existing Substances Risk Assessment Bureau, Health Canada, October 2018). 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 c2007-2019).

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 draft screening assessment (Canada, 2019) 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, was identified as a potential concern. The margin of exposure for specialty body makeup was determined to be potentially inadequate to address uncertainties in the health effects and exposure databases.

No current sources of exposure other than cosmetics were identified as a concern in the draft screening assessment (ECCC, HC 2020).

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.

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

Domestically, no risk management actions specifically addressing coumarin 1 were identified.

7.2 Pertinent International Risk Management Context

Internationally, no risk management actions specifically addressing coumarin 1 were 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 Scope or other information that would help to inform decision-making (such as outlined in section 3.2).

Should the final screening assessment confirm that coumarin 1 is harmful to human health, a Risk Management Approach document would be published outlining and seeking input on the proposed risk management instrument(s). The Risk Management Approach would be published at the same time as the final screening assessment report. At that time, there would 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
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.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 draft screening assessment report and Risk Management Scope: October 31, 2020 to December 29, 2020

Submission of public comments, additional studies, and/or information on coumarin 1: On or before December 29, 2020

Publication of responses to public comments on the draft screening assessment report and Risk Management Scope: concurrent to the publication of the screening assessment report and, if required, the Risk Management Approach document.

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

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

Canada. 2019. CMP Third phase update.

Canada. 2000. Canadian Environmental Protection Act, 1999: Persistence and Bioaccumulation Regulations, P.C. 2000-348, 23 March 2000, SOR/2000-107.

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[ECCC, HC] Environment and Climate Change Canada, Health Canada. 2020. Draft screening assessment: 2H-1-Benzopyran-2-one, 7-(diethylamino)-4-methyl-. Ottawa (ON): Government of Canada.

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[HCPA] Household & Commercial Products Association. 2019. Consumer Product Ingredients Database: Diethylaminomethylcoumarin [Internet]. Washington (DC): United States.

RB. Professional Resolve Carpet Extraction Cleaner. [Internet] c2012-2019 [accessed May 2019].

[SDS] Safety Data Sheet. 2015. Electrolux Pet Stain & Odor W/BS2X with Baking Soda [PDF]. Michigan City, IN: Fas-Pak. [accessed June 2019]

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

[TBS] Treasury Board of Canada Secretariat. 2018. Cabinet Directive on Regulation. Ottawa (ON): Government of Canada. [accessed 2018 Aug 29].