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Risk Management Scope

for

Aluminum hydroxychloride, CAS RN 1327-41-9 and Aluminum chlorohydrate, CAS RN 12042-91-0

Environment and Climate Change Canada

Health Canada

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Canada

Summary of proposed risk management

This document outlines the risk management options under consideration for aluminum hydroxychloride (CAS RN 1327-41-9) and aluminum chlorohydrate (CAS RN 12042-91-0) which have been proposed to be harmful to human health.

In particular, the Government of Canada is considering:

Measures to reduce inhalation exposure to aluminum hydroxychloride and aluminum chlorohydrate from certain aerosol cosmetic products, specifically aerosol antiperspirant and aerosol foot deodorant spray, by modifying the current entry on Health Canada's Cosmetic Ingredient Hotlist, which currently describes "aluminum chlorohydrate and its associated complexes" as "restricted" ingredients. The Cosmetic Ingredient Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* (F&DA) or provisions of the *Cosmetic Regulations.* A Consultation on proposed updates to the Cosmetic Ingredient Hotlist to prohibit aluminum chlorohydrate and its associated complexes in aerosol products has been published. This revision to the Cosmetic Ingredient Hotlist, if finalised, will achieve the Risk Management Objective described in this document.

To inform risk management decision-making, information on the following topics should be provided (ideally on or before March 27, 2024 to the contact details identified in section 8 of this document:

- Potential alternatives to aluminum and aluminum for the uses of concern; and
- Socio-economic impacts of replacing aluminum hydroxychloride and aluminum chlorohydrate for the uses of concern.

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 effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options 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 the 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 substances referred to throughout this document as aluminum hydroxychloride, Chemical Abstracts Service Registry Number[3] (CAS RN) 1327-41-9 and aluminum chlorohydrate, CAS RN 12042-91-0, are included in the Aluminium-containing Substances Group of the Chemicals Management Plan (CMP).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of Aluminium-containing Substances in Canada. A notice summarizing the scientific considerations of the draft assessment for these substances was published in the *Canada Gazette*, Part I, (Canada 2024). For further information, refer to the Draft Assessment for aluminium-containing Substances.

2.1 Draft assessment conclusion

On the basis of the information available, the draft assessment proposes that, of the substances in the Aluminium-containing Substances Group: aluminum hydroxychloride and aluminum chlorohydrate are toxic under section 64(c) of

[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 *Hazard Product 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.

CEPA because they may constitute a danger in Canada to human life or health (Canada 2024).

The draft assessment proposes that these substances do not meet the criteria under sections 64(*a*) and 64(*b*) of CEPA. The draft assessment also proposes that aluminum hydroxychloride and aluminum chlorohydrate meet the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000).

The exposure sources of concern identified in the draft assessment are based on the potential release of aluminum hydroxychloride and aluminum chlorohydrate during the use of certain aerosol cosmetic products, specifically aerosol antiperspirant and aerosol foot deodorant spray. As such, this document will focus on these exposure sources of concern (refer to section 5).

2.2 Proposed recommendation under CEPA

On the basis of the findings of the draft assessment conducted pursuant to CEPA, the Ministers propose to recommend that aluminum hydroxychloride and aluminum chlorohydrate be added to Part 2 of Schedule 1 of CEPA[4]. Addition of a substance to Schedule 1 to CEPA enables the Government to propose certain risk management measures under CEPA to manage potential ecological and human health risks associated with the substance.

Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic or toxic to reproduction are available, aluminum hydroxychloride and aluminum chlorohydrate are proposed to be recommended for addition to Part 2 of Schedule 1. Following the availability of the aforementioned criteria, the substances may be moved to Part 1 of Schedule 1, if applicable.

CEPA sets out a 2-track approach for managing risks.

