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Risk Management Scope

for

Talc

($Mg_3H_2(SiO_3)_4$)

Chemical Abstracts Service Registry Number (CAS RN): 14807-96-6

Health Canada

December, 2018

Canada

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for talc. If the proposed conclusion for talc is confirmed in the final screening assessment, the Government of Canada is considering:

1. Measures to prohibit or restrict talc in certain cosmetics which can be inhaled or used perineally by modifying the existing entry on Health Canada's 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*.
2. Measures to reduce exposures from talc in certain natural health products and non-prescription drug products which can be inhaled or used perineally by modifying the existing entry(ies) in the Natural Health Products Ingredients Database and impacted monographs
3. Communications to the public to help avoid inhalation or perineal exposure to talc.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (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 1999[1,2], and if so to manage the associated risks.

The substance talc is part of the Government of Canada's Chemicals Management Plan (Canada, 2016).

2. Issue

2.1 Draft Screening Assessment Report Conclusion

Health Canada and Environment and Climate Change Canada conducted an assessment of talc.

A summary of the draft Screening Assessment Report was published in the *Canada Gazette*, Part I, on Dec 8, 2018 (Canada, 2018a).

The draft Screening Assessment Report proposes that talc meets section 64 of CEPA 1999 because it is entering the environment in a quantity or concentration

[1] Section 64 [of CEPA 1999]: *For the purposes of* [Parts 5 and 6 of CEPA 1999]*, 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, products used by consumers. A conclusion under CEPA 1999 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 1999 does not preclude actions being taken under other sections of CEPA 1999 or other Acts.

or under conditions that constitute or may constitute a danger in Canada to human life or health (Canada 2018b).]

The draft Screening Assessment Report also proposes that talc meets the criteria for persistence but does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999 (Canada 2000).

The human exposure sources of concern, identified in the draft Screening Assessment Report, are exposures to talc from the use of certain talc containing self-care products available to consumers. Self-care products include cosmetics, natural health products and non-prescription drugs. This document will focus on these exposure sources of concern. The exposure routes of concern are inhalation for males and females and perineal for females.

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft Screening Assessment Report are preliminary and may be subject to change.

2.2 Proposed Recommendation under CEPA 1999

On the basis of the proposed conclusion set out in the draft screening assessment conducted under CEPA 1999, the Ministers propose to recommend that talc be added to the List of Toxic Substances in Schedule 1 of the Act[3].

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment Report and Risk Management Scope document. If the Ministers proceed with the recommendation to add talc to Schedule 1, risk management instruments must be proposed and finalized within the time frames described in sections 91 and 92 of CEPA 1999.

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA 1999, 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.

The proposed human health objective for talc is to decrease inhalation and perineal exposures from certain talc containing self-care products available to consumers to a level which is 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.

The proposed risk management objective for talc is to decrease inhalation and perineal exposures from certain talc containing self-care products available to consumers.

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

(1) Measures to prohibit or restrict talc in certain cosmetics which can be inhaled or used perineally by modifying the existing entry on Health Canada's 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*.
(2) Measures to reduce exposures from talc in certain natural health products and non-prescription drug products which can be inhaled or used perineally by modifying the existing entry(ies) in the Natural Health Products Ingredients Database and impacted monographs
(3) Communications to the public to help avoid inhalation or perineal exposure to talc.

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[4]. 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.

The proposed health and risk management objectives may be revised in the RM Approach document that will be published concurrently with the final Screening Assessment Report for this substance(s), or in subsequent risk management documents (e.g. consultation document on proposed instrument).

4. Background

Talc is a naturally occurring mineral, mined in many countries. Canada makes 50 000 to 75 000 tonnes and imports 100 000 tonnes, per year. In Canada, talc may be used in a variety of products including paper, plastics, paint, ceramics, putties, food, food packaging materials, drugs, natural health products and cosmetics. It may be present as a dusting powder on some medical devices, although the market seems to have shifted away from this use.

5. Exposure Sources and Identified Risks

The assessment did not identify human health risks of concern from oral exposures, including talc in food and drugs, dermal exposures such as the application of talc containing products to skin, or inhalational exposures from dry hair shampoo or pressed powder products, such as cosmetics like eye shadows and blushes. Given the limited number of industrial sites producing and processing talc in Canada, talc exposure from ambient air is not expected to be significant. Additionally, concerns due to the potential use of talc in paper, plastics, paint, ceramics, putties and food packaging materials were not identified.

