

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:

1677-281

4/30/25

Term of Issuance:

Conditional

Name of Pesticide Product:

Klercide Rapid Sporicide

Name and Address of Registrant (include ZIP Code):

Franklin Adams

Ecolab Inc.

Electronic Transmittal: 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:

Date:

4/30/25

Steven Snyderman, Product Manager 33

Regulatory Management Branch II Antimicrobials Division (7510M)

Office of Pesticide Programs

Steven Dryderman

EPA Form 8570-6

Page 2 of 2 EPA Reg. No. 1677-281 Action Case No. 00613497

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

a. Hydrogen Peroxide: GDCI-000595-1127b. Peracetic Acid: GDCI-063201-1125

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): <a href="https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division#rb">https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division#rb</a>

- 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. 1677-281."
- 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, 05/21/2024

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

**Enclosure: Stamped Label** 

## Klercide Rapid Sporicide

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

# SPORICIDE / ONE-STEP DISINFECTANT / HARD SURFACE DISINFECTANT / FUNGICIDE / NON-FOOD CONTACT SANITIZER

[Filtered to 0.2 microns] [0.2 Micron Filtered] [Filtered] [Blended with WFI] [Blended with Water for Injection] [WFI Formula] [Water for Injection] [USP Water] [USP Purified Water] [DI Water]

For use on hard nonporous surfaces in [Cleanrooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Biomedical Facilities], [Biotechnology Facilities], [Medical Device Facilities], [Medical Device Manufacturing Facilities], [Life Science Laboratories], [Industrial Facilities]

#### **Active Ingredient:**

Total:	100.00%
Other Ingredients:	97.03%
Octanoic Acid	
Peracetic Acid	0.070%
Hydrogen Peroxide	2.83%

## ACCEPTED

04/30/2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1677-281

#### **KEEP OUT OF REACH OF CHILDREN**

### DANGER[/PELIGRO]

["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

**DANGER:** Causes irreversible eye damage. Do not get in eyes or on clothing. Wear goggles, face shield, or shielded safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the restroom. Remove and wash contaminated clothing before reuse.

#### **FIRST AID**

**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. **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. Do not give anything by mouth to an unconscious person. **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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Call a poison control center or doctor for treatment advice.

FOR EMERGENCY MEDICAL INFORMATION, CALL [TOLL-FREE]: [1-800-328-0026] [or] [X-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.]

#### PHYSICAL AND CHEMICAL HAZARDS:

**STRONG OXIDIZING AGENT:** Keep away from combustible materials. Do not mix this product with other chemicals, organic substances, or other cleaners. Incompatible with acids, alcohols, alkali, powdered metals, metal salts, reactive chemicals, organic materials and reducing agents.

**COMBUSTIBLE:** Do not use near heat or open flame.

**ENVIRONMENTAL HAZARDS:** Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

#### **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.

**USE**: This product is designed as a [one-step] disinfectant [fungicide] [sanitizer] [sporicide] for use in manufacturing locations in areas such as:

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

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

Use on hard, non-porous surfaces [in] [or] [on]:

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

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

This product is compatible with [the listed materials]. If the product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

Stainless Steel	Glass	Laminates
PVC coated mild steel	Acrylic	Vinyl
Polycarbonate	PVC	Terrazzo
Polymeric Flooring	Epoxy-coated Flooring	Polyurethane

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

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

Use only on hard, non-porous surfaces. Clean the surface to be treated of debris, organic material, and other visible soil. Thoroughly wet or completely immerse the surface by flooding, soaking, or mopping with the ready to use solution. The surface must remain visibly wet for the required contact time of 15 minutes. 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

# DISINFECTION [ONE-STEP CLEANING / DISINFECTION] [COMBINATION DISINFECTION AND CLEANING]

This product is ready to use. Do not dilute. This product is a one-step disinfectant cleaner for use on hard, non-porous surfaces in cleanrooms and controlled areas [according to the AOAC Use Dilution Test Method] [in the presence of 5% organic soil load]. For visibly soiled areas, a pre- cleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to wet all surfaces thoroughly. All surfaces must remain wet for a minimum of 3 minutes and then either allow to air dry or wipe dry with a [sterile] cloth or wiper. When used as directed at a 3 minute contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538) Pseudomonas aeruginosa (ATCC 15442)

#### **FUNGICIDE**

For visibly soiled areas, a pre-cleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to wet all surfaces thoroughly. All surfaces must remain wet for the required contact time and then either allow to air dry or wipe dry with a [sterile] cloth or wiper. This product is effective against *Trichophyton interdigitale* (ATCC 9533) [formerly known as *Trichophyton mentagrophytes*] [the athlete's foot fungus] at a contact time of 3 minutes [in the presence of 5% organic soil load] and *Aspergillus brasiliensis* (ATCC16404) at a contact time of 4 minutes [in the presence of 5% organic soil load].