[4] After an assessment of a given substance under Part 5 of CEPA, other than section 83, the Ministers shall propose one of the following measures: take no further action with respect to the substance, add the substance to the List referred to in section 75.1 of the Act (unless the substance is already on that List), recommend the addition of the substance to Part 1 of the list of toxic substances of Schedule 1 to CEPA (for substances that pose the highest risk) or recommend the addition of the substance to Part 2 of the list of toxic substances in Schedule 1 to CEPA (for other CEPA-toxic substances).

Under sub-section 77(3), the Ministers are required to propose recommending the addition of a substance that poses the highest risk, as defined in paragraph (a), (b) or (c), to Part 1[5] of Schedule 1 of the Act and, in developing a proposed regulation or instrument respecting preventive or control actions, to give priority to the total, partial or conditional prohibition of activities in relation to the substance or to the release of the substance into the environment.

For other substances recommended for addition to Part 2 of Schedule 1 of the Act, the Ministers shall give priority to pollution prevention, and this could include regulatory or non-regulatory measures such as prohibition if warranted.

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the Draft Assessment for Aluminium-containing Substances and its associated Risk Management Scope document for aluminum hydroxychloride and aluminum chlorohydrate. In addition, other activities which may address the exposures of concern identified in the draft assessment will be considered.

If the Ministers finalize the proposed recommendation to add aluminum hydroxychloride and aluminum chlorohydrate, to Part 2 of Schedule 1, risk management instruments must be proposed within 24 months from the date on which the Ministers recommended that aluminum hydroxychloride and aluminum chlorohydrate be added to Schedule 1 to CEPA, and finalized within 18 months from the date on which the risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to these two substances).

3. Proposed risk management

3.1 Proposed human health objective

Proposed human health objectives are quantitative or qualitative goals to address human health concerns.

[5] Under subsection 77(3), a substance must be recommended for addition to Part 1 of Schedule 1 to the Act when the substance is determined to be toxic and the Ministers are satisfied that:

a) the substance may have a long-term harmful effect on the environment and
    i. is inherently toxic to human beings or non-human organisms, as determined by laboratory or other studies,
    ii. is persistent and bioaccumulative in accordance with the regulations,
    iii. is present in the environment primarily as a result of human activity, and
    iv. is not a naturally occurring radionuclide or a naturally occurring inorganic substance;
b) the substance may constitute a danger in Canada to human life or health and is, in accordance with the regulations, carcinogenic, mutagenic or toxic for reproduction; or
c) the substance is, in accordance with the regulations, a substance that poses the highest risk.

For these substances, the proposed objective addresses the exposure sources of concern outlined in section 5 of this document. The proposed human health objective for aluminium hydroxychloride and aluminum chlorohydrate chlorohydrate is to:

> Reduce exposure to aluminum hydroxychloride and aluminum chlorohydrate from certain cosmetic products to levels that are 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, instruments and/or tools for a given substance or substances. In this case, the proposed risk management objective for aluminum hydroxychloride and aluminum chlorohydrate is to:

> Reduce inhalation exposure to aluminum hydroxychloride and aluminum chlorohydrate from certain aerosol cosmetic products, specifically aerosol antiperspirant and aerosol foot deodorant spray.

This objective will be refined on the basis of stakeholder consultation and new information, the proposed risk management, the outcome of the assessment, and socio-economic and technical considerations (refer to section 6). Revised human health risk management objectives will be presented in the Risk Management Approach document that will be published concurrently with the final assessment for these substances.

3.3 Proposed risk management option 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 aluminum hydroxychloride and aluminum chlorohydrate is to:

> Modify the current entry on the Cosmetic Ingredient Hotlist for aluminium chlorohydrate substances, which currently describes “aluminum chlorohydrate and its associated complexes” as “restricted” in cosmetic deodorants and antiperspirants.

Health Canada's Cosmetic Ingredient Hotlist is used to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* (F&DA), or provisions of the *Cosmetic Regulations.*[6]

Health Canada published a Consultation on proposed updates to the Cosmetic Ingredient Hotlist, including a revision to the entry for aluminum chlorohydrate and its associated complexes in July 2023 (Health Canada [modified 2023). This revision proposes to prohibit aluminum chlorohydrate and its associated complexes in aerosol products. If this revision is finalised, the inhalation exposure of concern to Canadians identified in the Draft Assessment will be reduced and the risk management objective will be achieved.

