



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 31, 2008

OPP Decision Number: D-386516

Mike Ebers
Steris Corporation
7501 Page Avenue
P.O. Box 147
St. Louis, MO 63166-0147

Subject: ProKlenz™ One
EPA Registration No. 1043-122
Application Date: November 20, 2008
Receipt Date: November 21, 2008

Dear Mr. Ebers:

The following label amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed amendment:

- Label amendment: Review of acute inhalation study

General comments:

The acute inhalation data (MRID #472893-01), submitted in support of the subject product registration is acceptable. The current acute toxicity profile for EPA Registration Number 1043-122 is:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	469885-10	II	Acceptable
Acute Dermal Toxicity	469885-09	III	Acceptable
Acute Inhalation Toxicity	472893-01	III	Acceptable
Primary Eye Irritation	469885-08	I	Waived
Primary Skin Irritation	469885-08	I	Waived
Dermal Sensitization	469885-11	Nonsensitizer	Acceptable

Label comments:

1. The Signal Word is "**DANGER**", based upon the classification of the primary eye and skin irritation studies.
2. The precautionary statements must be revised to read as follows:

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, sock 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."

3. The First Aid statements must be revised to state as follows:

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.
- Call a Poison Control Center or doctor for treatment advice.

If On Skin:

- 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:

- 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 a Poison Control Center or doctor.

If Inhaled:

- 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 a Poison Control Center or doctor for treatment advice.

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.

4. Add the add the following Statements for Contaminated Personal Protective Equipment (PPE):

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.”

Other comments:

Submit three copies of the final printed label bearing the revisions listed above. A copy of the stamped labeling is included for your record.

For detail information and consideration, refer to the enclosed EPA/AD Product Science Branch memorandum dated March 25, 2008.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epamail.epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epamail.epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



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

Enclosure: Stamped label and Tox memorandum dated 3/25/08

ProKlenz™ One

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

For Industrial and Institutional use only

Bacterial/Virucidal*

EPA Reg. No. 1043-xxx

ACTIVE INGREDIENTS:

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

**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

FIRST AID	
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.
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 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 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.
Hotline Number: 800-548-4873	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. 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	

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 31 2008

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

1043-122

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 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 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 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. Do not apply product by manual spraying or by other means that would produce particles that are inhalable.

***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. 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 absorbed through skin. Harmful if inhaled. Do not breathe spray mist. Do not get in eyes, on skin, or on clothing. 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 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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