

Proposed Environmental Performance Agreement for the Formulation of Chlorhexidine Products (“Agreement”)

Between

Her Majesty the Queen in Right of Canada,
as represented by the Minister of the Environment

(“Environment and Climate Change Canada” or “ECCC”)

And

Participating Companies

Preamble

WHEREAS in order to determine whether or not they are toxic or capable of becoming toxic to the environment or human health, the Minister of the Environment and the Minister of Health have conducted a screening assessment of chlorhexidine and its salts, including, but not limited to:

CAS RN	Substance
55-56-1	Chlorhexidine
56-95-1	Chlorhexidine diacetate
3697-42-5	Chlorhexidine dihydrochloride
18472-51-0	Chlorhexidine digluconate

WHEREAS the Minister of the Environment and the Minister of Health have concluded that chlorhexidine and its salts meet the criteria under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999* (CEPA) as they are entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity;

WHEREAS it was concluded that chlorhexidine and its salts do not meet the criteria under paragraph 64(b) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends and do not meet the criteria under paragraph 64(c) of CEPA as they are not 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;

WHEREAS it has been determined that the chlorhexidine and its salts meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA;

WHEREAS the characterization of the ecological risk indicates that releases of chlorhexidine moiety in the aquatic environment from the industrial formulation of chlorhexidine-based products pose a risk to aquatic and benthic organisms;

WHEREAS Participating Companies use chlorhexidine and its salts in the industrial formulation of chlorhexidine-based products in Canada and their releases of chlorhexidine moiety may pose a risk to the environment;

WHEREAS the Minister of the Environment recognizes voluntary action of industry as an efficient means to achieve environmental objectives;

WHEREAS Provincial, Aboriginal Governments and stakeholders of non-government organizations were informed about the publication of the proposed Agreement as part of this consultation process;

AND WHEREAS Participating Companies are willing to work with ECCC towards reducing the contribution of chlorhexidine moiety released from their facilities to levels that are protective of the environment;

The parties to this Agreement agree as follows:

1. Purpose

The purpose of this Agreement is to protect the aquatic environment by minimizing Participating Companies' releases of chlorhexidine and its salts, from their Facilities that formulate chlorhexidine-based products.

2. Definitions

In this Agreement:

“Chlorhexidine moiety” means the chlorhexidine molecule without the salt. Chlorhexidine salts dissociate (split apart) in water, releasing the chlorhexidine moiety.

“Facility” means an industrial Facility using chlorhexidine and its salts to formulate chlorhexidine-based products.

“Final discharge point” means an identifiable discharge point beyond which Participating Company no longer exercises control over quality of the effluent.

“Normal operating conditions” means conditions that are representative of regular or typical operating conditions related to the formulation of chlorhexidine-based products.

“Participating Company” means a company that owns one or more Facilities using chlorhexidine and its salts to formulate chlorhexidine-based products and that has signed the “List of Participating Companies” found at Annex A to this Agreement.

3. Non-Binding Agreement

3.1 This Agreement represents an understanding between ECCC and Participating Companies. It is not intended to create legally binding obligations and is therefore not legally enforceable.

3.2 This Agreement does not preclude Participating Companies from implementing any other environmental initiatives or measures as it sees fit. Adherence to this Agreement does not in any way exempt Participating Companies from complying with all applicable laws and regulations.

3.3 This Agreement does not preclude ECCC from taking other measures or actions, including making laws, or enforcing the existing laws of the Government of Canada.

3.4 Participating Companies agree to participate fully in this Agreement to attain the objective of minimizing the release of chlorhexidine and its salts from their Facilities to levels that are protective of the aquatic environment as set out in this Agreement.

3.5 ECCC may add other companies that release chlorhexidine and its salts in a concentration that may result in levels that are not protective to the environment as a party to this Agreement.

3.6 This Agreement will apply to the successors or assignees of the parties.

3.7 In the event that a company is no longer a party to the Agreement, the Agreement shall survive and remain in effect for the remaining parties.

4. Duration, Amendment and Termination

4.1 Participating Companies agree to be subject to this Agreement by signing “Annex A: List of Participating Companies”.

4.2 The Agreement is in effect until XXX, XXX, 2028.

4.3 The term of Agreement may be extended with the written consent of the Participating Parties and ECCC.

4.4 This Agreement may be amended with the written consent the Participating Companies and ECCC.

4.5 A Participating Company may end its participation in this Agreement at any time, without cause and for their sole convenience, by providing at least three (3) month’s written notice to ECCC of its intention to terminate. The Agreement will then remain in effect for the remaining Participating Companies.

