Order Adding a Toxic Substance to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999: SOR/2025-13

Canada Gazette, Part II, Volume 159, Number 4

Registration
SOR/2025-13 January 31, 2025

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

P.C. 2025-55 January 31, 2025

Whereas, under subsection 332(1) [a] of the *Canadian Environmental Protection Act, 1999* [b], the Minister of the Environment published in the *Canada Gazette*, Part I, on March 6, 2021, a copy of the proposed *Order Adding a Toxic Substance to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999*, substantially in the annexed form, under the title *Order Adding a Toxic Substance to Schedule 1 to the Canadian Environmental Protection Act, 1999*, and persons were given an opportunity to file comments with respect to the proposed Order or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

And whereas, under subsection 90(1) [c] of that Act, the Governor in Council is satisfied that the substance set out in the annexed Order is toxic;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of the Environment and the Minister of Health, makes the annexed *Order Adding a Toxic Substance to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999* under subsection 90(1) [c] of the *Canadian Environmental Protection Act, 1999* [b].

Order Adding a Toxic Substance to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999

Amendment

1 Part 2 of Schedule 1 to the *Canadian Environmental Protection Act, 1999* [b] is amended by adding the following in numerical order:

133 2,4,11,13-Tetraazatetradecanediimidamide, N,N"-bis(4-chlorophenyl)-3,12-diimino-(chlorhexidine), which has the molecular formula $C_{22}H_{30}Cl_2N_{10}$, and its salts

Coming into Force

2 This Order comes into force on the day on which it is registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order.*)

Issues

The substance 2,4,11,13-Tetraazatetradecanediimidamide, N,N"-bis(4-chlorophenyl)-3,12-diimino-(chlorhexidine) and its salts were assessed under the *Canadian Environmental Protection Act, 1999* (CEPA or the Act) in June 2019. Chlorhexidine and its salts meet the ecological criterion set

out in paragraph 64(a) of CEPA. In accordance with subsection 90(1) of CEPA, as it read before the coming into force of the *Strengthening Environmental Protection for a Healthier Canada Act*, which received royal assent on June 13, 2023, the Minister of the Environment and the Minister of Health (the ministers) recommended that the Governor in Council make an Order adding chlorhexidine and its salts to Schedule 1 to the Act. Under subsection 61(2) of the *Strengthening Environmental Protection for a Healthier Canada Act*, that recommendation is deemed a recommendation to add chlorhexidine and its salts to Part 2 of Schedule 1 to CEPA. [1]

Chlorhexidine and its salts notably include the four substances in Table 1 below.

Table 1: Chlorhexidine and its salts

CAS RN [a]	Common name	DSL [b] name or chemical name
55-56-1	Chlorhexidine	2,4,11,13-Tetraazatetradecanediimidamide, N,N''-bis(4-chlorophenyl)-3,12-diimino-(chlorhexidine)
56-95-1	Chlorhexidine diacetate	2,4,11,13-Tetraazatetradecanediimidamide, N,N''-bis(4-chlorophenyl)-3,12-diimino-, diacetate
3697-42-5	Chlorhexidine dihydrochloride	2,4,11,13-Tetraazatetradecanediimidamide, N,N''-bis(4-chlorophenyl)-3,12-diimino-, dihydrochloride
18472-51-0	Chlorhexidine digluconate	D-Gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-Tetraazatetradecanediimidamide

a	The Chemical Abstracts Service Registry Number (CAS RN) 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.
b	Canada's *Domestic Substances List* (DSL) provides an inventory of substances in the Canadian marketplace.

Background

Strengthening Environmental Protection for a Healthier Canada Act

On June 13, 2023, the *Strengthening Environmental Protection for a Healthier Canada Act* received royal assent. It amended various provisions of CEPA and, for that reason, some provisions referenced throughout this document have since been repealed or replaced and are no longer in force. Particular to additions of substances to Schedule 1 to CEPA, it divided Schedule 1 in two parts. Toxic substances added to Part 1 require the ministers to prioritize the total, partial, or conditional prohibition of activities involved with those substances when managing their risks. Toxic substances added to Part 2 require the ministers to prioritize pollution prevention actions, which may include total, partial or conditional prohibition, when managing their risks. This Act provides transitional provisions under subsections 60(1), (2) and 61(1), (2) to determine whether substances assessed prior to this Act meet the criteria for addition to Part 1 or Part 2 of Schedule 1 to CEPA.

