

1043-122

08-20-2010

1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

AUG 2 0 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. Michael G. Sarli  
Manager Regulatory Affairs  
Steris Corporation  
P.O. Box 147  
St. Louis, MO 63166-0147

Subject: Notification Application per PR Notice 2007-4  
Proklenz™ One  
EPA Registration No 1043-122  
Application Date: 7/27/10  
Receipt Date: 7/29/10

Dear Mr. Sarli:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 2007-4.

**Proposed Notification:**

- Modify label according to PR Notice 2007-4.

**General Comments**

Based on a review of the material submitted, the following comment applies:

The notification is acceptable. The label has been added to your file.

Should you have any questions concerning this letter, please contact Chris Jiang at (703) 305-0545 or by e-mail at [jiang.chris@epa.gov](mailto:jiang.chris@epa.gov).

Sincerely,

*Jacqueline Campbell-McFarlane*  
Jacqueline Campbell-McFarlane  
Product Manager (34)

CONCURRENTLY Regulatory Management Branch II

Antimicrobials Division (7510P)

|         |         |  |  |  |  |  |
|---------|---------|--|--|--|--|--|
| SYMBOL  | 7510P   |  |  |  |  |  |
| SURNAME | CHIANG  |  |  |  |  |  |
| DATE    | 7/29/10 |  |  |  |  |  |

|  |                      |                       |
|--|----------------------|-----------------------|
| EPA<br>United States Environmental Protection Agency<br>Washington, DC 20460 | Registration         | OPP Identifier Number |
|  | X Amendment<br>Other |                       |

**Application for Pesticide - Section I**

|   |   |                            |
|---|---|----------------------------|
| 1. Company/Product Number 1043-122  | 2. EPA Product Manager<br>Jacqueline McFarlane  | 3. Proposed Classification |
| 4. Company/Product (Name) ProKlenz ONE  | PM # 34   | X None Restricted          |
| 5. Name and Address of Applicant (include Zip Code)<br><br>STERIS Corporation<br>P.O. Box 147<br>St. Louis, MO 63166-0147<br><br>Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:<br><br>EPA Reg. No.<br><br>Product Name |                            |

**Section - II**

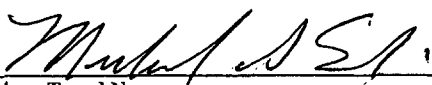
|   |  |
|---|--|
| Amendment - Explain Below<br>Resubmission in response to Agency letter dated _____<br>X Notification - Explain below. | Final printed labels in response to Agency letter dated<br>"Me Too" Applicaton<br>Other - Explain below. |
|---|--|

Reason: Addition of Container Disposal verbiage for disposable tote container sizes in compliance with PR Notice 2007-4.

**Section - III**

|  |  |   |   |   |   |
|--|--|---|---|---|---|
| 1. Material This Product will be Packaged In:                |  |   |   | 2. Type of Container  |   |
| Child-Resistant Packaging<br>Yes*<br>X No                    | Unit Packaging<br>Yes<br>No X<br><br>If "Yes"<br>Unit Packaging wgt. | No. per<br>container  | Water Soluble Packaging<br>Yes<br>No X<br><br>If "Yes"<br>Package wgt | No. per<br>container  | Metal<br>Plastic X<br>Glass<br>Paper<br>Other (Specify) |
| *Certification must be submitted                             |  |   |   |   |   |
| 3. Location of Net Contents Information<br>Label X Container |  | 4. Size(s) Retail Container<br>5 gallon, 55 gallon, 200 gallon and 300 gallon |   | 5. Location of Label Directions<br>On Label X<br>On Labeling accompanying product |   |
| 6. Manner in Which Label is Affixed to Product               |  |   | Lithograph<br>Paper glued X<br>Stenciled                              | Other   |   |

**Section - IV**

|   |  |  |  |   |   |
|---|--|--|--|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)   |  |  |  |   |   |
| Name<br>Michael G. Sarli  |  | Title<br>Manager Regulatory Affairs    |  | Telephone No. (Include Area Code)<br>314-290-4704 |   |
| <p align="center"><b>Certification</b></p> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. |  |  |  |   | 6. Date Application Received<br><br>(Stamped) |
| 2. Signature<br>   |  | 3. Title<br>Manager Regulatory Affairs |  |   |   |
| 4. Typed Name<br>Michael G. Sarli   |  | 5. Date<br>July 27, 2010               |  |   |   |



July 27, 2010

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Regulatory Management Branch 1  
Antimicrobials Division (7510C)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
Attn: Jacqueline McFarlane, PM #34

Re: Application for Amended Registration for ProKlenz® ONE (EPA Reg. No. 1043-122)  
Revision of Container Disposal Language in Compliance with PR Notice 2007-4

Dear Ms.McFarland:

Enclosed in support of the subject action, please find the following:

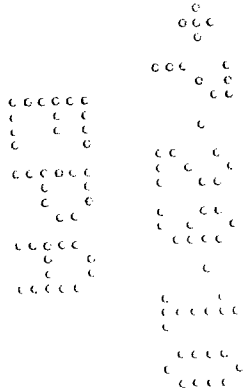
- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy) - Changes described with comments
- Labeling (1 copy) - "Clean" copy

The Container Disposal statement has been revised for disposable tote container sizes in compliance with PR Notice 2007-4.

If you have any questions I can be reached at 314-290-4704 or at mike\_sarli@steris.com.