4.6 ECCC may terminate the Agreement with all or some of the Participating Companies without cause and at its sole convenience by providing at least three (3) month’s written notice of its intention to terminate.

4.7 In the event that a Participating Company no longer uses or releases chlorhexidine and its salts, it shall so inform ECCC, and that party's responsibilities under this Agreement shall end. However, the Agreement will remain in effect for the remaining Participating Companies.

4.8 ECCC may amend Annex A: List of Participating Companies to include a new Participating Company without the consent of existing Participating Companies. The Agreement will become effective for the new Participating Company after ECCC and the new Participating Company sign Annex A.

5. Performance Objectives

A Participating Company agrees to:

5.1 minimize releases of chlorhexidine and its salts from its facilities so that the resulting contribution of chlorhexidine moiety to the aquatic environment is protective of the aquatic environment. The procedure to estimate a Facility's concentration of chlorhexidine moiety to the aquatic environment is in Annex B;

5.2 prepare and implement a chlorhexidine management plan that applies the best management practices contained in Annex C that:

5.2.1 identifies all activities or operations through which chlorhexidine moiety may be released in wastewater;

5.2.2 identifies, for each of the above activities and operations, the best management practices that are currently in place and that will be implemented to reduce the release of chlorhexidine moiety to levels that are protective of the environment;

5.2.3 includes record-keeping procedures as described in section 6 of this Agreement;

5.2.4 provides a commitment or endorsement of the chlorhexidine management plan by the senior management level of the Facility; and

5.2.5 includes a procedure for yearly review of the chlorhexidine management plan by the Facility;

5.3 conduct sampling and analysis as follows:

5.3.1 samples should be representative of the highest expected concentration of chlorhexidine moiety in industrial effluent at its Facilities' final discharge point(s) resulting from normal operating conditions during production of chlorhexidine products. If possible, sample collection should be conducted using composite sampling methods;

- 5.3.2 samples should be collected and analyzed at a minimum frequency of two times per year, with a minimum of at least 2 months between sampling; taken at each final discharge point;
- 5.3.3 analysis of samples should be performed in accordance with generally accepted standards of good scientific practice at the time of the analysis and by a laboratory that is accredited:
- 5.3.3.1 under the International Organization for Standardization standard ISO/IEC 17025, entitled *General requirements for the competence of testing and calibration laboratories*, by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; or
 - 5.3.3.2 under the *Environment Quality Act*, CQLR, c. Q-2; and
- 5.3.4 analysis of samples can also be performed by a laboratory that is not accredited but that uses an analytical method that meets the minimum following criteria:
- 5.3.4.1 Method Detection Limit: 14 µg/L;
 - 5.3.4.2 Accuracy: 30%; and
 - 5.3.4.3 Precision: 30%.

6. Retention of Records

A Participating Company will keep copies of its chlorhexidine management plan and chlorhexidine evaluation reports for the duration of this Agreement plus one (1) year thereafter.

7. Reporting

7.1 A Participating Company will provide to ECCC the following documents:

7.1.1 a copy of its chlorhexidine management plan within one (1) year after signing the List of Participating Companies at Annex A of this Agreement; and

7.1.2 a copy of its chlorhexidine evaluation report as set out in Annex B by March 30 of each year that the Agreement is in effect, plus one year thereafter.

7.2 The above documents will be sent to:

The Chemical Production Division
Environmental Protection Branch, Industrial Sectors and Chemicals Directorate
Environment and Climate Change Canada, Government of Canada
Email: pgpc-dppc-cmp-cpd@ec.gc.ca;

7.3 ECCC will review a Participating Company's chlorhexidine management plan and evaluation reports and prepare a draft annual summary of the progress and results. ECCC will provide a Participating Company with a copy of the draft annual summary of progress and results.

7.4 A Participating Company will review the ECCC summary of its progress and results and provide any comments they may have to ECCC within 30 days of receipt of the summary from ECCC.

7.5 ECCC will post the annual summary of progress and results of Participating Companies in the environmental performance agreements section of canada.ca at <https://www.canada.ca/en/environment-climate-change/services/environmental-performance-agreements.html>.

8. Verification

8.1 ECCC will review and verify the documents submitted under subsection 7.1 and will assess progress made under this Agreement on an annual basis. ECCC may request additional information from a Participating Company if necessary to conduct its review and verification.

