

1043-122

03/29/2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:
1043-122

Date of Issuance:
March 29, 2007

Term of Issuance:
Unconditional

Name of Pesticide Product:
ProKlenz™ One

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Steris Corporation
7501 Page Avenue
St. Louis, MO 63144

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Revise the "EPA Registration Number to read, "EPA Reg. No. 1043-122".

Signature of Approving Official:

Adam Heyward
Product Manager Team-34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Date:

March 29, 2007

This product meets the criterion for Restricted-Use classification based upon data that place it in toxicity category I for primary eye irritation, primary skin irritation and the toxicity I categorization of acute inhalation toxicity. Therefore, the following label revisions must be made:

- b. Revise the precautionary statements and heading to read:

**PRECAUTIONARY STATEMENT
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER**

“Corrosive. Fatal if inhaled. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Do not breathe vapor or spray mist. Do not get in eyes, on skin, or on clothing. Wear respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter. Wear goggles or face shield. Wear chemical-resistant gloves. 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.”

- c. In accordance with the toxicity category I classification of the acute inhalation toxicity study, revise the child hazard statement to read:

KEEP OUT OF REACH OF CHILDREN

DANGER  **POISON**

FATAL IF INHALED. IRREVERIBLE EYE DAMAGE AND SHIN BURN

Refer to the Label Review Manual (8/2003), Chapter 7, III, B.

- d. Revise the First Aid Statement so that it follows the format listed below:

**IF INHALED
IF IN EYES
IF SWALLOWED
IF ON SKIN OR CLOTHING**

In addition, an emergency phone number should also be included at the end of the first aid statement.

- e. Revise the following statement to read “ProKlenz One is recommended for use to clean in...”

- f. The label must specify "Pharmaceutical, cosmetic and Medical Manufacturing Industry."

3. *Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.*

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Branch II
Antimicrobials Division (7510P)

Enclosure: (Stamped Label, Efficacy and Toxicity Reviews)

ProKlenz™ One

Alkaline Process & Research
Cleaner/Disinfectant/Virucide* For the
Pharmaceutical, Cosmetic and Medical
Industry

Bacterial/Virucidal*

EPA Reg. No. 1043-xxx

ACTIVE INGREDIENTS:

Sodium Hydroxide-----13.5%
Inert Ingredients-----86.5%
TOTAL-----100%

For Industrial and Institutional use only

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautions.

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63144

800-JIT-4-USE (800-548-4873)

www.steris.com

EPA Est. No. 1043-MO-2

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAR 29 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1043-122

FIRST AID	
If in Eyes:	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 the eye. Call a poison control center or doctor for treatment advice.
If on Skin or Clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call Poison Control Center or doctor immediately for treatment advice.
If Swallowed:	Call 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. Do not give anything by mouth to an unconscious person.
If Inhaled:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call Poison Control Center or doctor immediately for treatment advice. Hot Line Number Have the product label or container with you when calling a poison control center or doctor, or when going for treatment. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage

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 and other high risk 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.

ProKlenz ONE is recommended for use in clean in place equipment and manual operations on hard non-porous surfaces including mixing vessels, packaging equipment, floors, walls and counter tops. 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, course 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.

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.

PRECAUTIONARY STATEMENTS

Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear goggles or face shield, protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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:** Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by State or Local authorities by burning. If burned, stay out of smoke.

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