



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 7, 2018

Bridget Middleton, M.S.  
Regulatory Specialist  
Ecolab Inc.  
1 Ecolab Place  
St. Paul, MN 55102

Subject: PRIA Label Amendment – Adding Efficacy Claims and Emerging Viral Pathogens Language  
Product Name: XHC-IA  
EPA Registration Number: 1677-249  
Application Date: January 16, 2018  
Decision Number: 537595

Dear Ms. Middleton:

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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is: small non-enveloped, large non-enveloped, enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Piconavirus and Canine Parvovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/16/2018

Any CSFs other than those listed above are superseded/no longer valid.

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 with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at [johnson.zeboraj@epa.gov](mailto:johnson.zeboraj@epa.gov).

Sincerely,



Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped Label

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

**XHC-IA**  
**[WFI Formula] [Water for Injection] [USP Water for Injection] [DI Water]**  
 [Gamma Irradiated]

ONE-STEP DISINFECTANT / HARD SURFACE DISINFECTANT / SANITIZER /  
 VIRUCIDE\*/VIRUCIDAL\*/ FUNGICIDE

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

**Active Ingredient:**

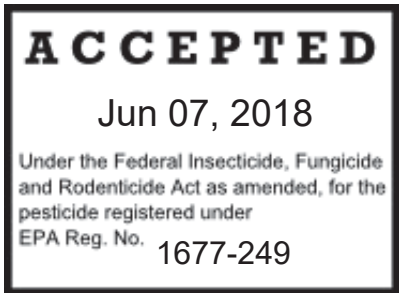
Isopropyl Alcohol\*\* ..... 62.7%

**Other Ingredient:**

Water ..... 37.3%

**Total:** ..... 100.0%

\*\*Isopropyl Alcohol 70% by volume



**KEEP OUT OF REACH OF CHILDREN**

**CAUTION  
Flammable**

Keep away from heat and open flame. Store at room temperature below 71.2°F (21.8°C).

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

**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.

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

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

### PHYSICAL AND CHEMICAL HAZARDS

**Flammable:** Keep away from heat and open flame. Do not mix this product with other chemicals such as acids, oxidizers, combustible materials, halogens, peroxides, bases and metal salts.

[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] [cleaner] disinfectant [virucide\*] [fungicide] [sanitizer] for use on hard, non-porous surfaces 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 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
Gloved Hands [for transfer disinfection]	(Biosafety Level) (BSL) hoods	Equipment
Gloves	Hoods	Laboratory benches
Laminar flow curtains	Products in non-porous packaging for transfer disinfection	Anywhere contamination control is required for hard, non-porous surfaces

\*\*\*\* 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	Zinc galvanized mild steel	Anodized aluminum
Polypropylene	PVC	Polyvinyl chloride
Polycarbonate	Cast acrylic	Extruded acrylic
Laminate		

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

### **[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 cleanrooms and controlled areas [tested in accordance with the AOAC Use Dilution test method] [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)  
*Staphylococcus epidermidis* (ATCC 12228)

**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 cleanrooms 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 [tested in accordance with the Virucidal Qualification test method] [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)

**FUNGICIDAL** in 10 minutes against *Trichophyton mentagrophytes* (ATCC 9533) on hard, non-porous surfaces [tested in accordance with the AOAC Fungicidal test method] [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 [tested in accordance with 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 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 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. 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.

US EPA Reg. No. 1677-249  
US EPA Est. No. 001677-GBR-001, 5389-NC-1 (G)  
Canadian DIN: 02447789

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

Net Contents:	473mL (16 fl oz)
	500mL (16.9 fl oz)
	946mL (32 fl oz)
	1L (33.8 fl oz)
	3.78L (1 US Gallon)
	4L (1.06 US gal)
	5L (1.32 US gal)
	208L (55 US Gallon)

(Made in Great Britain)  
(Made in USA) (Made in United States of America)

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

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



### Optional Claims (Marketing Claims)

- Ready to Use, hard surface disinfectant solution for use in cleanrooms and controlled areas containing 70% v/v Isopropyl Alcohol blended with Water for Injection
- Isopropyl Alcohol blended with WFI
- [Ready to use] [product] [hard, non-porous surface disinfectant solution]
- [This] [ready to use] [product] [hard, non-porous surface disinfectant solution] [is double bagged] [is triple bagged] [for easy transfer into cleanrooms]
- Triple bagged
- Double bagged
- [This] [ready to use] [product] [hard, non-porous surface disinfectant solution] is gamma irradiated
- [Gamma irradiated] [Sterile] [Validated  $10^{-6}$  SAL (Sterility Assurance Level)]
- [This] [ready to use] [product] [hard, non-porous surface disinfectant solution] is a blend of 70% v/v Isopropyl Alcohol with Water for Injection
- [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]
- Easy to use
- There is a choice of easy to use trigger sprays available in [500mL] [16 fl oz] [32 fl oz] [1L] containers [and capped ready to use available in 1 Gallon (3.78 L) and 5L (1.32 Gallon)]
- [This] [ready to use] [product] can be used to remove residues [in cleanrooms and controlled areas]
- [Application Area:] For use on floors, walls and hard, non-porous surfaces in cleanrooms and controlled areas.

#### Manufacturing claims:

- [This] [ready to use] [product] [is] [0.2 micron filtered] [to remove [particulates] [particles] from end use product]
- This product is 0.2 micron filtered
- Certificate of Analysis with reported Endotoxin levels (less than 0.25 EU/mL) is included with every batch
- Certificate of Analysis [Conformity] for irradiation is included with every batch
- Endotoxin tested to an approved pharmacopeia method
- Manufactured according to ISO [9001:2008] [9001:2015], ISO 13485:2016 standards

(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 six 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] [closed system]

- Bag in the bottle [Bag-in-the-bottle]
- Medical grade silicone composition
- Validated for use in all grades of cleanroom
- 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 disinfection procedures are effective].
- All the disinfectant solution can be dispensed from the bottle [so there is no waste]
- Cost effective [unused product] [does not need to be discarded after opening] [or] [after initial use]
- Always close the nozzle after use.
- SteriShield Delivery System

(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.



**Emerging Viral Pathogens**

This product qualifies for emerging viral pathogen claims per the EPA’s “Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels” when used in accordance with the appropriate use directions indicated below.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to long term care professionals, food safety professionals, environmental services professionals, health care facilities, physicians, nurses, pharmaceutical and cosmetic professionals, veterinarians and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). **These statements shall not appear on marketed (final print) product labels.** )

Statements shall adhere to the following format:

1. **In the case of an Emerging (Large Non-Enveloped) (Enveloped) virus:**

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus] (at) (add dilution rate) for a contact time of 5 mins on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Herpes Simplex Virus Type 1 (ATCC VR-733) Herpes Simplex Virus Type 2 (ATCC VR-734) Influenza A Virus H1N1 Rhinovirus Type 37 (ATCC VR-1147)
Large, non-enveloped virus	Rhinovirus Type 37 (ATCC VR-1147)