8.2 ECCC will perform verifications of the content of the reports at the Facilities of a Participating Company as set out in Annex D. These verifications will be conducted at least two times throughout the Agreement that may include Facility personnel interviews, site visits and verification of records.

8.3 A Participating Company will complete any agreed upon corrective actions identified by the verification team and confirm completion in writing and by providing supporting documentation to ECCC within the agreed timeline as described in the Verification Protocol set out in Annex D.

9. Roles and Responsibilities

9.1 A Participating Company agrees to:

9.1.1 achieve and maintain the performance objectives outlined in section 5 of this Agreement;

9.1.2 report to ECCC pursuant to section 7 of this Agreement;

9.1.3 collaborate with ECCC during the verification process, and complete any resulting follow up actions within an agreed timeframe;

9.1.4 take all necessary actions to implement all sections of the Agreement that pertain to its operation; and

9.1.5 continually strive to further reduce releases of chlorhexidine moiety.

9.2 ECCC agrees to:

9.2.1 advise on the requirements of the Agreement, if required;

9.2.2 monitor progress under this Agreement, oversee its administration, and evaluate its effectiveness with respect to the objectives and requirements;

9.2.3 participate in the verification process as outlined in section 8;

9.2.4 post annual progress reports on the Government of Canada's website summarizing progress made under this Agreement; and

9.2.5 review information annually on facilities that report releases of chlorhexidine and its salts to the National Pollutant Inventory (NPRI) and undertake an analysis of whether such releases to the aquatic environment may contribute to exceeding the concentration specified in Annex B. If the analysis suggests the concentration may be exceeded, ECCC will encourage such facilities to participate in this Agreement.

10. Acknowledgements and Failure to Implement

10.1 ECCC agrees to acknowledge publically the accomplishments of a Participating Company made pursuant to this Agreement. The time and manner of any such acknowledgement will be at the discretion of ECCC.

10.2 Participating Companies understand that when ECCC is assessing whether regulatory or other measures are required to prevent or reduce adverse impacts of releases of chlorhexidine moiety into the aquatic environment, it will consider whether the objectives and requirements of this Agreement have been met.

11. Availability of Agreement and Confidential Information

11.1 A copy of this Agreement, and related information such as status reports, will be made available on Government of Canada's website at <https://www.canada.ca/en/environment-climate-change/services/environmental-performance-agreements/list.html>.

11.2 Correspondence with ECCC related to this Agreement should be sent to ECCC by electronic mail at pgpc-dppc-cmp-cpd@ec.gc.ca.

11.3 ECCC agrees to keep confidential and not disclose any confidential information obtained from Participating Companies under this Agreement as set out in section 321 of CEPA. A request for confidentiality from a Participating Company will specify the information that is considered to be confidential and the reason why it should be treated as such.

11.4 Nothing in this Agreement shall be interpreted to preclude ECCC from disclosing information that ECCC may be required or ordered to disclose pursuant to any applicable federal laws or court orders, including, the Access to Information Act, R.S.C. 1985.

12. Signatures

By signing Annex A to this Performance Agreement, the parties acknowledge that they have read and accept all of the terms and provisions of the Agreement.

ECCE may add other companies to this Agreement by accepting the signature of a duly authorized representative on Annex A: List of Participating Companies.

Annex A: List of Participating Companies

<p>Agrisan Specialty Chemical and Pharmaceutical</p> <p>Signature: _____</p> <p>Name (Print):</p> <p>Title:</p> <p>Date:</p>	<p>Environment and Climate Change Canada</p> <p>Signature: _____</p> <p>John Moffet Assistant Deputy Minister, Environmental Protection Branch Environment and Climate Change Canada</p> <p>Date:</p>
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<p>Germiphene Corporation</p> <p>Signature: _____</p> <p>Name (Print):</p> <p>Title:</p> <p>Date:</p>	<p>Environment and Climate Change Canada</p> <p>Signature: _____</p> <p>John Moffet Assistant Deputy Minister, Environmental Protection Branch Environment and Climate Change Canada</p> <p>Date:</p>
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<p>Insert New Co. Name</p>	<p>Environment and Climate Change Canada</p>
<p>Signature: _____</p>	<p>Signature: _____</p>
<p>Name (Print):</p>	<p>Name: (Print):</p>
<p>Title:</p>	<p>Title:</p>
<p>Date:</p>	<p>Date:</p>

Annex B: Chlorhexidine Annual Evaluation Report

Complete and submit a copy of this report to pgpc-dppc-cmp-cpd@ec.gc.ca by March 30th for every year that this Agreement is in effect plus one year after. In accordance with subsection 11.3 and 11.4, ECCC agrees not to disclose any confidential information obtained with this form.

