



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

1677-280

Date of Issuance:

4/14/25

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Klercide Cleanroom Peroxide

Name and Address of Registrant (include ZIP Code):

Franklin Adams  
Ecolab Inc.  
Electronic Transmittal: [franklin.adams@ecolab.com](mailto:franklin.adams@ecolab.com)

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

Date:

4/14/25

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

- a. Hydrogen Peroxide: GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): <https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division#rb>

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 1677-280."
5. 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 12/20/2024

If you have any questions, please contact Srinivas Gowda by phone at 202-565-0078, or via email at [gowda.srinivas@epa.gov](mailto:gowda.srinivas@epa.gov).

Enclosure: Stamped Label

4/10/2025

# Klercide Cleanroom Peroxide

[Note to reviewer: Wording in brackets is considered optional or interchangeable]

## SPORICIDE

For use on hard non-porous non-food contact surfaces in [Clean Rooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Biomedical Facilities], [Biotechnology Facilities], [Medical Device Facilities], [Medical Device Manufacturing Facilities], [Life Science Laboratories], [Industrial Facilities]

### Active Ingredient:

Hydrogen Peroxide .....6.16%

Other Ingredients: .....93.84%

Total: ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION[/AVISO]

[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.)]

[See [back], [side], [inside], [front] [inner], [other] [fold-out] [booklet] [hang tag] [product container] [label[s]] [panel[s]] [container] [case label] for [complete] [additional] [information] [precautionary statements,] [and] [first aid,] [and] [directions for use,] [and] [storage and disposal] [container handling and disposal]]

[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.]

[Pull tab at label corner to see additional directions for use.]

[Please [refer to] [see] reference sheet for [additional] [directions for use] [information]].

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Causes moderate eye irritation. Harmful if swallowed or absorbed through skin.

Avoid contact with eyes or clothing. Wear protective eyewear (such as goggles, safety glasses, or a face shield). Wear long sleeve shirt and long pants, socks, shoes, and waterproof gloves.

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.

### FIRST AID

**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.

**ACCEPTED**

04/14/2025

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 1677-280

4/10/2025

**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 by a poison control center or doctor. Do not give anything to an unconscious person.

**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 INHALED:** 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.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

**FOR EMERGENCY MEDICAL INFORMATION, CALL [TOLL-FREE] [1-800-328-0026] [or] [X-XXX-XXX-XXXX]**

**OUTSIDE NORTH AMERICA, CALL: [1-651-222-5352] [or] [X-XXX-XXX-XXXX]**

**[GENERAL INFORMATION:** Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday – Friday, 8:00 am – 12:00 pm Pacific Time; email: npic@ace.orst.edu; or web site: www.npic.orst.edu. For emergencies, call the Poison Control Center 1-800-222-1222]

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. (Read the label before using.)

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.

#### **DIRECTIONS FOR USE AS A HARD, NON-POROUS SPORICIDE:**

Use only on hard, non-porous surfaces. Clean the surface to be treated of debris, organic material and other visible soil. Apply ready to use solution by thoroughly wetting or completely immersing the surface to be treated. The surface must remain visibly wet for the required contact time of 6 hours. After the allotted contact time, allow surfaces to drain and [air dry] [or] [wipe] after the directed contact time with a [sterilized] cloth or wiper. When used as directed this product is effective against the spores of *Clostridium sporogenes* (ATCC 3584) and *Bacillus spizizenii* (ATCC 19659) (formerly *Bacillus subtilis*) [with a 5% organic soil load]. Do not use this product as a sterilant on medical devices.

#### **STORAGE & DISPOSAL**

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

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**PESTICIDE STORAGE:** Store this product in original container in a cool, dry area, away from direct sunlight and heat.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely 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 HANDLING AND DISPOSAL:**

[For containers equal to or less than 5 gallons]

Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Offer container for recycling if available and dispose of in a sanitary landfill, or by incineration.

[Lot Number / Batch Code XXXXXX]  
EXPIRY: Day/Month/Year]

Net Contents: 946 mL (32 fl oz) 1 US gal (3.78 L)
------------------------------------------------------

US EPA Reg. No. 1677-[pending]  
US EPA Est. No.: 001677-GBR-001, 5389-NC-1 (G)

Manufactured by:  
Ecolab Inc.  
1 Ecolab Place  
St. Paul, MN 55102 [USA]  
[www.ecolab.com]

[Made in Great Britain] [Made in USA] [Made in United States of America]

[See [back], [side], [inside], [other] [fold-out] [booklet] [label] [panel] for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid]

[This product may be patented] | [Ce produit peut être breveté] | [Este producto puede ser patentado]: [www.ecolab.com/patents](http://www.ecolab.com/patents)

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**OPTIONAL MARKETING LANGUAGE**

- Klercide Cleanroom Peroxide is a ready-to-use, sterile, sporicide solution containing [6.16%] hydrogen peroxide blended with water for injection (WFI)
- Klercide Cleanroom Peroxide is a [6.16%] blend of hydrogen peroxide and Water for Injection (WFI)
- Klercide Cleanroom Peroxide is a registered sporicide that is a hydrogen peroxide solution designed for pharmaceutical cleanrooms