#### **SANITIZATION**

This product is ready to use. Do not dilute. This product is a hard surface sanitizer for hard, non-porous, non-food contact surfaces in cleanrooms and controlled areas. This product is not to be used as a sanitizer in hospitals or healthcare facilities. For visibly soiled areas, a precleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking, so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] Allow surfaces to remain visibly wet for a minimum of 15 seconds and then either allow to air dry or if desired wipe dry with a [sterile] cloth or wiper. When used as directed at a 15-second contact time, this product is effective against: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella aerogenes* (ATCC 13048).

#### STORAGE & DISPOSAL

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

**PESTICIDE STORAGE:** Store this product 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

Net Contents: 32 fl oz (946 mL)

1 US gal (3.78L)

Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

#### **CONTAINER HANDLING AND DISPOSAL:**

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. 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 or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

[QR Code] [SKUXXXXXXX] [LOTXXXXXXXXX] [EXPXXXXXXX] [SERXXXXXX]

[Lot Number / Batch Code XXXXXX

EXPIRY: Day/Month/Year]

US EPA Reg. No. 1677-[pending]

US EPA Est. No.: [1677-MN-1 (P)], [1677-CA-2 (R)], [1677-TX-1 (D)], [1677-IL-2 (J)], [1677-GA-

1 (M)], [1677-WV-1 (V)], [1677-GBR-001], [5389-NC-1 (G)], [1677-CAN-1], [303-IN-1 (L)]

[FOR COMMERCIAL USE]
Manufactured by:
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102 (USA)
[www.ecolab.com]

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

[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: <a href="https://www.ecolab.com/patents">www.ecolab.com/patents</a>

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#### **OPTIONAL MARKETING CLAIMS**

#### **Product Descriptors**

- [Versatile] [innovative] [cleanroom sporicide] [disinfectant solution]
- Bleach free
- [RTU] [Ready to Use] [peracetic acid based] solution for [hard, non-porous surfaces] [for use in cleanrooms] and [controlled areas].
- Designed [built] for [routine] [rotational] manual cleaning and disinfection.
- Non-corrosive.

#### **Format**

- [Insert product name] is a ready to use [sterile] peracetic acid solution.
- [Insert product name] is 0.2 micron filtered.
- [Insert product name] is available in 1 gallon and 32oz formats.
- [Insert product name] is [single bagged] [double bagged] [triple bagged].
- [Double bagged] [triple bagged] [for transfer into Grade A and B (ISO Class 5 and 6) cleanrooms]
- [Validated] sterile.
- [0.2 Micron] Filtered.

#### **Efficacy**

- [Insert product name] is a versatile sporicide with a broad spectrum of activity and is specifically formulated to help control microbial contamination on hard, non-porous surfaces most likely found in a cleanroom environment, including difficult-to-kill bacterial spores.
- [Insert product name] is a ready to use sterile peracetic acid solution. It is 0.2 micron filtered and filled in an ISO Class 5 cleanroom. Its broad-spectrum activity includes bacterial spores.
- [Optimize your contamination control strategy] with [insert product name] proven [sporicidal] efficacy.
- Broad Spectrum disinfectant [that includes sporicidal, bactericidal, sanitizing, and fungicidal activity].
- [Sporicidal] [Bactericidal] [Fungicidal] [Sanitizing] solution.
- [Insert product name] is a ready-to-use [disinfectant] [sporicide] for proactive control of spores on hard, non-porous surfaces.
- [Insert product name] effectively kills spores commonly found on hard non-porous surfaces in a cleanroom environment.
- 99.9% [3 log reduction] of bacteria in 15 seconds.
- Sporicidal in 15 minutes.
- Effective against *Bacillus spizizenii* [formerly Bacillus subtilis] and *Clostridium sporogenes* in 15 minutes.
- Effective against Aspergillus brasiliensis in 4 minutes.
- Fungicidal in 3 minutes.

#### Residue

- [Insert product name] reduces the need for frequent rinsing [which may help reduce costs related to residue management such as labor].
- [Insert product name] minimizes visible residues, helping customers comply with Annex
- Formulated to leave [minimal] [low] visible [residues] [streaks] [making it ideal for high grade cleanrooms].
- Leaves minimal visible [residues] [streaks], minimizing the need for [rinsing] [cleaning] to achieve visibly clean on non-product contact surfaces within [cleanrooms] [controlled areas].

