



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 9, 2016

Nicole Listner
Ecolab Inc.
370 Wabasha St N
St. Paul, MN 55102

Subject: Notification per PRN 98-10 –Adding optional marketing language:
Product Name: XHC-EA
EPA Registration Number: 1677-252
Application Date: May 9, 2016
Decision Number: 517401

Dear Ms. Listner:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

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If you have any questions, please contact Stacey Grigsby by phone at 703.305.6440, or via email at grigsby.stacey@epa.gov .

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

Stacey Grigsby
Risk Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)

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

XHC-EA [WFI Formula] [Water for Injection] [Deionized Water] [Alcohol blended with WFI]

[Gamma Irradiated] [Filtered to 0.2 microns] [0.2 Micron Filtered] [Sterile]

ONE-STEP DISINFECTANT / HARD SURFACE DISINFECTANT /
NON-FOOD CONTACT SANITIZER /
VIRUCIDE*/VIRUCIDAL*/ FUNGICIDE

For use in [Hospitals], [Hospital Compounding Pharmacies], [Compounding Pharmacies], [Clean
Rooms], [Controlled Areas], [Pharmaceutical Manufacturing Facilities], [Biomedical Facilities],
[Biotechnology Facilities], [Medical Device Facilities], [Life Science Laboratories]

Active Ingredient:

Ethanol** 59.2%

Other Ingredients.....40.8%

Total:..... 100.0%

**Ethanol denatured with IPA at 70% by volume

**[Ethanol][Ethyl alcohol] denatured with isopropyl alcohol

[USP Water for Injection] [(meets EP WFI requirements)] [Deionized Water]

KEEP OUT OF REACH OF CHILDREN

NOTIFICATION

1677-252

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

06/09/2016

CAUTION Flammable

Keep away from heat or open flame. Store at room temperature below 120°F (48.8°C).

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:

Flammable: Keep away from heat and open flame.

[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

Read the label before using

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

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 specifically as a [one-step] disinfectant [virucide*] [fungicide] [sanitizer] for use in hospital / manufacturing locations in areas such as: (NOTE TO REVIEWER: use sites to be selected from table below):

Hospitals	Hospital Compounding Pharmacies	Compounding Pharmacies
Clean Rooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Pharmaceutical Manufacturing 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
Research Facilities	Biotechnology Facility	

Use on hard non-porous, non-food contact 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	Transfer disinfection
Laminar Flow benches	Shelves	Transfer Hatches
Carts	Ceilings	Countertops
Laminar flow curtains	(Biosafety Level) (BSL) hoods	Equipment
Hoods	Laboratory benches	
Products in non-porous packaging for transfer disinfection.	Anywhere contamination control is required***	

*** For use on hard, non-porous, non-food contact 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	Zinc galvanized mild steel	Anodized aluminum
Polypropylene	PVC	Polyvinyl chloride
Polycarbonate	Cast acrylic	Extruded acrylic
Laminate		

[DISINFECTION] [ONE-STEP CLEANING/DISINFECTION] [COMBINATION DISINFECTION AND CLEANING] [HARD SURFACE DISINFECTION]

This product is ready to use. Do not dilute. This product is a one-step disinfectant cleaner on hard, non-porous surfaces in clean rooms and controlled areas [according to the AOAC Use Dilution Test modified] [in the presence of 5% blood serum]. For heavily 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. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] All surfaces must remain wet for a minimum of 5 minutes and then either allow to air dry or 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)
Pseudomonas aeruginosa (ATCC 15442)
Brevundimonas vesicularis (ATCC 51560)
Burkholderia cepacia (ATCC 25416)
Corynebacterium jeikeium (ATCC 43216)
Escherichia coli (ATCC 11229)
Micrococcus luteus (ATCC 49732)

FOR USE AS A VIRUCIDE*

This product is ready to use. Do not dilute. For heavily soiled areas, a pre-cleaning step is required. Apply solution to hard, non-porous surfaces in clean rooms and controlled areas with a 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.] All surfaces must remain wet for the required contact time indicated in the directions for use. Allow surfaces to air dry or wipe dry with a [sterilized] cloth or wiper.

VIRUCIDAL* in 5 minutes against the following viruses [according to the Virucidal Qualification Test modified][in the presence of 5% blood serum]:

*Herpes Simplex Type I Virus (Herpes) (ATCC VR-733)
 *Herpes Simplex Type II Virus (Genital Herpes) (ATCC VR-734)
 *Influenza A Hong Kong H3N2 Virus (ATCC VR-544)

FUNGICIDAL in 10 minutes against *Trichophyton mentagrophytes* (ATCC 9533) on hard, non-porous surfaces [according to the AOAC Fungicidal Test] [modified in the presence of 5% blood serum].

FUNGICIDAL in 5 minutes against *Candida albicans* (ATCC 10231) and *Penicillium chrysogenum* (ATCC 10003) on hard, non-porous surfaces [according to the AOAC Fungicidal Test method] [modified in the presence of 5% blood serum].

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 clean rooms 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 3 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 3 minute contact time, this product is effective against:

- Staphylococcus aureus* (ATCC 6538)
- Klebsiella pneumoniae* (ATCC 4352)
- Enterobacter aerogenes* (ATCC 13048)

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER OR FOOD OR FEED BY STORAGE OR DISPOSAL.
DO NOT STORE NEAR HEAT OR OPEN FLAME.