1. Contact information

Name and civic address of the person providing information or duly authorized representative:

- a. Name of participating company/corporation
- b. Facility address where the evaluation is performed
- c. Name of contact
- d. Email address
- e. Telephone number

2. The Facility's estimated concentration of chlorhexidine moiety entering the aquatic environment.

Use the following procedure to estimate the Facility's concentration of chlorhexidine moiety in the aquatic environment.

Add rows as necessary to complete the evaluation report.

Step 1: Calculate the total quantity of chlorhexidine moiety used per year (kg/yr)	
<p>Chlorhexidine moiety is the chlorhexidine molecule without the salt. To convert the mass of chlorhexidine and its salts to the mass of the chlorhexidine moiety, the following conversion factors are used.</p> <ul style="list-style-type: none"> • Chlorhexidine digluconate: 0.56 • Chlorhexidine diacetate: 0.81 • Chlorhexidine dihydrochloride: 0.87 <p style="text-align: center;">Chlorhexidine moiety used (kg/yr) = (0.56a + 0.81b + 0.87c)</p> <p>Where;</p> <p>a = quantity of chlorhexidine digluconate used per year (kg/yr) b = quantity of chlorhexidine diacetate used per year (kg/yr) c = quantity of chlorhexidine dihydrochloride used per year (kg/yr)</p>	
Evaluation Criteria	Result/Comments
(a) kg of chlorhexidine digluconate	
(b) kg of chlorhexidine diacetate	

(c) kg of chlorhexidine dihydrochloride	
Total chlorhexidine moiety used (kg/year) = (0.56a + 0.81b + 0.87c)	
Step 2: Estimate the average quantity of chlorhexidine moiety entering the aquatic environment (kg/day)	
$Average\ Quantity\left(\frac{kg}{day}\right) = \frac{Chlorhexidine\ Moiety\ Used\left(\frac{kg}{yr}\right) \times Fraction\ lost\ to\ WW}{Release\ Days\ per\ year} \times \left[1 - \left(\frac{WWTP\ EFF}{100}\right)\right]$	
<p>Where;</p> <p>WWTP_{EFF} = Wastewater Treatment Plant Removal Efficiency</p> <p>Assumptions¹ that may be used:</p> <ul style="list-style-type: none"> • Fraction lost to Wastewater (WW) = 0.00426 • WWTP_{EFF} for Primary Treatment ~ 84% • WWTP_{EFF} for Secondary Treatment ~ 98% • WWTP_{EFF} for Lagoons ~ 94% 	
Evaluation Criteria	Result/Comments
Fraction lost to Wastewater (If using an assumption that differs from the one provided in Step 2, please provide assumption and justification)	
Number of release days/batches per year	
Wastewater treatment type	Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Lagoon <input type="checkbox"/>
Wastewater Treatment Efficiency (%) (If using an assumption that differs from the one provided in Step 2, please provide assumption and justification)	
Estimated daily release of chlorhexidine moiety (kg/day)	
Step 3: Estimate the Facility's concentration of chlorhexidine moiety in the aquatic environment (ng/L)	

¹ Environment Canada (June 2019), *Screening assessment – Chlorhexidine and its salts*.

$$\text{Concentration } \left(\frac{\text{ng}}{\text{L}}\right) = \left[\frac{\text{Average Quantity } \left(\frac{\text{kg}}{\text{day}}\right)}{\text{WWTP Flow } \left(\frac{\text{L}}{\text{day}}\right)} \times \left(10^{12} \frac{\text{ng}}{\text{kg}}\right) \right] / DF$$

Where;

DF = Dilution factor² = 10

WWTP Flow = Wastewater treatment effluent flow³ may be estimated as follows:

- Arthur Wastewater Treatment Plant Effluent Flow ~ 1,733,000 L/day
- Cainsville Lagoon Effluent Flow ~ 1,775,000 L/day

Evaluation Criteria	Result/Comments
Wastewater treatment effluent flow to the river (L/day) (If using an assumption that differs from the one given in Step 3 please provide assumption and justification)	
Estimated concentration of chlorhexidine moiety entering the aquatic environment (ng/L)	
Is the estimated concentration of chlorhexidine moiety entering the aquatic environment lower than the Predicted No Effect Concentration (PNEC) of 210 ng/L. If no, please explain what best management practices will be implemented to reduce the contribution of chlorhexidine moiety from the Facility:	Yes <input type="checkbox"/> No <input type="checkbox"/>

3. Completion of the annual review of the Chlorhexidine Management Plan as per subsection 5.2 of the Agreement Yes No

4. Reporting on implementation of Best Management Practices

Has the Facility implemented the recommended best management practices as described in Annex C?

