Government of Canada Gouvernement du Canada

Canada

Risk Management Approach

for

Talc

($Mg_3H_2(SiO_3)_4$)

Chemical Abstracts Service Registry Number 14807-96-6

Environment and Climate Change Canada

Health Canada

April 2021

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for talc, which has been found to be harmful to human health. In particular, the Government of Canada is proposing:

1. Measures to help reduce exposures to talc from certain cosmetics which may be inhaled or which may result in perineal exposure by modifying the existing entry on the 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*; and
2. Measures to help reduce exposures to talc from certain natural health products and non-prescription drugs which may be inhaled or which may result in perineal exposure by modifying the existing entry(ies) of the Natural Health Products Ingredients Database and applicable monograph(s).

The risk management actions 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 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 and/or to human health as set out in section 64 of CEPA[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

Health Canada and Environment and Climate Change Canada conducted an assessment of talc. A notice summarizing the scientific considerations of the screening assessment for this substance was published in the *Canada Gazette*, Part I, on April 24, 2021 (Canada 2021). For further information, please refer to the screening assessment for talc.

2.1 Screening Assessment Conclusion

On the basis of the information available, the screening assessment concludes that talc meets section 64 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 (ECCC, HC 2021).

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[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 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 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.

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

The human exposure sources of concern, identified in the screening assessment, are inhalation and perineal exposures to talc from the use of certain self-care products. 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 (refer to section 5).

2.2 Recommendation under CEPA

On the basis of the findings of the screening assessment conducted under CEPA, the ministers propose to recommend that talc be added to the List of Toxic Substances in Schedule 1 of the Act[3].

The ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for talc and associated Risk Management Scope. As the ministers finalize the recommendation to add talc 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 talc (ECCC, HC 2018a) and its associated Risk Management Scope (ECCC, HC 2018b) summarizing the proposed risk management options under consideration at that time were published on December 8, 2018. 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. For further information, please refer to the summary of responses to public comments received.

[3] 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.

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 to a level which is protective of human health.

3.2 Proposed Risk Management Objective

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.

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 proposed risk management actions being considered for talc are:

(1) Measures to help reduce exposures to talc from certain cosmetics which may be inhaled or which may result in perineal exposure by modifying the existing entry on the Cosmetic Ingredient Hotlist[4]; and
(2) Measures to help reduce exposures to talc from certain natural health products and non-prescription drugs which may be inhaled or which may result in perineal exposure by modifying the existing entry(ies) of the

[4] The Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the *Food and Drugs Act* (F&DA) or may contravene one or more provisions of the *Cosmetic Regulations*. Section 16 of the F&DA states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user." In addition, the Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the F&DA. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the F&DA, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

Natural Health Products Ingredients Database (NHPID)[5] and applicable monograph(s).

Following the publication of this Risk Management Approach, additional information submitted during the public comment period or obtained from other sources will be considered, along with the information presented in this document, in the instrument(s) selection and development process[6]. The risk management actions 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.

3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances[7]. 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, so that risks are managed effectively over time.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data, including data on talc prevalence and usage in cosmetics, natural health products and non-prescription drugs in order to measure progress towards meeting the risk management objectives.

[5] The NHPID provides an electronic tool which enables members of the public to access information on the following topics:

- medicinal and non-medicinal ingredients used in Natural Health Products;
- standard terminology used by the Natural Health Products Online System, known as "Controlled Vocabulary", referring to quality test methods, dosage forms, non-medicinal ingredient purposes, and so on; and
- pre-cleared information such as single ingredient monographs and product monographs.

[6] 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 Regulation* (TBS 2018), Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

[7] 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 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

Talc is a naturally occurring mineral, mined in many countries. According to information submitted in response to a CEPA section 71 survey and publically available information, in 2011 talc was manufactured in Canada in quantities ranging between 50 to 75 million kg, and in 2016, approximately 100 million kg of talc was imported. In Canada, talc may be used in a variety of products including paper, plastics, paint, ceramics, putties, drugs, natural health products and cosmetics. In Canada, talc is a permitted food additive in a small number of foods and may be used as a component in the manufacture of food packaging materials. It may be present as a dusting powder on some medical devices, although there is no evidence to suggest that talc is currently being used this way.