Chemicals Management Plan

The Chemicals Management Plan (CMP) is a federal program that assesses and manages chemical substances and living organisms that may be harmful to the environment or human health. As part of the CMP, the ministers assessed chlorhexidine and its salts under sections 68 and 74 of CEPA as it read before the coming into force of the *Strengthening Environmental Protection for a Healthier Canada Act*.

Description, uses, and sources of release

Chlorhexidine and its salts do not occur naturally in the environment. Mandatory surveys issued pursuant to section 71 of CEPA [2] for chlorhexidine (reporting year 2011), chlorhexidine diacetate (reporting years 2005, 2006 and 2011), chlorhexidine digluconate (reporting year 2011) and chlorhexidine dihydrochloride (reporting year 2015), along with voluntary information submitted for chlorhexidine dihydrochloride in 2013, indicate that these substances were not reported to be manufactured in Canada above the 100 kilograms (kg) reporting threshold, though they were reported to be imported in the following quantities per year:

(a) chlorhexidine: no imports reported above reporting threshold of 100 kg (2011);

(b) chlorhexidine diacetate: 100 kg to 1 000 kg (2005, 2006 and 2011);

(c) chlorhexidine digluconate: 10 000 kg to 100 000 kg (2011); and

(d) chlorhexidine dihydrochloride: 100 kg to 1 000 kg (2013); 1 000 kg to 10 000 kg (2015).

In Canada, chlorhexidine and its salts are used as broad-spectrum antiseptics, hand sanitizers, hard-surface disinfectants and as antimicrobial preservatives in products such as cosmetics, natural health products, prescription and non-prescription drugs for human and

veterinary uses. However, use of these substances in hand sanitizers and hard-surface disinfectants promoted to combat COVID-19 is not the principal intended use.

The quantity of chlorhexidine and its salts imported into Canada, along with information on their uses, indicate potential for both periodic and continual releases into the Canadian environment. Releases of these substances come from consumer use and the formulation of chlorhexidine-based products, mainly through the municipal and industrial wastewater, as treatment technologies may only partially remove chlorhexidine. Chlorhexidine salts dissociate in water releasing chlorhexidine, the moiety of toxicological concern. In the aquatic environment, chlorhexidine will have an affinity for dissolved and suspended solids and bed sediment. Chlorhexidine may also be released to soil through the application of biosolids from wastewater treatment systems [3] (WWTSs) to agricultural and pasture lands.

Current risk management activities

National

The transportation of chlorhexidine substances is subject to the *Transportation of Dangerous Goods Act, 1992* and *Transportation of Dangerous Goods Regulations* as well as to the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* and the *Interprovincial Movement of Hazardous Waste Regulations*. A number of regulatory and non-regulatory instruments also exist under the *Food and Drugs Act*, administered by the Department of Health, to limit the presence of chlorhexidine and its salts found in cosmetics, natural health products, and non-prescription drugs.

International

There are no known existing international risk management measures for controlling the releases of chlorhexidine and its salts to the environment. However, the United States Environmental Protection Agency completed a Reregistration Eligibility Decision for chlorhexidine diacetate as a pesticide active ingredient in 1996 and the substance, along with chlorhexidine digluconate, has been under a reregistration review since 2011.

In December 2017, the United States Food and Drug Administration issued a final rule regarding over-the-counter health care antiseptics, which includes chlorhexidine digluconate used in non-prescription antiseptic products intended for use by health care professionals in a hospital setting or other health care situations outside the hospital. As of December 20, 2018, companies can no longer market health care antiseptics (i.e. patient antiseptic skin preparation, health care personnel hand wash, health care personnel hand rub, surgical hand scrub and surgical hand rub) containing chlorhexidine digluconate, without first gaining approval of these products as new drugs.

Chlorhexidine and its digluconate salt are also registered as part of the registration, evaluation, authorisation and restriction of chemicals (REACH) regulation in the European Union. The REACH regulation aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. When a substance is registered under REACH, this means that companies have submitted information on hazards and assessment of risks to the European Chemicals Agency.