PESTICIDE STORAGE: Store in the original container in a dry cool place below 120°F (48.8°C). 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.

[For containers >5-55 gallons.]

Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or 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.

[Totes]

Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

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

[Quality system Reference] [LABXXXX/XX]

US EPA Reg. No. 1677-252
US EPA Est. No.: 001677-GBR-001

Net Contents:	33.8 fl oz (1L)
	1.06 US gal (4L)
	1.32 US gal (5L)

Manufactured by:
Ecolab Inc.
370 Wabasha Street N.
St. Paul, MN 55102-1390
USA

Made in Great Britain

[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, disinfectant solution for hard, non-porous surfaces for use in clean rooms and controlled areas containing 70% v/v Ethanol Denatured with IPA blended with Water for Injection
- Alcohol blended with WFI
- [High quality][ready to use][product][sterile alcohol][hard, non-porous surface disinfectant solution]
- Sterile [ready to use][product][hard, non-porous surface disinfectant solution]
- [Sterile spore free 70/30 v/v Ethanol Denatured with IPA][blended with the highest grade (EP) Water for Injection][blended with Water for Injection][blended with USP Water for Injection]
- [This] [ready to use][product][sterile alcohol][hard, non-porous surface disinfectant solution] is triple bagged [for easy transfer into Grade A (ISO Class 5) and B (ISO Class 6) clean rooms]
- Triple bagged
- [This] [ready to use][product][sterile alcohol][hard, non-porous surface disinfectant solution] is gamma irradiated [to ensure a sterile, spore free product]
- Gamma irradiated
- [This] [ready to use][product][sterile alcohol][hard, non-porous surface disinfectant solution] is a blend of 70% v/v Ethanol Denatured with IPA with Water for Injection
- Endotoxin levels less than 0.25 EU/mL
- Endotoxin levels are guaranteed to be below 0.25 EU/ml.
- The alcohol blend is 0.2 micron filtered, [filled and triple bagged under Grade A (ISO class 5) laminar flow in a Grade C (ISO Class 7) clean room,] [before irradiation using a validated process at no less than 25 kGy.]
- [This] [ready to use][product][sterile alcohol] is manufactured in clean rooms for use in cleanrooms.
- [This] [ready to use][product][sterile alcohol] is made in accordance to the principles of GMP
- Easy to use
- [This] [ready to use][product][sterile alcohol] can be used to remove residues [in clean rooms and controlled areas]
- [Application Area:] For use on floor, walls and hard non-porous surfaces in clean rooms and controlled areas.
- Low Residue
- [This] [ready to use][product][sterile alcohol][hard non-porous surface disinfectant solution] uses IPA as the denaturant, ensuring that the residues on evaporation are low and are comparable to those of pure ethanol
- [This] [ready to use][product][sterile alcohol][hard non-porous surface disinfectant solution] does not contain Bitrex or MEK
- [This] [ready to use][product][sterile alcohol][hard non-porous surface disinfectant solution] is suitable for use in direct product areas as all the alcohol flashes off and non-soluble denaturants such as Bitrex are completely absent.
- **Refer to the (MSDS)(SDS) for additional product hazard information**

Manufacturing claims:

- Manufactured by a ISO 9001:2008, ISO 13485:2003 and European Medical Device Directive

93/42/EEC accredited company

- EPA Establishment Registration Number: 001677-GBR-001
- Certificates of analysis, [irradiation] [and quantitative endotoxin level <0.25 EU/ml] with every batch
- Sterility and endotoxin tested to an approved pharmacopoeia method.
- Samples from each batch are tested for sterility and residue on evaporation [and a quantitative endotoxin analysis is carried out before QC release]

(NOTE TO REVIEWER: The following claims are to be used on products packaged in the Ecolab SteriShield Delivery System container: 1L and 4L)

- The trigger spray bottle incorporates the patented SteriShield Delivery System and an adjustable trigger.
- SteriShield Delivery System [incorporated]
- SteriShield Delivery System protects the integrity of the contents throughout use
- Guaranteed sterility during use
- The SteriShield Delivery System on the trigger spray formats remains sterile for 3 months once opened
- The SteriShield Delivery System on the trigger spray formats has been validated to give an in use shelf life of three months [so there is no need to discard unused product]
- The unique way in which the SteriShield Delivery System works as a closed system ensures that the sterility of the contents is preserved throughout use
- Closed trigger system provides:[Comfort and ease of use] [Optimum surface coverage][Fully adjustable (variable) nozzle][Completely 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 through wetting of the surface],[so that disinfection procedures are effective].
- All the disinfectant solution can be dispensed from the bottle [so there is no waste]
- Always close the nozzle after use.
- SteriShield Delivery System
[Applicable US patent numbers; International patent application no. PCT/GB2010/051761]

(NOTE TO REVIEWER: The following claims are for use on sell sheets)

- Ready to use, can be sprayed directly onto the surface.
- Ready to use – apply directly onto surface – for optimum results also wipe
- For optimum results, wipe the surface to physically remove any contaminants.

User Information

Date Opened/Operator:

Expiration Date:

Area:

