

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

JAN 22 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

Subject:

ProKlenz ONE

EPA Registration Number: 1043-122 Application Date: December 28, 2010 Application Receipt: December 30, 2011

Dear Mr. Sarli:

This acknowledges receipt of the following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

Proposed Amendment:

Revise Salmonella choleraesuis to Salmonella enterica.

General Comments:

Based on review of submitted material, your amended labeling is accepted and an EPA stamped accepted label is enclosed for your records.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 email address at swift.killian@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,

Jacqueline Compbell-McFarlane

'Product Manager 34

Regulatory Management Branch II Antimicrobials Division (7510P)

Enclosure: EPA stamped label

STERIS*

ProKlenz® ONE

1421-05

18.93L (5 Gal.)

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

Active Ingredients:	
Sodium Hydroxida	13.5%
tnert Ingredients	88.5%
TOTAL	100.00%

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

KEEP OUT OF REACH OF CHILDREN DANGER

See side panel for additional precautions. For Industrial and Institutional use only

STERIS Corporation 7501 Page Avenue ■ St. Louis, MO 63133 ■ USA 800-548-4873 www.steris.com

1421-05D(310)

61885

Product Made in the U.S.A.

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. Take off contaminated clothing.
 Rinse skin immediately with plenty of water for If on Skin: 15-20 minutes. Call a Poison Control Center or doctor for treatment advice. If Swallowed: · Call a Poison Control Center or doctor immediately for treatment advice. Have person slp a glass of water if able to swallow.
 Do not induce vomiting unless told to do so by the Poison Control Center or doctor. · Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-tomouth it possible. · Call Poison Control Center or doctor for treatment

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.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent

its a violation or better a text of see in a product or a mainter involvable. Profilers ORF is a high-performance, phosphate-free, alkaline detergent disinfection. 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-provide surfaces including to the provide of the production of the provides 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 spreying or by other means that would produce particles that are inhalable. ACCEPTED

JAN 22 2011

Under the Federal Insecticide, Fungicide, and Rodenticids, Act as amended, for the pesticide, registered under

EPA Reg. No. 1043-

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.

of this procuse.

Obtainfection: Proklenz ONE is effective against Staphylococcus aureus, Salmonetta enterica, 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 solied 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 6 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 inhabite.

vibracidal Activity: Profilers OHE is effective against Policovirus (type 1)* when used at a 11% concentration of product per gation 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

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS DANGER

DORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Harmful if inhated or absorbed through skin. Do not get in eyes, on skin, or on oldthing, Avoid breathing vapor or spray mist. Wear face shield or goggles. Wear chemical-resistant gloves, knop-deeved shirt, long parts, socks and shoes. Wear nowang and loading, wear a chemical-resistant apron. Wash thoroughly with soap and water after thanefling and before eating, drinking, chewing gurn, using tobacco, or, using restroom. Remove and wash contaminated clothing before reuse. Personel Protective Equipment (PPE): Follow the manufacturer's instructions for leasting/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other faundry.

STORAGE AND DISPOSAL

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

Pesticide Storage: Oo not store on side. Avoid creasing or impacting of side container

Pesticide Oisposal: 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

Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA regional Office for guidance. Contailner Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple nines as rollows: 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 ½ full with water and recap. Shale for 10 seconds. Pour insiste 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.



SODIUM HYDROXIDE SOLUTION UN 1824