

1043-122

01/22/2011

1/2



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 Campbell-McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped label

STERIS®



ProKlenz® ONE

Reorder Number: 1421-05 Net Contents: 18.93L (5 Gal.)

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

Active Ingredients: Sodium Hydroxide 13.5%, Inert 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.

Table with 2 columns: Category (e.g., If in Eyes, If on Skin) and First Aid instructions. Includes sections for First Aid, Hotline Number (800-548-4873), and Note to Physician.

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...

ACCEPTED JAN 22 2011 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1043-122

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 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.

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.

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.



Ⓢ SODIUM HYDROXIDE SOLUTION UN 1824

2/2