5. Exposure Sources and Identified Risks

The assessment did not identify human health risks from oral exposure to talc resulting from food intake, oral and dermal exposures from the use of self-care products, or inhalation exposure from foot powder, dry hair shampoo or pressed powder products, such as face makeup. Given the limited number of industrial and commercial sites producing and processing talc in Canada, talc exposure from ambient air is not expected to be significant. Additionally, there were no concerns identified due to the potential use of talc in paper, plastics, paint, ceramics and putties. Therefore, no risk management for these scenarios is being proposed.

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. In Canada, these products are considered cosmetics, natural health products or non-prescription drugs, depending on, among other things, the ingredients present in the product and the claims made on the label.

One exposure scenario of concern was inhalation of respirable particles of talc during the use of body powder, baby powder and loose face powder, potentially resulting in damage to the lungs.

The other exposure scenario of potential 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, bubble bath), 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 adverse respiratory effects (Health Canada 2016). Talc-containing products available to consumers which are not in a loose powder format would be expected to emit fewer respirable particles available for inhalation during use (ECCC, HC 2021).

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 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 objective(s) as per the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (Treasury Board of Canada Secretariat TBS 2007). In addition, 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), Red Tape Reduction Action Plan (TBS 2012) and the *Red Tape Reduction Act* (Canada 2015).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

In Canada, cosmetics, natural health products and non-prescription drugs all require disclosure of the ingredients (medicinal and non-medicinal) on the product label.

The Cosmetic Ingredient Hotlist currently lists 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 reach of children" and "keep powder away from child's face to avoid inhalation which can cause breathing problems". As per the *Cosmetic Regulations*, the label of a cosmetic that presents an avoidable hazard must include directions for safe use, in both English and French.

The NHPID entry for talc refers to the presence of talc and its associated risk statements as set out on the Cosmetic Ingredient Hotlist, and indicates that this ingredient must be used in accordance with the restrictions described on 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 [modified 2019]).

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 (Health Canada 2018), associated with concentrations of 45-100%; and for all powder products, with the following cautions and warnings: "For external use only", "Avoid contact with eyes. If contact occurs, rinse thoroughly with water", "Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if symptoms worsen or last for more than 7 days", "Keep out of reach of children", "Keep powder away from face to avoid inhalation, which can cause breathing problems", and "Do not use on broken skin" (Health Canada 2018).

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

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 per B.01.045 of the *Food and Drug Regulations*, when used as a food additive, talc must meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex*, published by the United States Pharmacopeial Convention, or the *Combined Compendium of Food Additive Specifications,* prepared by the Joint FAO/WHO Expert Committee on Food Additives, and must be free from asbestos.

The safety of chemicals used in incidental additives and food packaging materials is subject to section 4(1)(a) of the *Food and Drugs Act* and Division 23 (Food Packaging Materials) of the *Food and Drug Regulations*.

7.2 Pertinent International Risk Management Context

The United States (U.S.) and the European Union also allow talc to be used in cosmetics, and the European Union requires a warning statement for cosmetics similar to that in Canada (U.S. FDA 2017; EC 2009).

In the European Union, talc is an approved food additive and is also permitted to be used in food packaging materials (EC 2008; EU 2011). In the U.S., talc is "Generally Recognized As Safe" for specific uses in food packaging (U.S. FDA 2019a; U.S. FDA 2019b).

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. Please submit additional information and comments prior to June 23, 2021.

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
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 Approach: April 24, 2021 to June 23, 2021.

Publication of responses to public comments on the Risk Management Approach: Concurrent to the publication of the proposed instrument(s).

Publication of the proposed instrument(s): At the latest, 24-months from the date on which the ministers proposed to recommend that talc be added to Schedule 1 of CEPA.

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

Publication of the final instrument(s): At the latest, 18-months from the publication of each proposed instrument(s).

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

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