



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 24, 2018

Jennifer Pavlovsky
Manager, Regulatory Affairs
STERIS Corporation
PO Box 147
St. Louis, MO 63166-0147

Subject: PRIA Label Amendment – Add Biofilm Claim to the Master Label
Product Name: PROKLENZ ONE
EPA Registration Number: 1043-122
Application Date: March 9, 2018
Decision Number: 539637

Dear Ms. Pavlovsky:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

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

If you have any questions, please contact Srinivas Gowda by phone at (703) 308-6354 or via e-mail at gowda.srinivas@epa.gov

Sincerely,

A handwritten signature in brown ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is enclosed within a faint, light-colored rectangular border.

Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division

Enclosure: EPA Stamped Label

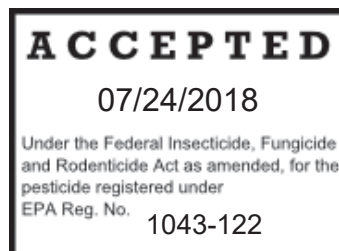
ProKlenz® ONE

Alkaline Process & Research Cleaner/Disinfectant/Virucide* For use in Pharmaceutical, Medical Device, Biotech and Cosmetic Manufacturing Facilities

For Industrial and Institutional use only
Bactericidal/Virucidal*

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

ACTIVE INGREDIENTS:
Sodium Hydroxide 13.5%
Inert Ingredients 86.5%
TOTAL 100%



**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 the eye.· 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 [below] for additional precautions.

STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133
800-548-4873

Draft 07/19/2018

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, medical manufacturing and other manufacturing operations where disinfection is critical.

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 Account Manager 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 enterica*, and *Pseudomonas aeruginosa* in 5% blood serum when used at a 1% concentration of product per gallon of 250 ppm of hard water at 60° C. Pre-clean 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, 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.

Kills Biofilm Bacteria*: **ProKlenz ONE** kills biofilm bacteria* on hard, non-porous surfaces.

**Pseudomonas aeruginosa* and *Staphylococcus aureus* tested as biofilms.

FOR REMOVAL OF BIOFILM: For use on hard, non-porous, nonfood contact surfaces. Pre-clean surfaces to remove gross or visible soil. Allow to dry. Thoroughly wet pre-cleaned surface with product diluted at a 5% use solution. Add 6.5 ounces of product to 121.5 ounces deionized water for one gallon use solution. Allow surface to remain wet for 10 minutes at 60° C. Rinse thoroughly.

***Virucidal Activity: ProKlenz ONE** is effective against Poliovirus (type 1)* in 5% blood serum when used at a 1% concentration of product per gallon of 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

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.

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: (*For ≤5 gal.:*) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture, and discard in a sanitary landfill or by other procedures approved by state and local authorities. 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 ¼ 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 ¼ 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.

(*For ≥ 200 gallon disposable tote:*) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, puncture, and discard in a sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents through the bottom valve into application equipment or mix tank and continue to drain for 10 seconds after the flow begins to drip. Insert pressure rinsing nozzle through top opening and rinse all surfaces at about 40 psi for at least 30 seconds. Drain for 10 seconds through bottom valve for 10 seconds after the flow begins to drip. Repeat pressure rinse twice more. Save rinsate for later use or disposal.

[optional text]