However, the assessment did identify two exposure scenarios of potential concern to human health. Both scenarios involved exposures to certain talc-containing self-care products available to consumers. In Canada, these products are considered cosmetics, natural health products or non-prescription drugs, depending on, among other things, the claims made on the label and the function of the product.

One exposure scenario of concern was inhalation of fine particles of talc during the use of loose powder self-care products (e.g., body powder, baby powder, face powder, foot powder), potentially resulting in damage to the lungs.

[4] 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 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the Red Tape Reduction Act (Canada, 2015).

The other exposure scenario of concern was exposure of the female perineal area, which includes the genitals, to self-care products containing talc (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs), as this type of exposure has been associated with ovarian cancer in studies of the human population.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

We ask that stakeholders submit information on alternatives and alternate technologies, if known.

Not specific to talc, but in general, inhaling ambient air particles of less than 10 microns has been associated with respiratory effects (Health Canada, 2016). Talc containing products available to consumers which are not in a loose powder format will have fewer particles available for inhalation during use (Canada, 2018b)

Loose powder products containing cornstarch rather than talc are currently available on the market. Starch (CAS RN 9005-25-8), including cornstarch, did not meet the criteria used by the departments to prioritize existing substances for assessment, including the requirements set out in subsection 73(1) of CEPA (Canada, 2006, 2017).

6.2 Socio-economic and Technical Considerations

No information on socio-economic or technical considerations was identified. We ask that stakeholders submit information on these considerations, if known.

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

The Cosmetic Ingredient Hotlist currently lists suggested cautionary statements for cosmetics containing talc in powder form intended to be used on infants and children. The label of these products should contain statements to the effect of "keep out of the reach of children" and "keep powder away from child's face to avoid inhalation that can cause breathing problems".

The Natural Health Products Ingredients Database (NHPID) entry for talc refers to the presence of talc and its associated risk statements on the Cosmetic Ingredient Hotlist, and indicates that this ingredient must be used in accordance with the restrictions described in the Cosmetic Ingredient Hotlist when included in topical natural health products, unless additional evidence for safety is submitted. The NHPID also includes two additional entries for talc, one for its use in homeopathic medicines with a minimum homeopathic potency of 12 CH, and the other for its use in Traditional Chinese Medicines (TCM), where its preparation must comply with the method(s) described in the most current edition of the Pharmacopoeia of the People's Republic of China (NHPID 2018).

Consistent with its NHPID TCM entry, talc is listed as a medicinal ingredient, named as Talcum or Hua shi, in the Natural and Non-prescription Health Products Directorate (NNHPD)'s Traditional Chinese Medicine Ingredients (TCMI) monograph (Health Canada 2015). It is also listed as a medicinal ingredient in the NNHPD Diaper Rash Products monograph, associated with concentrations of 45-100%; and for all powder products, with the following cautions and warnings: "Keep out of reach of children", "Keep powder away from face to avoid inhalation, which can cause breathing problems", and "Not intended for use on broken skin" (Health Canada 2007).

Talc is on the *List of Permitted Food Additives with Other Accepted Uses,* incorporated by reference into its respective Marketing Authorization issued under the *Food and Drugs Act,* for limited uses in a small number of foods. As a food additive, talc must meet the purity specifications set out in the Food Chemicals Codex or the *Combined Compendium of Food Additive Specifications,* prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Talc can be used as a colourant in drugs under the *Food and Drug Regulations*.

7.2 Pertinent International Risk Management Context

The US and Europe also allow talc use in cosmetics and food. Europe requires a warning statement similar to that in Canada for cosmetics (US FDA, 2017; EC, 2009; USA, 2018; EU, 2011).

The US and Europe also allow talc in food packaging materials (USA, 2018; EC, 2011).

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. Please submit additional information and comments prior to February 6, 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 Report. 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
Gatineau Quebec K1A 0H3
Tel: 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 talc are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding talc and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the Risk Management Scope: December 8, 2018 to February 6, 2019

Submission of additional studies or information on talc: on or before February 6, 2019

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before Winter, 2020

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: on or before Winter, 2020

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): at the latest, 24-month from the publication of the final Screening Assessment Report

Consultation on the proposed instrument(s), if required: 60-day public comment period starting upon publication of each proposed instrument(s)

Publication of the final instrument(s), if required: at the latest, 18-month from the publication of each proposed instrument(s)

Please note that the review and consultation of the Talc entry on the Cosmetic Ingredient Hotlist will be carried out alongside the CMP assessment on Talc. The targeted timing for posting of the final Hotlist entry will be at the same time or shortly after the publication of the final Talc screening assessment.

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