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

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
1043-140	11/21/22

Term of Issuance:
Conditional

Name of Pesticide Product:
Prolystica Pass-Thru Disinfectant Wipes

Name and Address of Registrant (include ZIP Code):

Kent Ediger, Manager of Regulatory Affairs
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 (FIFRA).

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Steven Snyderman

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)
Office of Pesticide Programs

Date:

11/21/22

2. You are required to comply with the data requirements described in the DCI identified below:

    a. Alkyl (C14-50%, C12-40%, C16-10%) Dimethyl Benzyl Ammonium Chloride: GDCI-069105-1679
    b. Octyl Decyl Dimethyl Ammonium Chloride: GDCI-069165-1736
    c. Dioctyl Dimethyl Ammonium Chloride: GDCI-069166-1737
    d. Didecyl Dimethyl Ammonium Chloride: GDCI-069149-1681

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 1043-140."

4. Submit one copy of the 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). 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 CSFs:

- Basic CSF dated 08/25/2022

If you have any questions, please contact Heather A. Garvie via email at garvie.heather@epa.gov.

Enclosure: Stamped Final Label

Prolystica™ Pass-Thru Disinfectant Wipes

Ready-to-Use ● One-Step Cleaner Disinfectant

EPA REG. NO. 1043-XXX
EPA Est. No. 1043-M0-2 EPA Est. No. 92998-NC-1

Cleaner ● Bactericidal ● *Virucidal ● Fungicidal ● Tuberculocidal

For Hospital and Healthcare Institutional Use

Active Ingredients:

Alkyl (C_{14}-50%, C_{12}-40%, C_{16}-10%) Dimethyl Benzyl Ammonium Chloride	0.40%
Octyl Decyl Dimethyl Ammonium Chloride	0.30%
Dioctyl Dimethyl Ammonium Chloride	0.12%
Didecyl Dimethyl Ammonium Chloride	0.18%
Isopropyl Alcohol	45.00%
Other Ingredients	54.00%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

[Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.]

NOT TO BE USED AS A BABY WIPE

FIRST AID

In case of emergency, call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. **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 eye. Call a poison control center or doctor for treatment advice. **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 a poison control center or doctor for treatment advice. **IF ON SKIN OR CLOTHING:** 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.

For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.

REORDER NUMBER: ( ) NET CONTENTS: ( )

Manufactured by:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133
PRODUCT MADE IN THE U.S.A.

ACCEPTED
11/21/2022
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1043-140

See (side panel) (back panel) (insert) for additional (precautionary statements) (directions for use)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Harmful if inhaled. Avoid breathing vapor. Do not get in eyes or on clothing. Wear appropriate protective eyewear such as goggles, face shield, or safety glasses. 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

Prolystica™ Pass-Thru Disinfectant Wipes are intended for use in hospitals and other healthcare facilities to clean and disinfect washable, hard, non-porous medical device surfaces such as metals, plastics, elastomers, coatings, and medical grade adhesives. These surfaces may be found on non-submersible and heat sensitive medical devices such as cameras, drills, handpieces, power tools, and rechargeable batteries for power devices.

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.

DISINFECTANT: This RTU (ready-to-use) product is effective in 3 minutes at 20°C on washable hard, non-porous medical device surfaces, in the presence of 5% organic soil against the following: **Mycobacterium:** *Mycobacterium bovis* (BCG) (ATCC 35743), **Bacteria:** *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus epidermidis* (ATCC 35984), *Burkholderia cepacia* (ATCC 25416), *Enterobacter cloacae* (ATCC BAA-2341), *Streptococcus pyogenes* (ATCC 19615), *Listeria monocytogenes* (ATCC 19111), *Micrococcus yunnanensis* (ATCC 7468), *Serratia marcescens* (ATCC 14756) *Mycoplasma gallisepticum* (ATCC 19610), *Methicillin-resistant staphylococcus aureus* (MRSA) (ATCC 33591), and *Vancomycin-resistant enterococcus faecium* (VRE) (ATCC 51559). **Fungi:** *Trichophyton interdigitale* (ATCC 9533) and *Candida albicans* (ATCC 10231), ***Viruses:** Influenza A2 Virus (A/2/Japan/305/57) (H2N2)*, Human Immunodeficiency Virus Type 1 (HIV-1) (IIIB)*, Adenovirus Type 2 (Adenoid 6) (ATCC VR-846)*, Poliovirus Type 1(Chat) (ATCC VR-1562)*, Duck Hepatitis B Virus (Grimaud)*, Bovine Viral Diarrhea Virus (NADL)*, Feline calicivirus* (Surrogate for Human Norovirus) Strain: F9 (ATCC VR-782)* and Avian Influenza Virus (H5N1) (NIBRG-14/CDC#2006719965)*.
ODOR CONTROL: This product eliminates many odors by killing odor-causing bacteria. Follow **DIRECTIONS FOR USE**.

DIRECTIONS FOR USE

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

DISPENSER PREPARATION:

Turn lid counterclockwise to remove lid from canister.

Remove covering seal and discard.

Locate wipe at center of the roll and pull wipe corner up and thread corner through hole from underside of canister lid. Pull wipe through about one inch (1”).

Replace lid and turn clockwise until lid is tight. Dispense wipes by pulling out at an angle. Self-closing lid will close to prevent loss of disinfectant.

Ensure nothing is blocking self-closing lid.

To clean and disinfect non-critical medical device surfaces: Use the Prolystica Pass-Thru Disinfectant Wipe(s) to preclean and disinfect visibly soiled hard, non-porous medical device surfaces. Treated surfaces must remain visibly wet for **3 minutes**. Wipe may be used until there is no longer enough disinfectant for surface to remain visibly wet for **3 minutes**. If necessary, use additional wipes to ensure coverage and required contact time. To remove remaining disinfectant, rinse all treated surfaces for at least **10 seconds.**

To clean critical or semi-critical medical device surfaces prior to terminal sterilization/high-level disinfection: Use the Prolystica Pass-Thru Disinfectant Wipe(s) to preclean hard, non-porous medical device surfaces. Treated surfaces must remain visibly wet for **3 minutes**. Wipe may be used until there is no longer enough disinfectant for surface to remain visibly wet for **3 minutes**. If necessary, use additional wipes to ensure coverage and required contact time. To remove remaining disinfectant, rinse all treated surfaces for at least **10 seconds.** Critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.

After use, ensure lid is properly closed to prevent evaporation.

***KILLS HIV ON ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:
Personal Protection: Specific barrier protection items to be used when handing items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.
Cleaning Procedure: Apply the product as directed in paragraphs above.
Contact Time: Allow surface to remain visibly wet for 3 minutes.
Infectious Materials Disposal: Blood and other body fluids should disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

Do not contaminate food, feed or water by storage or disposal.
Pesticide Storage: Store in original container in a cool, well-ventilated area. Do not store near heat or open flame.
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate from container 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:
Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.
Wipes Disposal:
Nonreusable one-time use container. Discard used and unused wipes in trash. Do not flush wipes down toilet.
Optional Label Text is enclosed in parentheses.
(STERILE UNLESS PACKAGING IS COMPROMISED)
{Note to reviewer: The following is considered optional graphics and marketing language}


NOT A HAND, SKIN, OR BABY WIPE


DO NOT FLUSH


3
minutes
DISINFECTS IN 3 MINUTES