



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

1043-134

Date of Issuance:

11/5/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

ProKlenz TWO Acid Cleaner and
Disinfectant

Name and Address of Registrant (include ZIP Code):

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 1043-134."

Signature of Approving Official:

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

11/5/19

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSF:

- Basic Confidential Statement CSF dated 03/07/2019

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at rivas.lorena@epa.gov

Enclose: Accepted Stamped Label
Product Chemistry review dated 10/3/2019

ProKlenz TWO Acid Cleaner and Disinfectant

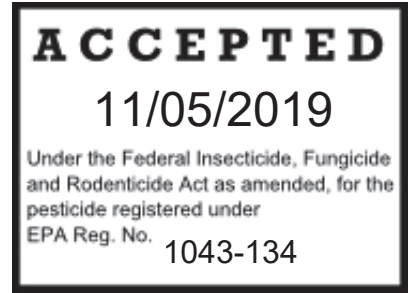
For use in the Pharmaceutical, Medical Device, Biotech, and Cosmetic Manufacturing Facilities

For Industrial and Institutional Use

Bactericidal

EPA Reg. No. 1043-134 EPA Est. No. 1043-MO-2

ACTIVE INGREDIENTS:
 Citric Acid 37.00%
 Inert Ingredients 63.00%
 TOTAL 100%



Reorder Number: XXX

Net Contents: XXX

**KEEP OUT OF REACH OF CHILDREN
 DANGER/PELIGRO**

FIRST AID	
If in Eyes:	<ul style="list-style-type: none"> • Hold eyes 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 eyes. • Call a poison control center or doctor for treatment advice.
If on Skin or Clothing:	<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.
If Inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
Hotline Number: 800-424-9300	
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.	

See [side panel] [back panel] [insert] for additional precautionary statements [and] [or] [directions for use].

STERIS Corporation
 7501 Page Avenue
 St. Louis, MO 63133
 800-548-4873
 [Brackets denote optional text.]

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

Precautionary Statements: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wear protective eyewear such as goggles, face shield, or safety glasses. Coveralls worn over long-sleeve shirt and long pants, socks, chemical-resistant footwear, chemical resistant gloves (Barrier Laminate, or Butyl Rubber, or Neoprene Rubber, or Polyvinyl Chloride (PVC), or Vitron). Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE): Avoid all unnecessary exposure. Personal protective equipment should be selected based upon the conditions under which this product is handled or used. Protective clothing. Gloves. Protective goggles.

Directions For Use:

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

ProKlenz TWO Acid Cleaner and Disinfectant is a phosphate-free, acid liquid detergent/disinfectant. This product is low-foaming and free-rinsing to meet the unique cleaning demands found in clean-in-place and automatic washing equipment. This product 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 0.25 fl oz/gal to 4.0 fl oz/gal (0.2-3.1% v/v) of deionized 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 TWO Acid Cleaner and Disinfectant is to be used 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 TWO Acid Cleaner and Disinfectant is effective against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442) when used at a 2% concentration of product per gallon of deionized water in 5% blood serum at 60°C. Preclean all visibly soiled surfaces. Prepare a 2% use solution by adding 2.6 fluid ounces per gallon of deionized water. Product must be applied to surfaces by circulating or direct immersion for a contact time of at least 10 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.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but

which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

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

Pesticide Storage: Always store pesticides in the original container. If a leaky container must be contained with another, mark the outer container and identify the contents.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide spray 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. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill by incineration.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill container ¼ full with water. Replace and tighten closure. 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. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill by incineration.