



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

EPA Reg. Number:

1677-257

Date of Issuance:

1/22/18

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

XLS-FRTU

Name and Address of Registrant (include ZIP Code):

Brandy Koslop
Principle Regulatory Specialist II, Life Sciences
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

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.

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:

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

Date:

1/22/18

2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. DDAC GDCI-069149-0681
 - b. DDAC GDCI-069149-30869

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI 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. 1677-257.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

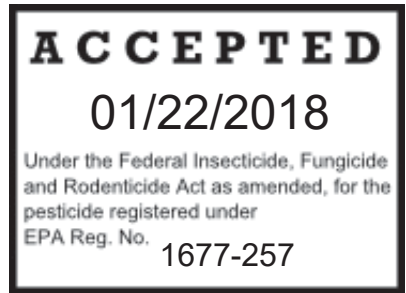
Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded 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.

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 12/15/2017

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

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

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

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

PHYSICAL AND CHEMICAL HAZARDS:

[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):

Cleanrooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Research Facilities	Industrial Facilities	Laboratory Facilities
Biopharmaceutical Manufacturing Facilities	Institutional Facilities	Comparative 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.]

316 Stainless Steel	304 Stainless Steel	Aluminum
PVC	PVC-Coated Mild Steel	Acrylic
Vinyl	Trespa	

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 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:

Staphylococcus aureus (ATCC 6538)
Enterobacter aerogenes (ATCC 13048)
Burkholderia cepacia (ATCC 25416)
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 ¼ 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-[pending]
 US EPA Est. No.: 001677-GBR-001, 5389-NC-1 (G)

Manufactured by:
 Ecolab Inc.
 1 Ecolab Place
 St. Paul, MN 55102
 USA

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)

[Made in Great Britain]
 [Made in USA]

[See [side][back][other][label][panel] for [complete] directions for use, [additional] precautionary statements and first aid information]

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

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] [Water for Injection][DI][Deionized Water]
- [Aseptic Processed][Sanitizer][product]
- [Aseptic Processed][rotational][product][sanitizer][hard, non-porous surface sanitizer solution][no rinse required]
- [Ready to Use] [solution][product] [hard, non-porous surface sanitizer solution]
- [RTU] [solution][product] [hard, non-porous surface sanitizer solution]
- [Ready to use] [hard, non-porous surface][sanitizer solution] [containing a quaternary ammonium compound with][WFI][DI]
- [Ready to use][sanitizer][solution]
- [This] [product] [sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] [is a blend of quaternary ammonium compound and [Water for Injection][Deionized Water]
- No additional activators are required
- [This] [product] [sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] [leaves no visible residues] making it ideal for high grade cleanrooms
- [This] [product] [sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] is blended with [Water for Injection][USP Water for Injection] [Deionized Water] [DI Water]
- [This] [product] [non-food contact sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] is [triple bagged] [double bagged] [for easy transfer into Grade A and B cleanrooms]
- Easy to use
- [This] [product] [non-food contact sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] [minimal][residue product] is non-corrosive [can be used in most cleanroom [cleaning][and][sanitizing] applications]
- [This] [product] [non-food contact sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] is [0.2 micron filtered], [aseptically filled][triple bagged][double bagged][under unidirectional flow in a *Grade B (ISO Class 5)* 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
- [This] [product] [non-food contact sanitizer][hard, non-porous surface sanitizer solution] [Ready To Use solution] can be used as part of a rotation with other Ecolab Contamination Control [products]

Manufacturing claims:

- Manufactured by a ISO 9001:2008, ISO 13485:2003
- 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] [ready to use][product] is manufactured in cleanrooms for use in cleanrooms.
- [This] [ready to use][product][is made in accordance to the principles of Good Manufacturing Practices]

[See [back],[side],[other] label[panel] for [complete][additional][directions for use][precautionary statements][and][first aid]]

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

- The trigger spray bottle incorporates the patented SDS container and an adjustable trigger.
- SDS [incorporated]
- Trigger system provides:[Comfort and ease of use] [Optimum surface coverage][Fully adjustable (variable) nozzle][sealed system]
- Fully adjustable trigger spray [which 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 [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.