1. Implementation of an Environmental Management System (EMS)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:
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² Idem

³ Idem

<p>2 Training on operational procedures</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>3. Written procedures of best practices for receiving, storing and transfer of chemical substances and their packaging.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>4. Batch Process Operations</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>5. Written procedures of best practices for packaging, loading, shipping and handling chemical substances and their packaging.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>6. A waste management plan that includes waste minimization, re-use, recycling, storage and disposal procedures.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>7. Maintenance operations for pollution control, safety and other critical equipment.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>
<p>8. Spills and leak procedures.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> Please describe:</p>

9. Other	Please describe:
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5. Sampling and analysis as per subsection 5.3 of the Agreement.

Was sampling conducted twice within the reporting year? If no, please explain:	Yes <input type="checkbox"/> No <input type="checkbox"/>
1. Date and concentration range (lowest to highest) for first batch of samples (ng/L)	
2. Date and concentration range (lowest to highest) for second batch of samples (ng/L)	
Were samples taken at the final discharge point of the Facility and representative of the highest expected concentration of chlorhexidine moiety resulting from normal operating conditions? Please explain:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Were samples analyzed by an accredited laboratory as described in subsection 5.3 of the Agreement? If no, please explain (describe the method used and provide the method detection limit, accuracy and precision of the method):	Yes <input type="checkbox"/> No <input type="checkbox"/>

Annex C: Best Management Practices

The following best management practices should be considered in preparing the chlorhexidine management plan.

1. Environmental Management System (EMS)

- A Participating Company should develop, implement and maintain an EMS consisting of a set of policies and procedures for the responsible management of chemical substances using the best management practices below. The EMS should be consistent with nationally recognized EMS standards (e.g., ISO14001) and an annual or more frequent review of the EMS should be conducted to identify and implement EMS improvement.

2. Training on operational procedures

- Training on environmental policy and procedures, including clear definitions of roles and responsibilities with respect to environmental management work.
 - The training program should ensure that all management, employees and contractors are familiar with the EMS and associated best practices. Training could also be extended to customers.
 - Training should cover task-specific (e.g., equipment cleaning) and Facility-wide activities (e.g., chemical storage, spill response) while providing employees with context regarding the importance of them following procedures.

3. Written procedures of best practices for receiving, storing and transfer of chemical substances and their packaging.

a. Reception of chemicals

Only individuals with training as per section 2 should be permitted to use, handle and transport chemicals including chemical waste. The Facility's loading/unloading area should:

- be located within the site premises and not on public roads.
- be located away from waterbodies or other possible sensitive areas.
- have proper drainage and anti-slip flooring, and be frequently cleaned and kept free of snow, ice and tripping hazards.
- have lighting adequate for discharge operations during the hours of darkness at the loading/unloading area, and
- be inspected by site operators before, during and after the loading/unloading to ensure all requirements are met.

b. Storage of chemicals

- Store chemicals according to need, with minimal product inventory kept on hand.
- Ensure that inventory information is recorded and maintained up-to-date at all times.
- Ensure that chemical containers are kept tightly sealed, covered and stored upright in order to reduce potential leaks, spills and evaporation.
- Ensure that appropriate physical storage requirements are considered, such as specific temperature, pressure and humidity requirements, or incompatibilities with other potentially stored materials. These considerations are usually described in Safety Data Sheets and/or are available from the supplier.
- Store chemicals away from sewers, drains, and other openings that may allow environmental releases in the event of an undetected leak.

c. Transfer of chemical substances

Chemical substances transferred from storage containers into processing vessels for production operations can result in unintended releases. There is often precise handling guidelines outlined for specific substances or substance groups, and the Facility operators should be cognizant of which practices should be applied within their facilities. Regardless of the type of container utilized, all employees and contractors involved in the transferring of chemicals should be fully trained to understand the contents of containers and the prevention of spills.