Summary of the screening assessment

On June 29, 2019, the ministers published a screening assessment under subsection 77(6) on chlorhexidine and its salts on the Canada.ca (Chemical substances) website. The screening assessment was

conducted to determine whether the substances meet one or more of the criteria for a toxic substance as set out in section 64 of CEPA.

Under section 64 of CEPA, a substance is considered 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.

The Department of the Environment and the Department of Health (the departments) collected and considered information from multiple sources (e.g. literature reviews, internal and external database searches, modelling, data gathered from mandatory surveys issued pursuant to section 71 of CEPA and, where warranted, data from targeted follow-ups with stakeholders) to inform the screening assessment conclusion. The ecological and human health portions of the assessment underwent external peer review and consultation with academics and other relevant stakeholders.

The screening assessment concluded that chlorhexidine and its salts meet the ecological criterion for a toxic substance as set out in paragraph 64(a) of CEPA and thus, constitute a risk to the environment in Canada. Below are summaries of the ecological and human health assessments.

Summary of the ecological assessment

The ecological assessment found that chlorhexidine and its salts, at low concentrations, have the potential to cause adverse effects, such as reduced growth and increased mortality in aquatic and benthic

organisms, with algae being particularly sensitive to the effects of chlorhexidine. Available studies on chlorhexidine indicate that chlorhexidine has a low potential to bioaccumulate in aquatic organisms, but that it tends to persist in water, sediment and soil, resulting in potential prolonged exposure to chlorhexidine both near and far from points of discharge to the environment.

As this assessment identified no data on measured chlorhexidine concentrations in environmental media in Canada, environmental concentrations were estimated from limited data collected through monitoring and surveillance of specific WWTSs and available information on quantities of chlorhexidine and its salts imported and consumed in Canada. The exposure assessment focused on the releases of chlorhexidine and its salts from the industrial formulation of chlorhexidine-based products and from down-the-drain releases resulting from the consumer use of such products. To determine if these scenarios may pose an ecological risk, a risk quotient was calculated as the ratio between predicted environmental concentrations (PECs) for these substances and predicted no-effect concentrations (PNECs). When PEC values are greater than PNEC values, there is potential for ecological harm. The results of this analysis indicate that at current levels of use, chlorhexidine and its salts pose a risk to aquatic and benthic organisms when released from industrial use, but not from the use of products containing these substances (down-the-drain releases).

The screening assessment concluded that chlorhexidine and its salts meet the ecological criterion for a toxic substance set out in paragraph 64(a) of CEPA. The assessment also determined that the chlorhexidine moiety meets the persistence criteria, but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

Summary of the human health assessment

No evidence for carcinogenicity [4] or genotoxicity [5] was observed in the available empirical data for chlorhexidine and its salts. Therefore, characterization of risk in the screening assessment was based on non-cancer effects.

Dietary exposure resulting from the use of chlorhexidine digluconate and chlorhexidine diacetate as components in incidental additives (e.g. cleaning products) used in food processing establishments is not expected. Exposure to chlorhexidine through consumption of potentially contaminated drinking water is estimated to be negligible. Therefore, the risk to human health from drinking water is considered to be low at current levels of exposure.

Exposure of the general population to chlorhexidine and its salts occurs predominantly through the use of cosmetics and natural health products that are applied to the skin. For cosmetics and natural health products that are used either daily or on an infrequent basis, comparisons of dermal exposure estimates with the critical effect level [6] showed that the risk to human health from the use of these products is considered to be low. Although concurrent or consecutive use of products containing chlorhexidine and its salts may occur, simultaneous exposures from a number of products containing these substances would not be of concern based on the conservative nature of this exposure scenario and the very low dermal absorption of chlorhexidine that has been observed experimentally.

Exposure to chlorhexidine and its salts can also occur orally from the use of a limited number of cosmetics such as lipsticks and lip balms, as well as natural health products such as mouthwashes. Given the limited number of products available and the small market share of these products, exposure of the general population by mouth to these

substances is limited. The assessment concluded that the risk to human health from oral exposures to lipsticks, lip balms and mouthwashes is expected to be low at current levels of exposure.

As the risk to human health from chlorhexidine and its salts is considered to be low at current levels of exposure, the screening assessment concluded that these substances do not meet the human health criterion for a toxic substance as set out under paragraph 64(c) of CEPA.