Note that the proposed risk management option is preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will also be considered in the instrument selection and development process[7]. The risk management option 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[8]. ECCC and HC have developed a Performance Measurement Evaluation Strategy that sets out the approach to evaluate the effectiveness of actions taken on substances found toxic under CEPA. 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. In evaluating progress and revisiting risk management, as warranted, these activities together will aim to manage risks effectively over time. To achieve this, the Government of Canada will review the

[6] 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 Cosmetic Ingredient 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* to the F&DA, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

[7] The proposed risk management regulations, instruments or tools 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).

[8] 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 (*that is*, evaluate whether risk management objectives have been met); and
- Performance measurement evaluation 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 (*that is*, evaluate whether human health and/or environmental objectives have been met).

effectiveness of the risk management action for aluminum hydroxychloride and aluminum chlorohydrate.

The Government of Canada plans to measure the effectiveness of the risk management action by collecting and analyzing data, including data regarding the presence of aluminum hydroxychloride and aluminum chlorohydrate in certain aerosol cosmetic products 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.

3.5 Risk management information gaps

Interested stakeholders can provide further information to inform risk assessment and risk management decision-making regarding aluminum hydroxychloride and aluminum chlorohydrate, including:

- Alternatives to these substances for use in certain cosmetic products, specifically aerosol antiperspirant and aerosol foot deodorant spray.
- Socio-economic impacts associated with the risk management action presented.

Stakeholders that have information to help address these gaps should provide it on or before March 27, 2024 to the address identified in section 8.

4. Background

4.1 General information on aluminum hydroxychloride and aluminum chlorohydrate

Aluminium-containing substances belong to various categories, including inorganic compounds, organic-metal salts, organometallic compounds and unknown or variable composition, complex reaction products or biological materials (UVCBs).

The two substances discussed here: aluminum hydroxychloride and aluminum chlorohydrate, belong to a sub-category of aluminium-containing substances called aluminium chlorohydrate substances. They were evaluated by Health Canada and Environment and Climate Change Canada under the Chemicals Management Plan.

4.2 Current uses and identified sectors

Aluminum hydroxychloride and aluminum chlorohydrate were included in surveys issued pursuant to Section 71 of CEPA (Canada 2012; Canada 2017). Aluminum hydroxychloride was reported to be used as a solids separation agent and processing aid as well as for other industrial uses. Aluminum chlorohydrate was reported to be used as a solids separation agent, processing aid and antiperspirant and deodorant ingredient.

5. Exposure sources and identified risks

Human health exposure and risks

According to the draft assessment, general population inhalation exposure to aluminum hydroxychloride and aluminum chlorohydrate may occur through the use of aerosol deodorant / antiperspirant products. On the basis of the available information, the route-specific critical health effect of repeated inhalation exposure to aluminium chlorohydrate and its associated complexes (which includes both of the substances discussed here) was determined to be lung effects, specifically granulomatous pneumonia, based upon a six-month rodent study. Margins of exposure were found to be potentially inadequate for repeated inhalation exposure to aerosol deodorant/antiperspirant products containing these substances.

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to these substances. As part of the Chemicals Management Plan, the Government asked industry and interested stakeholders to submit any information on these substances that may be used to inform risk assessment, risk management and product stewardship.

6. Risk management considerations

6.1 Alternatives and alternate technologies

No aluminium-free alternatives functionally identical to aluminum hydroxychloride and aluminum chlorohydrate were identified for the products of concern (aerosol antiperspirant/deodorant products).

Stakeholders are asked to submit information on alternative substances or alternate technologies, if known.