Some best practices for transferring chemicals may include the following activities:

- Where possible, purchase pre-weighed chemicals in sealed polyethylene bags instead of manually weighing to reduce fugitive air emissions and spills.
- Ensure adequate containment by using drip pans to prevent residual product drips from valves and connections from entering the environment.
- In procedures that involve the handling of powder materials, such as the loading of reactor vessels, the use of a local exhaust capture system will avoid dust emissions.
- Close windows and doors near transfer operations in order to avoid interference with the exhaust system. Where local exhaust ventilation is used, ensure that air passes through an appropriately designed filter system before discharge to the environment.

4. Batch Process Operations

Products containing chlorhexidine are generally prepared in batches using a tank where pure chlorhexidine salt is diluted and mixed with other substances. These batch processes involve equipment cleaning/rinsing between batches to avoid cross contamination. This cleaning/rinsing process can result in releases of chlorhexidine moiety to the aquatic environment. All efforts should be made to minimize release of chemicals in the environment from batch process rinsing.

Best practices include the following activities:

- Batch process equipment and process should be designed to minimize chemical residues (e.g., piping to be flushed is as short as possible (less piping will have less rinsate residue) and is installed on an incline to help complete flushing and draining, the tank designed to maximize its emptying, and the temperature of fluids should be set higher or additives used to minimize viscosity and chemical substance residues).
- The schedule for batch preparation should be optimized to minimize tank cleaning requirements.
- Pre-rinsing and collection of the first rinsate for reuse.
- Rinsate from additional rinsing stages can then be collected and sent to municipal wastewater treatment systems. The rinsate must not be disposed of/released without appropriate treatment to municipal storm water collection systems or surface watercourses. Consider using several specialized treatment technologies in order to destroy or neutralize chlorhexidine.
- Waste residue should be minimized by totally emptying tank and piping. When possible, dry cleaning/flushing, using pressure air or vacuum, should be done to maximize chemical recuperation for its end purpose.
- Disposal in secure landfill that will prevent any waterborne connection between waste products and the surrounding natural environment or incineration of harmful chemical residue.

5. Written procedures of best practices for packaging, loading, shipping and handling chemical substances and their packaging.

A Participating Company should engage with transportation partners and logistics service providers to ensure that it has properly implemented chemical spill prevention procedures, as losses can occur at transport interfaces (loading, unloading, and handling) during transport from the distributor to end-user.

Best practices include the following activities:

- Ensure that chemicals are received in sealed containers.
- Inspect and document the condition of packaging before offloading to detect any potential leaks. If the shipment is damaged in a way that may result in a spill, notify the transporter and importer and/or consider refusing to accept delivery.
- Repair or replace punctured packages immediately and clean up any spills immediately to prevent environmental releases.
- Ensure that packaging is designed to minimize the possibility of breakage and subsequent chemical leakage.
- Use reinforced containers/bags if damage to containers/bags is a recurring problem.

6. A waste management plan that includes waste minimization, re-use, recycling, storage and disposal procedures.

A Participating Company should develop and implement a waste management plan covering all aspects of waste management at its Facilities. This waste management plan should address opportunities for recycling/reuse of waste materials as well as the disposal of waste materials.

Best practices include the following activities:

- Ensure that a designated safe storage area is made available for hazardous and liquid waste.
- Ensure that waste is stored in the proper designated safe area, and that it is clearly labelled and kept in appropriate containers in closed areas.
- Ensure waste containers are suitable for the specific chemicals they contain.
- Transport waste in completely sealed containers to avoid possible releases into the environment.
- Routinely inspect and confirm the proper handling and storage procedures are in place.
- If an outside carrier/collector is used for waste removal to an off-site disposal Facility, ensure that the disposal company provides a written confirmation that the waste will be disposed of in the manner agreed to.
- Totes and drums can be reused, recycled, or disposed of depending on the supplier and user's circumstances. After the contents are used, and before the packaging is returned to a designated handler, it is important to properly seal the empty package by closing valves, caps, lids, etc. This will prevent losses of residual product from the package into the environment.

7. Maintenance operations for pollution control, safety and other critical equipment

In regards to maintenance of equipment, an effective maintenance program should be in place.