Objective

The objective of the *Order Adding a Toxic Substance to Part 2 of Schedule 1 to the Canadian Environmental Protection Act, 1999* (the Order) is to enable the ministers to propose risk management instruments for a toxic substance under the Act that prioritize pollution prevention actions, which may include prohibitions, when managing potential environmental risks associated with the substance.

Description

The Order adds the substance 2,4,11,13-Tetraazatetradecanediimidamide, N,N"-bis(4-chlorophenyl)-3,12-diimino-(chlorhexidine) and its salts to Part 2 of Schedule 1 to CEPA.

Regulatory development

Consultation

On August 19, 2017, the ministers published a Notice with a summary of the draft screening assessment of chlorhexidine and its salts (which included a link to the complete draft screening assessment) in the *Canada Gazette*, Part I, for a 60-day public comment period. The Notice also informed of the publication of the risk management scope for chlorhexidine and its salts to initiate discussions with stakeholders on the development of risk management actions, following its addition to

Schedule 1 to CEPA. During this period, comments from four stakeholders were received on the draft screening assessment. A table summarizing the complete set of comments received and the response to these comments is available on the Canada.ca (Chemical substances) website.

Industry stakeholders provided information on the usage and the sources of releases of these substances. They also provided comments regarding current risk management practices for chlorhexidine within their respective business activities. Officials acknowledged the information provided by all of the stakeholders. Those comments were generally in line with the information already considered in the screening assessment. Stakeholders also pointed out that certain aspects of the risk characterization could be revised to minimize uncertainty or results bias in the screening assessment. Officials responded by providing justifications for the methodological choices or the information presented in the screening assessment. These comments were considered in the development of the final screening assessment, published on June 29, 2019, but did not change the conclusion that chlorhexidine and its salts meet the criteria for a toxic substance as set out in paragraph 64(a) of CEPA.

On June 29, 2019, the ministers also published a risk management approach document on the Canada.ca (Chemical substances) website to continue discussions with stakeholders on the proposed risk management actions for chlorhexidine and its salts, including the implementation of a code of practice and an environmental performance agreement to reduce releases to the environment from the industrial use of these substances.

On March 6, 2021, the proposed Order recommending the addition of chlorhexidine and its salts to Schedule 1 to CEPA was published in the *Canada Gazette*, Part I, followed by a 60-day public comment period.

During this period, comments from one stakeholder (an individual) were received, supporting the addition of the substances to Schedule 1 to CEPA.

The departments informed the provincial and territorial governments about all publications through the CEPA National Advisory Committee (NAC) [7] via a letter and provided them with an opportunity to comment. No comments were received from the Committee.

Modern treaty obligations and Indigenous engagement and consultation

An assessment of modern treaty implications conducted in accordance with the *Cabinet Directive on the Federal Approach to Modern Treaty Implementation* concluded that orders adding substances to Schedule 1 to CEPA do not introduce any new regulatory requirements and, therefore, do not result in any impact on modern treaty rights or obligations. Therefore, specific engagement and consultations with Indigenous peoples were not undertaken. However, the prepublication comment period is an opportunity for Indigenous peoples to provide feedback on the proposed Order, which is open to all Canadians.

Instrument choice

Following an assessment conducted under section 68 of the Act, the publication of the assessment conclusion under section 77 of the Act must propose one of the following measures:

(a) taking no further action in respect of the substance;

(b) unless the substance is already on the List referred to in section 75.1 (List of substances that the ministers suspect to be capable of becoming toxic), adding the substance to that List;

(c) recommending that the substance be added to Part 1 of Schedule 1 to CEPA; or

(d) recommending that the substance be added to Part 2 of Schedule 1 to CEPA.

Toxic substances that pose the highest risk are added to Part 1 of Schedule 1. These are prioritized for total, partial, or conditional prohibition. Other toxic substances are added to Part 2 of Schedule 1 and are prioritized for pollution prevention actions, which may include total, partial or conditional prohibition. Until regulations specifying criteria for the classification of substances that pose the highest risk or that are carcinogenic, mutagenic, or toxic to reproduction are developed, toxic substances that have been found to meet the criteria in the existing *Persistence and Bioaccumulation Regulations* (the Regulations) will be added to Part 1 of Schedule 1. Should additional criteria be specified in regulation, some substances initially considered for addition to Part 2 of Schedule 1 may instead be considered for addition to Part 1 of Schedule 1. Since chlorhexidine and its salts do not meet the criteria set out in the Regulations, they are being added to Part 2 of Schedule 1 to CEPA.

