



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 30, 2021

Kent Ediger
Manager, Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Label Amendment –Correcting typographical errors specially the word Virucidal
And the recommended use rate units in the Directions for Use section. Plus,
Adding Reorder Number and Net Contents to the master label.
Product Name: CIP 200 Acid-Based Cleaner and Disinfectant
EPA Registration Number: 1043-135
Application Date: January 22, 2021
Action Case Number: 00216600

Dear Mr. Ediger:

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.

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 Lorena Rivas by phone at 703-305-5027, or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline Hardy". The signature is written in a cursive, flowing style.

Jacqueline Hardy, Chief
Regulatory Management Branch 2
Antimicrobials Division (7510P)

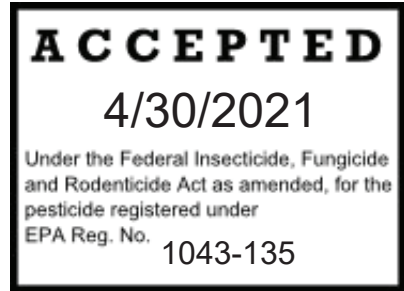
Enclose: Stamped label

CIP 200 Acid-Based Cleaner and Disinfectant

For the Pharmaceutical, Cosmetic and Medical Industry
For Industrial and Institutional use only
Bactericidal/Virucidal*

EPA Reg. No. 1043-135 EPA Est. No. 1043-MO-2

ACTIVE INGREDIENTS:	
Phosphoric Acid	45.00%
Citric Acid	5.00%
Inert Ingredients	<u>50.00%</u>
TOTAL	100.00%



KEEP OUT OF REACH OF CHILDREN
DANGER/PELIGRO

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 eye. • 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 advice.
If Swallowed:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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. Have product container or label with you when calling a Poison Control Center or doctor for treatment advice. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center at 1-800-858-7378 (NPIC web site: www.npic.orst.edu). For emergencies, call the poison control center 1-800-222-1222.	
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)

Reorder Number: XXX
[Brackets denote optional text.]

Net Contents: XXX

“Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)”

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

Precautionary Statements: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eye wear, clothing, and gloves. Coveralls worn over long-sleeved 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.

CIP 200 Acid-Based Cleaner and Disinfectant is a liquid, acidic disinfectant/detergent. 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 0.25 fluid ounces per gallon to 4.0 fluid ounces per gallon (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.

CIP 200 Acid-Based Cleaner and Disinfectant is used to clean hard non-porous surfaces in manufacturing equipment and automatic washing equipment including mixing vessels, and packaging equipment. Surfaces must be rinsed with water after use of this product.

Disinfection: **CIP 200 Acid-Based Cleaner and Disinfectant** is effective against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442) when used at a 1% use solution of product in 5% blood serum at 60°C. Preclean all visibly soiled surfaces. Prepare a 1% use solution by adding 1.3 fluid ounces per gallon of 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.

***Virucidal Activity: CIP 200 Acid-Based Cleaner and Disinfectant** is effective against Bovine Viral Diarrhea Virus (BVDV) when used at a 1% use solution of product in 5% blood serum 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.

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 preclean 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.