Best practices include the following activities:

- Ensure that all equipment (owned, leased or subcontracted) is adequately maintained to prevent and detect defects before they cause spills/leaks.
- Ensure that employees and contractors repair leaks and other problems immediately to reduce cleaning efforts, extend the life of the equipment and reduce the consumption of raw materials/avoid loss of manufactured product.
- Establish a schedule for maintaining and cleaning equipment employed at the Facility and ensure that the schedule is adhered to.
- Maintenance procedures to control chemical losses, disposal of fugitive process materials and proper handling of personal protective equipment and tools that may have come into contact with various chemicals.
- Procedures to prevent chemical substance spills and releases from service providers, transportation partners and customers.

8. Spills and leak procedures

In the event of a spill of chlorhexidine and its salts, the Participating Company should immediately take all necessary measures to contain and prevent releases into the environment.

Best practices include the following activities:

- The first priority is to minimize the amount of the spill and to cover all drains in the surrounding area.
- Isolate or interrupt the flow by immediately closing valves, rotating drums or transferring the contents to minimize the spill.
- Ensure that spill kits contain the necessary materials to contain, clean-up and securely store the spilled materials (e.g. absorbents, neutralizing agents, or clean-up tools) and are immediately available and easily accessible. Ensure that these kits are made available in areas where a risk of spills occurring has been identified (for example, chemical storage rooms), and maintained on a regular basis to ensure that they are fit for the intended purpose.
- Track all spills and document the cause, response, and steps taken to prevent their recurrence.
- Undertake advanced planning to prevent such incidents, in the form of written procedures for spill prevention, containment and cleanup (for example, a spill prevention and management plan).

Annex D: Verification Protocol for the Environmental Performance Agreement Concerning the Formulation of Chlorhexidine Products

The following verification protocols were developed to ensure participating companies are meeting the objectives and requirements of the agreement.

1.0 VERIFICATION SCOPE AND OBJECTIVE

This protocol establishes verification procedures for the second party verification of the requirements of the *Environmental Performance Agreement Concerning the formulation of Chlorhexidine Products* (the Agreement) between Environment and Climate Change Canada (ECCC) and a Participating Company.

The objective of the verification is to confirm that the Agreement is being fully implemented by a Participating Company in order to reduce the total concentration of chlorhexidine moiety released from industrial facilities that formulate chlorhexidine-based products.

2.0 DEFINITIONS AND ABBREVIATIONS

“Agreement” means the *Environmental Performance Agreement Concerning the formulation of Chlorhexidine Products*.

“Chlorhexidine Moiety” means the chlorhexidine molecule without the salt. Chlorhexidine salts dissociate (split apart) in water, releasing the chlorhexidine moiety

“Facility” means an industrial Facility using chlorhexidine and its salts to formulate chlorhexidine-based products.

“Participating Company” means a company that is a party to this Agreement that owns one or more Facilities using chlorhexidine and its salts to formulate chlorhexidine-based products.

“Verification” means a second party verification process to review, assess and confirm the information and claims made by a Participating Company under this Agreement. Verification will include a documentation review, site visit and follow-up activities.

3.0 VERIFIABLE INFORMATION

The following information will be kept on site at a Facility or on file by a Participating Company in order to demonstrate that the objectives of the Agreement have been met:

- (a) Chlorhexidine management plan as per subsection 5.2 of the Agreement; and
- (b) Completed chlorhexidine evaluation reports as per Annex B of the Agreement.

4.0 VERIFIER QUALIFICATIONS

The verification team will be made up of officials from ECCC who:

- have a thorough understanding of the Agreement and of this protocol;
- have appropriate education, work experience, and/or knowledge in order to conduct the verifications;
- respect applicable confidentiality and conflict of interest requirements; and
- maintain necessary records to substantiate verification.

5.0 ROLES AND RESPONSIBILITIES

This section outlines the roles and responsibilities for participating companies and ECCC.

Participating Companies

In addition to meeting the requirements outlined in the Agreement, a Participating Company agrees to second party verifications of the Agreement requirements.

Each Participating Company will:

- designate a representative who is familiar with the everyday operations of their Facility to cooperate with the ECCC verification team;
- ensure that the appropriate manager and operational staff involved in the activities verified are present during the verification;
- review the draft verification report provided by ECCC; and
- complete the corrective actions agreed upon with the verification team and confirm completion in writing and by providing supporting documentation to ECCC within the agreed timeline as per the final verification report.

