



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 19, 2020

Brandy Koslop
Senior Regulatory Affairs Manager
Ecolab, Inc.
1 Ecolab Place
St. Paul, Min 55102

Subject: PRIA Label Amendment – Sanitization claims for two microorganisms
Product Name: XLS-FRTU
EPA Registration Number: 1677-257
Application Date: February 25, 2020
Decision Number: 561274

Dear Ms. Koslop:

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

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with FIFRA section 6. If you have any questions, please contact Mohammad Alavi by phone at (703) 347-0522, or via email at Alavi.mohammad@epa.gov.



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

[Note to reviewer. Wording in brackets is considered optional.]

XLS-FRTU

[Filtered to 0.2 microns] [0.2 Micron Filtered] [Filtered] [Aseptically Filtered Formula][Quat blended with WFI][Quat blended with Water for Injection][WFI Formula][Water for Injection] [USP Water Pharma Grade][DI Water]

NON-FOOD CONTACT SANITIZER / HARD SURFACE NON-FOOD CONTACT SANITIZER

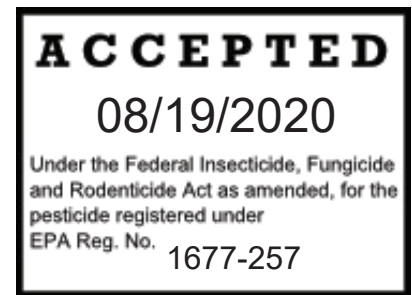
For Use in Industrial and Institutional Applications (not for use in hospital or healthcare settings) [such as] [Cleanrooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Industrial Applications]

Active Ingredient:

Didecyl dimethyl ammonium chloride..... 0.037%

Other Ingredients: 99.963%

Total:..... 100.000%



CAUTION KEEP OUT OF REACH OF CHILDREN

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

(See [front] [top] [label] [panel] for [precautionary statements] [and] [first aid])

[Reference sheet (INSERT) Retain this information for your files]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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.

**FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

Have the product container or label with you when calling a poison control center, doctor, or going for treatment.

[Note to Reviewer: For containers of 5 gallons or more, the following Environmental Hazards language will appear on the final product label.]

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds, fish, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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

USE: This product is designed specifically as a [non-food contact] sanitizer [hard surface non-food contact sanitizer] for use on environmental surfaces in cleanrooms and non-product contact surfaces in manufacturing locations in areas such as*: (NOTE TO REVIEWER: use sites to be selected from table below):

Animal Life Science Facilities	Biomedical Facilities	Biotechnology Facilities
Biopharmaceutical Manufacturing Facilities	Cleanrooms	Comparative Medicine Facilities
Compounding Pharmacies	Controlled Areas	Pharmaceutical Manufacturing Facilities
Diagnostic Manufacturing Facilities	Life Science [Facilities][Laboratories]	Medical Device Manufacturing Facilities
Research Facilities	Industrial Facilities	Laboratory Facilities
Pharmacies	Institutional Facilities	Comparative Facilities
Cell Therapy Facilities	Gene Therapy Facilities	

*Not for use on surfaces where the production of consumer good occurs.

Use on hard non-porous surfaces only [in] [or] [on]: (NOTE TO REVIEWER: surfaces to be selected from table below):

Aseptic Filling Rooms	Gowning Rooms	General Manufacturing Areas
Isolators	Tables	Counters
Machinery	Floors	Walls
Hard, non-porous surfaces only	Non-porous hard surfaces only	Material Transfer
Laminar Flow benches	Shelves	Transfer Hatches
Carts	Ceilings	Countertops
Hoods	Laminar flow curtains	Equipment
Benches	Production vessel exteriors	

** For use on hard, non-porous surfaces only

[This product is compatible with [the listed materials] (NOTE TO REVIEWER: may select surfaces from list below). 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		Aluminum
PVC	PVC-Coated Mild Steel	Acrylic
Vinyl	Trespa	Laminate
Polycarbonate	Polypropylene	Zinc Galvanized Mild Steel

SANITIZATION

This product is ready to use. Do not dilute. This product is a hard surface sanitizer for pre-cleaned, hard, non-porous, non-food contact surfaces in cleanrooms and controlled areas. 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 5 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper. When used as directed at a 5 minute contact time, this product is effective against:

Burkholderia cepacia (ATCC 25416)
Escherichia coli (ATCC 11229)
Enterobacter aerogenes (ATCC 13048)
Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Staphylococcus epidermidis (ATCC 12228)

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER OR FOOD OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE: Store in the original container in a dry cool place. Absorb spills with inert dry absorbent or sand, then place in a chemical waste container.