Sincerely,  
  
Michael G. Sarli  
Regulatory Affairs  
STERIS Corporation

Enclosures



4/6

# ProKlenz™ ONE

**Alkaline Process & Research Cleaner/Disinfectant/Virucide\* For the Pharmaceutical, Cosmetic and Medical Industry**  
For Industrial and Institutional use only  
**Bacterial/Virucidal\***

EPA Reg. No. 1043-122    EPA Est. No. 1043-MO-2

### ACTIVE INGREDIENTS:

|                   |             |
|-------------------|-------------|
| Sodium Hydroxide  | 13.5%       |
| Inert Ingredients | 86.5%       |
| <b>TOTAL</b>      | <b>100%</b> |

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

| FIRST AID   |   |
|---|---|
| If in Eyes:   | <ul style="list-style-type: none"> <li>· Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>· Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>· Call a Poison Control Center or doctor for treatment advice.</li> </ul> |
| If on Skin:   | <ul style="list-style-type: none"> <li>· Take off contaminated clothing.</li> <li>· Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>· Call a Poison Control Center or doctor for treatment advice.</li> </ul>   |
| If Swallowed:   | <ul style="list-style-type: none"> <li>· Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>· Have person sip a glass of water if able to swallow.</li> <li>· Do not induce vomiting unless told to do so by the Poison Control Center or doctor.</li> </ul>         |
| If Inhaled:   | <ul style="list-style-type: none"> <li>· Move person to fresh air.</li> <li>· If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>· Call Poison Control Center or doctor for treatment advice</li> </ul>           |
| Hotline Number: 800-548-4873  |   |
| For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.   |   |
| NOTE TO PHYSICIAN   |   |
| Probable mucosal damage may contraindicate the use of gastric lavage. Have product container or label with you when calling a Poison Control Center or doctor for treatment advice. |   |

See side panel for additional precautions.

STERIS Corporation  
7501 Page Avenue  
St. Louis, MO 63133  
800-JIT-4-USE (800-548-4873)  
www.steris.com

**NOTIFICATION**  
Date Reviewed: 8/20/10  
Reviewed By: [Signature]

DRAFT 07/27/10 – Revised 8/11/10

**PRECAUTIONARY STATEMENTS  
HAZARD TO HUMANS AND DOMESTIC ANIMALS  
DANGER**

**CORROSIVE.** Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or spray mist. Wear face shield or goggles. Wear chemical-resistant gloves, long-sleeved shirt, long pants, socks and shoes. When mixing and loading, wear a chemical-resistant apron. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or, using restroom. Remove and wash contaminated clothing before reuse.

**Personal Protective Equipment (PPE)**

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Directions For Use:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ProKlenz One is a high-performance, phosphate-free, alkaline detergent/disinfectant. It is low-foaming and free-rinsing to meet the unique cleaning demands found in clean-in-place and automatic washing equipment. It also provides broad spectrum disinfection of hard non-porous surfaces including stainless steel manufacturing, holding, filling and packaging equipment in pharmaceutical, cosmetic, medical manufacturing and other high risk manufacturing operations.

**Cleaning:** The dilution rate of this concentrate will depend on the residues, soil conditions and application method, but typically range from 0.5 oz/gal to 6.0 oz/gal of water. Contact your STERIS Sales Associate for recommendations based on the above conditions. Do not apply product by manual spraying or by other means that would produce particles that are inhalable.

ProKlenz ONE is recommended for use to clean hard non-porous surfaces in manufacturing equipment and automatic washing equipment including mixing vessels, and packaging equipment. Surfaces should be rinsed with water after use of this product.

**Disinfection:** ProKlenz ONE is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* when used at a 1% concentration of product per gallon of water in 5% blood serum and 250 ppm of hard water at 60° C. Preclean all heavily soiled surfaces. Prepare a 1% use solution by adding 1.3 ounces per gallon of water. Product must be applied to surfaces by circulating, coarse spray or direct immersion for a contact time of at least 5 minutes and the temperature maintained at or above 60° C. Following application, rinse product contact surfaces with potable water. Do not apply product by manual spraying or by other means that would produce particles that are inhalable.

**\*Virucidal Activity:** ProKlenz ONE is effective against Poliovirus (type 1)\* when used at a 1% concentration of product per gallon of water in 5% blood serum and 250 ppm of hard water at 60° C for a contact time of 10 minutes. Prepare and apply as directed above for disinfection. The product must remain in contact with the surface at 60° C for at least 10 minutes. Do not apply product by manual spraying or by other means that would produce particles that are inhalable.

### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Do not store on side. Avoid creasing or impacting of side container walls.

**Pesticide Disposal:** Pesticide wastes are acutely hazardous, improper disposal of excess pesticide, mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA regional office for guidance.

**Container Disposal:** *(For ≤5 gal.)* Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture, and discard in a sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

*(For > 5 gal.)*: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture, and discard in a sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

*(For ≥ 200 gallon disposable tote:)* Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture, and discard in a sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents through the bottom valve into application equipment or mix tank and continue to drain for 10 seconds after the flow begins to drip. Insert pressure rinsing nozzle through top opening and rinse all surfaces at about 40 psi for at least 30 seconds. Drain for 10 seconds through bottom valve for 10 seconds after the flow begins to drip. Repeat pressure rinse twice more. Save rinsate for later use or disposal.