- No sticky residue [left behind].
- Minimal residues help prevent slips and falls occurring from buildup on floors.

#### **Operator Acceptance & PPE**

- [Acceptable] [Pleasant] [Reduced] [smell] [odor].
- Innovative technology minimizes harsh peracid and vinegar smells.
- No additional PPE required than what is currently required for existing peracid sporicidal products.
- [Optimized] operator acceptance.
- [Insert product name] is a ready-to-use [sporicide] [sanitizer] [disinfectant] [and] [fungicide] that delivers improved operator acceptance through reduced smell, minimal visible residue, and even wetting.
- [When used as directed] [insert product name] requires no respirator while in use.
- Choose a solution that optimizes operator acceptance [insert product name]'s technology effectively transforms the peracid odor profile and reduces obnoxious malodors.

#### **Values Claims**

- When used according to disinfection instructions [Insert product name] cleans and disinfects in one labor saving step.
- [Insert product name] delivers technology for reduced malodors, minimized residue impact, and even wetting distribution, providing an enhanced solution for cleanroom operators.

#### Compatibility

- [Insert product name] [is less corrosive than active chlorine products] [and] can be [safely] used on a variety of surfaces including [stainless steel] [glass] [acrylic] [polycarbonate] [and many other surfaces commonly found in cleanrooms].
- [Insert product name] is suitable for use on hard, non-porous surfaces in cleanrooms and controlled environments, isolators, LAFs (Laminar Air Flows), equipment and production vessel exteriors.
- [Insert product name] can be used on hard non-porous surfaces in cleanrooms, controlled environments, isolators, equipment and product vessel exteriors.
- [Insert product name] is for use as a disinfectant [or] [sanitizer] on hard, non-porous floors and other hard surfaces.
- [This] [product] [disinfectant] [Insert product name] [ready to use solution] [peracetic acid-based solution] can be used as part of a rotation with other [disinfectants] [Klercide products] [Ecolab Contamination Control products].
- [Insert product name] is non-corrosive [and can be used in cleanrooms [cleaning][and][disinfecting] applications] on hard non-porous surfaces.

#### **Environments**

- [Insert product name] is [ideal] [suitable] for transfer disinfection when used according to the disinfection use directions.
- [Insert product name] is designed for use in critical aseptic core manufacturing areas.
- [Made in Cleanrooms, for Cleanrooms] [Designed for Cleanrooms].
- Reduce 99.9% (3 log reduction) of bacteria in 15 seconds, helping streamline material transfer procedures when used according to the sanitization use directions.
- [Insert product name] is suitable for transfer disinfection, providing a broad-spectrum of activity and even wetting distribution when used according to the disinfection use directions.
- [Insert product name]'s sporicidal efficacy helps to reduce contamination ingress when used for material transfer into cleanrooms.

#### **Wetting/Surface Tension**

- [Insert product name]'s low surface tension delivers even spread of the disinfectant allowing it to remain visibly wet [throughout the contact time].
- [insert product name's] wetting and low surface tension allows for even surface coverage, which can reduce the volume needed for total coverage.
- [Insert product name] is formulated with a wetting agent to minimize pooling and beading.
- [Insert product name] has low surface tension which allows for even distribution of the liquid over a surface.

#### **Quality & Manufacturing**

- [Insert product name] is manufactured in [our state-of-the-art facilities] [Ecolab's ISO 9001 accredited facilities] [to the principles of cGMP].
- Manufactured by an ISO 9001 facility.
- [Insert product name] is filtered to 0.2 micron, filled, and capped under grade A (ISO 5) laminar air flow and [single] [double] [triple] bagged in a Grade B [ISO 5 at rest / ISO 7 in operation] cleanroom.
- [Insert product name] is 0.2 micron filtered, filled and capped in an ISO 5 cleanroom and bagged in an ISO 7 cleanroom.
- Aseptically [processed] [filled].
- This ready to use product is [0.2 micron] filtered to remove [particulates][particles] from end use product.
- Certificate of analysis [and sterility] with every batch.
- This [sterile] [ready to use] product is manufactured in cleanrooms for use in cleanrooms. Made in accordance with the principles of Good Manufacturing Practice.

#### **Product Application**

• [When used as a hard non-porous surface disinfectant the product can be sprayed directly onto the surface]— for optimum results, a wipe may be used after the required contact time [to physically remove any contaminants].

- Apply directly onto hard, non-porous surfaces using a cleanroom wipe or mop to ensure complete coverage. Allow surfaces to remain wet for the required contact time and then wipe dry.
- No mixing [measuring] [or] [rinsing] [required].

#### **GRAPHICS**



[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.]