



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 15, 2016

Brandy Koslop
Principal Regulatory Specialist I
Ecolab Inc.
370 Wabasha St. N
St. Paul, MN 55120

Subject: Notification per PRN 98-10 – Addition of an ABN and Minor Label Revisions
Product Name: XHC-E
EPA Registration Number: 1677-254
Application Date: July 27, 2016
Decision Number: 520119

Dear Ms. Koslop

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.

The alternate brand name “Klercide Sporicidal Active Chlorine” has been added to the product record.

Page 2 of 2
EPA Reg. No. 1677-254
Decision No. 520119

If you have any questions, you may contact Donna Kamarei at (703) 347-0443 or via email at Kamarei.donna@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Wanda J. Fuller, for". The signature is written in a cursive style.

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

[Note to reviewer. Wording in brackets considered optional and interchangeable.]

XHC-E

[WFI Formula] [[Made With][Water for Injection]][Blended with WFI][Disinfectant blended with WFI]

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

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

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

Active Ingredients:

**Sodium Hypochlorite 0.58%

Other Ingredients*: 99.42%

Total: 100.00%

[**Equivalent to 0.55% available chlorine]

[*Made with USP Water for Injection]

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Wear gloves, safety glasses and protective clothing. 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.

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 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.

NOTIFICATION

1677-254

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:

08/15/2016

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.

FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent: Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces etc.) will release chlorine gas which is irritating to the eyes, lungs and mucous membranes.

[The following statement is required only for containers 5 gallons or larger.]

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][sterilant][sporicidal]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
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

Use on hard non-porous surfaces [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 surfaces	Non-porous hard surfaces	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 hard, non-porous surfaces	

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 coated mild steel	Acrylic	Vinyl
Trespa	PVC	

[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 7 minutes and then either allow to air dry or wipe dry with a [sterilized] cloth or wiper. When used as directed at a 7 minute contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538)
Pseudomonas aeruginosa (ATCC 15442)
Escherichia coli (ATCC 11229)

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)
- *Rhinovirus Type 37 (ATCC VR-1147)
- *Poliovirus 1 (ATCC VR-1562)
- *Adenovirus (ATCC VR-5)

FUNGICIDAL in 5 minutes against *Trichophyton mentagrophytes* (ATCC 9533), *Candida albicans* (ATCC 10231), *Aspergillus brasiliensis* (ATCC 16404) and *Penicillium chrysogenum* (ATCC 10003) on hard, non-porous surfaces [according to the AOAC Fungicidal Test] [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)
Enterobacter aerogenes (ATCC 13048)

DIRECTIONS FOR USE AS A HARD NON-POROUS SPORICIDE

Use only on hard, non-porous surfaces. Clean the surface to be treated of debris and organic material. Apply ready to use solution by immersion of objects in containers by covering interior surfaces of containers, or by confining (e.g. rimmed) surfaces (e.g. floors, tables, counters) that permit a continuous layer of liquid to cover the surface for the required contact time of 5 hours. This product is effective against *Clostridium sporogenes* (ATCC 3584) and *Bacillus subtilis* (ATCC 19659) [with a 5% organic soil load]. Remove used solution and entrapped soil with a clean, dry, sterile cloth. Do not use this product as a sterilant on medical devices.

DIRECTIONS FOR USE AS A DISINFECTANT WITH SPORICIDAL ACTIVITY AGAINST CLOSTRIDIUM DIFFICILE SPORES

This product kills and/or inactivates spores of *Clostridium difficile* (ATCC 43598) on hard, non-porous surfaces. This product is effective against *Clostridium difficile* spores after a 10 minute exposure time.

Directions for cleaning prior to disinfection against *Clostridium difficile* spores:

PERSONAL PROTECTION: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

CLEANING PRODECURE: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean [sterile] cloth, mop, and/or sponge saturated with the sporicidal product. This cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces.

Surfaces [in patient rooms] are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

INFECTION MATERIALS DISPOSAL: Materials used in the cleaning process that may contain feces / waste are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

To disinfect against *Clostridium difficile* spores 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 10 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. Keep this product in a tightly closed container, when not in use. In case of a spill, flood area with large quantities of water. Product rinsate that cannot be used must be diluted with water before disposal in a sanitary sewer.

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. 1677-254

US EPA Est. No.: 001677-GBR-001

Manufactured by:

Ecolab Inc.

370 Wabasha Street N.

St. Paul, MN 55102-1390

<p>Net Contents: 33.8 fl oz (1L) 1.32 US gal (5L)</p>

USA

Made in Great Britain

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

Optional Claims (Marketing Claims)

- [Gamma Irradiated] [Disinfectant][Sporicidal][product]
- [RTU][Ready to Use][disinfectant][solution][product][for hard, non-porous surfaces][for use in clean rooms and controlled areas][containing sodium hypochlorite]
- [Ready to use][hard, non-porous surface][disinfectant][solution][containing sodium hypochlorite]
- [Active Chlorine] [Solution][Disinfectant][product]
- Disinfectant solution
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready To Use solution] [Active Chlorine product] has broad spectrum activity, [controlling microbial contamination likely to be found in a clean room environment,] [including difficult bacterial spores]
- Easy to use
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] is non-corrosive [so it can be used in most clean room [cleaning][and][disinfecting] applications]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] [is a gamma irradiated sodium hypochlorite solution][containing 0.55% (5500ppm) available Chlorine][available in a 1 liter trigger spray or 5 liter capped container]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] [is filtered with a 0.2 micron filter] [and double bagged in a Grade C (ISO Class 7) clean room before gamma irradiation]
- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] is [double bagged] [and gamma irradiated]
- Double bagged [for easy transfer into Grade A and B (ISO Class 5 and 6) clean rooms]
- 100 ml contains: 0.75 ml sodium hypochlorite [in water for injection]
- Product is gamma irradiated
- Broad spectrum of antimicrobial activity [including spores]
- It has broad spectrum of antimicrobial activity [including spores and both enveloped and non-enveloped viruses]
- Application Areas: For use on floors, walls and hard, non-porous surfaces [in clean rooms and controlled areas]
- For use on floors, walls and hard, non-porous surfaces
- Broad Spectrum Activity
- Broad Spectrum Activity, including sporicidal, bactericidal, sanitizing, fungicidal and Virucidal* activity
- Sporicidal Activity
- Bactericidal Activity
- Fungicidal Activity
- Virucidal Activity
- Sanitizing Activity

- [This] [product][Disinfectant] [Active Chlorine Disinfectant] [Active Chlorine Ready to Use solution] [Active Chlorine product] can be used as part of a rotation with other disinfectants

Manufacturing claims:

- Manufactured by a ISO 9001:2008, ISO 13485:2003 and European Medical Device Directive 93/42/EEC accredited company
- Certificates of analysis [and certificate of gamma irradiation] with every batch
- [This][concentrate][product][is][filtered with a 0.2 micron filter][to remove [particulates][particles] from end use product]
- [This] [concentrate][product] is manufactured in clean rooms for use in clean rooms.
- [This] [concentrate][is 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 SteriShield Delivery System and an adjustable trigger.
- SteriShield Delivery System [incorporated]
- 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 three months [after opening] [or] [after initial use] [so there is no need to discard unused product]
- 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 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 also wipe
- For optimum results, wipe the surface to physically remove any contaminants.

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

Apply directly onto non-porous surfaces using a clean room low particulate wipe or mop to ensure complete coverage. Allow contact time and then wipe dry.

Where residues must be totally eliminated, wipe down with alcohol or water of suitable quality. *Use disinfectants safely. Always read the label and product information before use.*