6.2 Socio-economic and technical considerations

Socio-economic factors will be considered in the selection process for a regulation or instrument respecting preventive or control actions, and in the development of the risk management objective as per the guidance provided in the Treasury Board

document Assessing, Selecting, and Implementing Instruments for Government Action (TBS 2007). In addition, socio-economic factors will be considered in the development of regulations, instrument(s) or tool(s), to address risk management objectives, as identified in the Cabinet Directive on Regulation (TBS 2018), and 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

"Aluminum chlorohydrate and its associated complexes" are described on the Cosmetic Ingredient Hotlist as restricted. Both substances discussed here (that is, aluminum hydroxychloride and aluminum chlorohydrate) are specifically listed. The restrictions are:

1. Aluminum chlorohydrate and its associated complexes are not permitted in combination with aluminum chloride, other aluminum chlorohydrate complexes or aluminum zirconium complexes; and
2. Maximum of 25% (calculated as anhydrous form) permitted in deodorant and antiperspirant products and deodorants and antiperspirants in aerosol form.

Health Canada published a Consultation on proposed updates to the Cosmetic Ingredient Hotlist that includes a revision to the entry for aluminum chlorohydrate and its associated complexes in July, 2023 (Health Canada [modified 2023]). This revision proposes to prohibit aluminum chlorohydrate and its associated complexes in aerosol products.

The presence of such aluminum-containing substances on the Cosmetic Ingredient Hotlist is referred to in the relevant entries of the Natural Health Products Ingredients Database (NHPID) (that is the NHPID advises that ingredients must be used in accordance with any restrictions or prohibitions described on the Cosmetic Ingredient Hotlist when included in natural health products).

7.2 Pertinent international risk management context

7.2.1 United States

Antiperspirants are regulated as over-the-counter drugs in the United States via the Code of Federal Regulations, Title 21, Part 350. Aluminum chlorohydrate is limited to 25% on an anhydrous basis, in aerosol or nonaerosol dosage form in antiperspirant products. Aluminum hydroxychloride is not included in this regulation.

7.2.2 European Union

In the European Union, aluminum chlorohydrate is listed as a cosmetic ingredient without restrictions in antiperspirants and deodorants on the European Commission cosmetic substances and ingredients database. Aluminum hydroxychloride does not appear on this database.

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 3.5). Please submit additional information and comments prior to August 16, 2023.

The Risk Management Approach document, if needed, which would outline and seek input on the proposed risk management instrument, would be published at the same time as the final assessment. At that time, there would be further opportunity for consultation.

Comments and information submissions on the Risk Management 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: substances@ec.gc.ca

Companies who have a business interest in aluminium chlorohydrate substances: aluminum hydroxychloride (CAS RN 1327-41-9) and aluminum chlorohydrate (CAS RN 12042-91-0) are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding these substances and may be contacted for further information.

8.2 Timing of actions

Electronic consultation on the draft assessment report and Risk Management Scope: January 27, 2024 to March 27, 2024. This should include the submission of public comments, additional studies and/or information on aluminium chlorohydrate substances: aluminum hydroxychloride and aluminum chlorohydrate.

Publication of responses to public comments on the draft assessment report and Risk Management Scope concurrent to the publication of the assessment 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: At the latest, 24 months from the date on which the Ministers recommended that aluminum hydroxychloride and aluminum chlorohydrate be added to Schedule 1 of CEPA.

Consultation on the proposed instrument, if required: 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

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Annex A: List of substances included in the aluminum chlorohydrates and its associated complexes Cosmetic Ingredient Hotlist entry (not exhaustive):

CAS RN	CAS Name
1327-41-9	Aluminum hydroxychlorde
12042-91-0	Aluminum Chrlorohydrate
173762-81-7	Aluminum chlorohydrex PEG
173762-82-8	Aluminum chlorohydrex PG
10284-64-7	Aluminum dichlorohydrate
173720-80-4	Aluminum dichlorohydrex PEG
180324-83-8	Aluminum dichlorohydrex PG
245090-60-2	1,2-Propanediol, reaction products with aluminum chloride hydroxide