- Klercide Cleanroom Peroxide is suitable for use on all types of hard, non-porous surfaces in cleanrooms, controlled environments, isolators, LAFs, equipment exteriors and production vessels.
- Klercide Cleanroom Peroxide can be used to clean or remove residues without the need to wipe down with alcohol or water afterwards.
- Klercide Cleanroom Peroxide is a versatile sporicide on hard, non-porous surfaces.
- Klercide Cleanroom Peroxide can be used in rotation with any other Ecolab Klercide product
- Klercide Cleanroom Peroxide is manufactured in Ecolab's ISO 9001 accredited facilities to the principles of cGMP. These conditions ensure Klercide Cleanroom Peroxide is compliant for use in your critical areas
- Klercide Cleanroom Peroxide is made with hydrogen peroxide in water for injection
- Klercide Cleanroom Peroxide is filled in [a Grade A] [an ISO Class 5] cleanroom
- Klercide Cleanroom Peroxide is double bagged
- Klercide Cleanroom Peroxide is triple bagged
- Klercide Cleanroom Peroxide is single bagged
- Klercide Cleanroom Peroxide minimizes visible residues, helping customers comply with Annex 1
- Compatible with materials frequently used in a cleanroom
- Designed for Cleanrooms
- Bleach free sporicide
- Versatile cleanroom sporicide
- Klercide Cleanroom Peroxide is non-corrosive to most hard, non-porous, non-food contact surfaces
- Effective against *Bacillus subtilis* and *Clostridium sporogenes*
- [Sterile] [validated sterile]
- [RTU] [Ready to Use] [peroxide] [6.16% peroxide] [hydrogen peroxide] [6.16% hydrogen peroxide] for hard, non-porous surfaces [for use in cleanrooms] and [controlled areas]
- 6.16% hydrogen peroxide solution, made with USP Water for Injection (WFI)
- Manufactured by an ISO 9001 facility
- This ready to use product is 0.2 micron filtered to remove [particulates][particles] from end use product
- This [sterile] [ready to use] product is manufactured in cleanrooms for use in cleanrooms. Made in accordance with the principles of Good Manufacturing Practice
- Aseptically processed
- Filtered
- 0.2 Micron Filtered
- Designed [built] for [routine] [rotation] manual cleaning and disinfection
- Non-corrosive
- No mixing [required]
- No mixing [measuring] or [rinsing] required
- No sticky residue [left behind]
- No sticky residue [formula]
- [Single] [Double] [Triple] bagged [for easy transfer into Grade A and B (ISO Class 5 and 6) cleanrooms]
- [This product] [Klercide Cleanroom Peroxide] is 0.2 micron filtered, filled, and capped [under Grade A laminar air flow] [in a Grade A [(ISO Class 5)] cleanroom] [and [single][double][triple] bagged in a Grade B [(ISO Class 7)] cleanroom]
- [Klercide Cleanroom Peroxide] [This product] is 0.2 micron filtered, aseptically filled and [single][double][triple] bagged [under unidirectional air flow in cleanrooms using a strictly controlled and validated process]

- [This] [product] [sporicide] [Klercide Cleanroom Peroxide] [ready to use solution] [hydrogen peroxide] [hydrogen peroxide product] can be used as part of a rotation with other disinfectants
- Ready to use – apply directly onto surface – for optimum results, a wipe may be used after the appropriate contact time
- For optimum results, after the appropriate contact time, wipe the surface to physically remove any contaminants.
- Formulated to leave [minimal] [low] visible [residues] [streaks]
- Leaves no visible [residues] [streaks], minimizing the need for [rinsing] [cleaning] to achieve visibly clean results [on non-product contact surfaces] [within [cleanrooms] [controlled areas]] [to reduce contamination]]

**Table 1: Hard, Non-Porous Use Sites**

Hospitals	Hospital Compounding Pharmacies	Compounding Pharmacies
Cleanrooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Research Facilities	Biomedical Facilities	Biotechnology Facilities
Industrial Facilities	Healthcare Institutions	Biopharmaceutical
Biopharmaceutical Manufacturing Facilities	Medical Device Manufacturing Facilities	Diagnostic Manufacturing Facilities
Life Science Facilities	Animal Life Science Facilities	Pharmacies
Biomedical technology	Comparative Medicine Facilities	Laboratory Facilities

*[Note to reviewer: Any of the claims in the above table are considered optional and may or may not be included in marketed label.]*

**Table 2: Hard, Non-Porous Use Surfaces**

Aseptic Filling Rooms	Gowning Rooms	General Manufacturing Areas
Isolators	Tables	Counters
Machinery	Floors	Transfer disinfection
Hard surfaces	Non-porous hard surfaces	Transfer Hatches
Laminar Flow benches	Shelves	Countertops
Carts	(Biosafety Level) (BSL) hoods	Equipment
Laminar flow curtains	Laboratory benches	
Hoods	Anywhere contamination control is required for hard, non-porous surfaces	
Products in non-porous packaging for transfer disinfection.		

*[Note to reviewer: Any of the claims in the above table are considered optional and may or may not be included in marketed label.]*

**Table 3: Hard, Non-Porous Materials**

Stainless Steel	Glass	Laminates
PVC coated mild steel	Acrylic	Vinyl
Trespa	PVC	Terrazzo
Polymeric Flooring	Epoxy-coated Flooring	Neoprene

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*[Note to reviewer: Any of the claims in the above table are considered optional and may or may not be included in marketed label.]*



*[Note to reviewer: These graphics may appear in different colors on the marketed label. This product is not a sterilant, but is considered sterile under ISO 14644.]*