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 5 gallons or less]

Non-refillable container. Do not reuse or refill this container. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Lot Number / Batch Code XXXXXX

EXPIRY: Day/Month/Year]

US EPA Reg. No. 1677-257

US EPA Est. No.: 001677-GBR-001, 5389-NC-1 (G)

Superscript refers to first letter of date code

Net Contents:	32 fl oz (946 ml)
	33.8 fl oz (1 L)
	1 US gal (3.78 L)
	1.32 US gal (5 L)

Manufactured by:

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102

USA

[Made in Great Britain]

[Made in USA]

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

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(Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.) (If you cannot read English, ask your supervisor for the appropriate instructions before handling this product.)

Optional Claims (Marketing Claims)

- Ready to use sanitizer for hard, non-porous surfaces for use in cleanrooms and controlled areas, containing a Quaternary Ammonium compound blended with [WFI][or][DI][or][Water for Injection][or][Deionized Water]
- Aseptically Processed
- No rinse required
- [RTU][or][Ready to Use] [solution][or][product] for use on hard, non-porous surfaces
- No additional activators are required
- Leaves no visible residues making it ideal for high grade cleanrooms
- Blended with [Water for Injection][or][USP Water for Injection][or][Deionized Water][or] [DI Water]
- This [sterile] product is [triple bagged][or][double bagged] for easy transfer into [ISO 5] [or][ISO 6][or][Grade A] [or] [Grade B] cleanrooms
- Easy to use
- [minimal][or][low] visible residue product is non-corrosive [can be used in most cleanroom [cleaning and sanitizing] applications]
- This [sterile] [product][or] [non-food contact sanitizer] [or] [hard, non-porous surface sanitizer solution][or] [Ready To Use solution] is 0.2 micron filtered
- aseptically filled [triple bagged][or][double bagged] under unidirectional flow in an ISO Class 5 (*Grade B*) cleanroom using a strictly controlled and validated process
- [Application Areas:] For use on floors, walls and hard, non-porous surfaces in cleanrooms and controlled areas.
- For use on floors, walls and hard, non-porous surfaces
- It is suitable for use on hard, non-porous surfaces in cleanrooms and controlled environments, isolators, LAFs (Laminar Air Flows), equipment and production vessel exteriors
- Can be used as part of a rotation with other Ecolab Contamination Control [products]
- This product is a non-food contact sanitizer for use on hard, non-porous surfaces and leaves no visible [residues] [streaks], making it ideal for daily use in [all grades] [high grade] cleanrooms where visual cleanliness [to reduce contamination] is important
- This product [non-food contact sanitizer] with minimal visible [residue] [streaking] is non-corrosive to most surfaces [and can be used in most cleanroom [cleaning] [and] [sanitizing] applications]
- Formulated to leave [minimal] [low] visible [residues] [streaks]
- Leaves no visible [residues] [streaks], minimizing the need for [rinsing] [cleaning] to achieve visibly clean on non-product contact surfaces within [cleanrooms] [controlled areas] to reduce contamination

Manufacturing claims:

- Manufactured by an ISO 9001 facility
- EPA Establishment Registration Number: 001677-GBR-001, 5389-NC-1 (G)
- Certificates of analysis [and sterility] with every batch

- 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 to the principles of Good Manufacturing Practices

(NOTE TO REVIEWER: The following claims are to be used on products packaged in the Ecolab SteriShield Delivery System container)

- The trigger spray bottle incorporates the patented [SDS] [SteriShield Delivery System] container and an adjustable trigger.
- [SteriShield Delivery System] [SDS]
- SteriShield Delivery System protects the integrity of the contents throughout use
- The SteriShield Delivery System on the trigger spray formats has been validated to give an in use shelf life of six months [after opening] [or] [after initial use] [so there is no need to discard unused product]
- Trigger system provides:[Comfort and ease of use] [Optimum surface coverage][Fully adjustable (variable) nozzle][Completely sealed system] [closed system]
- Bag in the bottle [Bag-in-the-bottle]
- Validated for use in all grades of cleanroom
- Fully adjustable trigger spray allows the liquid to be dispensed as either a jet or spray [,which is particularly useful in critical areas]
- Fully adjustable trigger spray allows the liquid to be dispensed as either a jet or spray enabling thorough wetting of the surface [,so that sanitization procedures are effective]
- All the sanitizing solution can be dispensed from the bottle [so there is no waste]
- Always close the nozzle after use
- [SDS] [SteriShield Delivery System] [Applicable US patent numbers; International patent application no. PCT/GB2010/051761]

(NOTE TO REVIEWER: The following statements are for use on product sell sheets.)

- Ready to use, can be sprayed directly onto the surface.
- 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.



