

1043-122

11/24/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 24 2009

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

FILE COPY

Subject: Notification Application per PR Notice 2007-4
ProKlenz™ One
EPA Registration Number: 1043-122
Application Date: November 12, 2009
Receipt Date: November 13, 2009

Dear Mr. Sarli:

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

Proposed Notification:

Updated Storage and Disposal language

General Comment:

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

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "ShaRon Carlisle".

ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

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STERIS®



November 12, 2009

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: ShaRon Carlisle, PM #34

Re: Notification for ProKlenz® ONE (EPA Reg. No. 1043-122)
Revision of Container Disposal Language in Compliance with PR Notice 9007-4

Dear Ms. Carlisle:

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

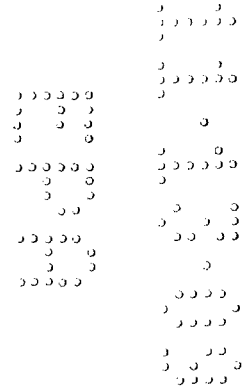
The Container Disposal statement has been revised in compliance with PR Notice 9007-4.

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

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

Enclosures



4016

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%
TOTAL 100%

NOTIFICATION
Date Reviewed: 11/24/09
Reviewed By: H. Barrie

KEEP OUT OF REACH OF CHILDREN
DANGER

FIRST AID	
If in Eyes:	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
If on Skin:	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the Poison Control Center or doctor.
If Inhaled:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call Poison Control Center or doctor for treatment advice
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

DRAFT 11/12/09

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**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.

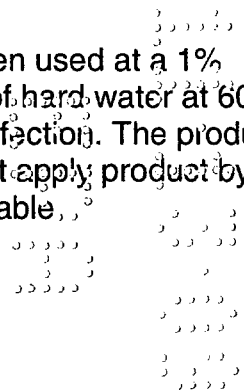
ProKlenz One is a high-performance, phosphate-free, alkaline detergent/disinfectant. It is low-foaming and free-rinsing to meet the unique cleaning demands found in clean-in-place and automatic washing equipment. It also provides broad spectrum disinfection of hard non-porous surfaces including stainless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



Leaf 6

STORAGE AND DISPOSAL

Do not contaminate water, food 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. 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 $\frac{1}{4}$ 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. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ 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.

Handwritten scribbles consisting of small loops and lines, possibly representing a signature or initials.