ECCC

The ECCC verification team will:

- prepare a verification plan and conduct onsite verifications at a Participating Company's Facilities;
- verify through documentation and other evidence, such as interviews and observations, how the Participating Company is implementing the Agreement;
- document the results of verifications;

- identify areas where the verification team is of the opinion that the Agreement has not been fully implemented, as well as continuous improvement opportunities of alternative practices and procedures that are not identified in the chlorhexidine management plan, but that are linked to the overall goal of the Agreement;
- Prepare a draft and final verification report; and
- prepare a summary of the annual verification results for review and validation by Participating Companies prior to publication in the environmental performance agreements section of canada.ca at <https://www.canada.ca/en/environment-climate-change/services/environmental-performance-agreements.html>.

6.0 VERIFICATION PROCESS

Each participating company agrees to the following verification steps.

6.1 Pre-Verification

When it is determined that a Participating Company will be verified via a site visit, a mutually agreed site visit date that provides the Participating Company with at least three months' notice will be identified. Two months prior to the verification, a conference call will be held to allow the Participating Company's staff to ask the verification team questions and to inform the verification team which of the Participating Company's staff will be present for the verification. At this time, the logistics of the verification will be confirmed.

The ECCC verification team will review reported data and information previously provided in the chlorhexidine management plan and chlorhexidine evaluation reports to ascertain completeness and consistency of these documents over time.

The ECCC verification team will prepare a verification plan and submit it to the Participating Company in advance of the site visit. The Participating Company will provide any necessary background documentation, such as procedures and records, prior to the commencement of verification activities.

6.2 Verification Execution

Activities conducted by the ECCC verification team may include:

- a meeting with senior staff of the Participating Company to discuss general Facility operations and the verification process;
- a tour, with Participating Company staff, of the receiving, storage, waste areas, processes where chlorhexidine and its salts are handled or used, and location of Facility wastewater release;
- on-site review of data, information and records, on-site observations, interviews with personnel, review of management systems and procedures;
- assessment of the Participating Company to determine whether the practices and procedures identified in the Agreement have been implemented;

- verbal presentation on preliminary findings by the verification team to the Participating Company staff that participated in the verification process;
- verbal response from Participating Company staff to the preliminary findings of the verification team; and
- seeking agreement with the Participating Company of next steps for the verification process.

The ECCC verification team will identify areas where they are of the opinion that the Agreement has not been fully implemented, provide recommendations, if any, on where the Participating Company should focus its attention in the future, and may suggest opportunities for continuous improvement. The verifiers will take into account that the Agreement provides flexibility for Facilities to apply measures that are most appropriate to their operations. The verifiers will make reference to specific sections of the Agreement when presenting their preliminary findings to the staff that participated in the verification process, in order to show how the findings are linked to the overall objectives of the Agreement.

6.3 Post-Verification

The outcome of the verification will be communicated to the Participating Company through a draft, written report prepared by the verification team. The draft verification report will contain, at a minimum:

- The date and location of the verification;
- The names of the members of the verification team and Participating Company staff members;
- Results of the verification;
- Identification of any areas of incomplete implementation of the Agreement; and,
- Recommendations regarding any opportunities for continuous improvement.

Within four weeks of the verification, the lead verifier will provide a draft, written report to the Participating Company representative for internal distribution, review and comment. Within four weeks of its receipt of the draft report, the Participating Company will provide any comments to the verification team, propose corrective actions to remedy any areas of incomplete implementation and suggest a timeline to complete the corrective actions. During its review of the report, the Participating Company should also identify any information that it would request be treated as confidential as per subsection 11.3 of the Agreement. The Participating Company should also inform the verification team of corrective actions taken since the verification, so that these can be noted in the final verification report.

The lead verifier will review the comments received from the Participating Company and modify the verification report as appropriate. If a consensus cannot be reached on the list of corrective actions or timelines for completing them, the Participating Company will outline its concerns in a letter that will be attached to the verification team's final verification report.

The final report, including the agreed list of areas of incomplete implementation and a timeline for corrective actions, will be submitted to the Participating Company representative within 16 weeks of the onsite verification.

ECCC will post a summary of the results of the annual verification publicly in the environmental performance agreements section of [canada.ca](https://www.canada.ca/en/environment-climate-) at <https://www.canada.ca/en/environment-climate->

<change/services/environmental-performance-agreements.html>.

7.0 FOLLOW-UP MECHANISMS

Within the agreed timeline, the Participating Company will complete the corrective actions identified in the final verification report and confirm this completion in writing, supported by documentation, to ECCC.