Regulatory analysis

Benefits and costs

The addition of chlorhexidine and its salts to Part 2 of Schedule 1 to CEPA does not, on its own, impose any regulatory requirements on businesses and, therefore, does not result in any incremental compliance costs for stakeholders or enforcement costs for the Government of Canada. The Order grants the ministers the authority to develop risk management instruments under CEPA for these substances. The Government of Canada will consult stakeholders on any future risk management measures for chlorhexidine and its salts before implementation and will consider their potential impacts. [8]

Small business lens

Analysis under the small business lens concluded that the Order will not impact Canadian small businesses, as it does not impose any administrative or compliance costs on businesses.

One-for-one rule

The one-for-one rule does not apply, as the Order does not result in a change in administrative burden imposed on businesses.

Regulatory cooperation and alignment

Canada cooperates with other international organizations and regulatory agencies for the management of chemicals (e.g. the United States Environmental Protection Agency, the European Chemicals Agency and the Organisation for Economic Co-operation and Development). Chlorhexidine and its salts are not listed in any multilateral agreement to which Canada is a party. While the Order does not on its own relate to any international agreements or obligations, it enables the ministers to propose risk management measures that may align with actions undertaken by other jurisdictions.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a strategic environmental assessment was completed for the CMP, inclusive of orders adding substances to Part 2 of Schedule 1 to CEPA. The assessment concluded that the CMP is expected to have a positive effect on the environment and human health.

Gender-based analysis plus

No gender-based analysis plus (GBA+) impacts have been identified for the Order.

Implementation, compliance and enforcement, and service standards

As no specific risk management measures are recommended as part of the Order, developing an implementation plan and a compliance and enforcement strategy as well as establishing service standards are not necessary at this time.

Contacts

Thomas Kruidenier
Executive Director
Substance Prioritization, Assessment and Coordination Division
Environment and Climate Change Canada
Gatineau, Quebec
K1A 0H3
Substances Management Information Line:
1-800-567-1999 (toll-free in Canada)
819-938-3232 (outside of Canada)
Email: substances@ec.gc.ca

Andrew Beck
Director
Risk Management Bureau
Health Canada
Ottawa, Ontario
K1A 0K9
Telephone: 613-266-3591
Email: andrew.beck@hc-sc.gc.ca

Footnotes

a S.C. 2023, c. 12, s. 55

b S.C. 1999, c. 33

c S.C. 2023, c. 12, s. 29

1 The *Strengthening Environmental Protection for a Healthier Canada Act* divided Schedule 1 of CEPA in two parts. Toxic substances added to Part 1 requires the ministers to prioritize the total, partial, or conditional prohibition of activities involved with those substances when managing their risks. Toxic substances added to Part 2 requires the ministers to prioritize pollution prevention actions, which may include total, partial or conditional prohibition, when managing their risks. For more information, see subsections 90(1) and 90(1.1) of CEPA.

2 Section 71 surveys are used as a tool by the departments to collect information from industry and individuals on surveyed substances, such as their uses, as well as manufacture and import quantities, which may inform assessment conclusions on those substances.

3 In this document, the term “wastewater treatment system” (WWTS) refers to a system that collects domestic, commercial and/or institutional household sewage and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term WWTS makes no distinction of ownership or operator type (municipal, provincial, federal, Indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents are identified by the terms “on-site WWTSs” and/or “industrial WWTSs.”

4 A carcinogen is any substance, radionuclide, or a radiation that promotes carcinogenesis, the formation of cancer.

5 Genotoxicity is a word in genetics defined as a destructive effect on a cell’s genetic material (DNA, RNA) affecting its integrity.

6 The critical effect level denotes the level of exposure at which there is no significant increase in the frequency or severity of any adverse effects in the exposed population.

7 Section 6 of CEPA provides that the CEPA NAC be the main intergovernmental forum for the purpose of enabling national action and avoiding duplication in regulatory activity among governments within Canada. This committee has a representative for the Department of the Environment and for the Department of Health, a representative of each of the provinces and territories, as well as up to six representatives of Indigenous governments.

8 Any future regulatory measures would be subject to the government’s regulatory policy and requirements for cost-benefit analysis and consultation.