



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 18, 2022

Mandy Sunde
Sr. Regulatory Specialist
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

Subject: PRIA Label Amendment – Additional Pathogen and Use Sites
Product Name: XHC-IA
EPA Registration Number: 1677-249
Received Date: 08/16/2021
Action Case Number: 00317000

Dear Mandy Sunde:

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.

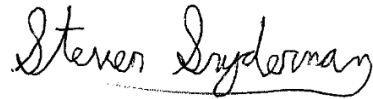
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Perri Moeller by phone at (202) 566-0813, or via email at moeller.perri@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Final Stamped Label

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

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

ONE-STEP DISINFECTANT / HARD, NON-POROUS SURFACE DISINFECTANT / FOOD
 CONTACT AND NON-FOOD CONTACT 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] [Dairy, Food & Beverage Processing Operations and Dairy Farms] [in] [Biofuel
 Operations] [Cereal Processors,] [Grain Processors,] [Milling Operations,] [Dry Food Ingredient
 Blending Operations,] [Dairies,] [Breweries,] [Wineries,] [Beverage Processing Plants,]
 [Produce Pack Houses,] [Protein,] [and] [Food Processing Plants]

Active Ingredient:

Isopropyl Alcohol**	62.7%
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Other Ingredient:

Water	<u>37.3%</u>
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Total:	100 .0%
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**Isopropyl Alcohol 70% by volume

KEEP OUT OF REACH OF CHILDREN

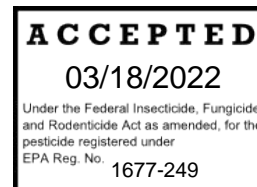
CAUTION
Flammable

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])

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 in English, ask your supervisor about the appropriate use instructions before
working with this product.



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 semicritical medical devices prior to sterilization or high level disinfection.

USE: This product is designed specifically as a [disinfectant] [cleaner] [virucide*] [fungicide] [sanitizer] for use on hard, non-porous surfaces. This product is designed specifically as a [one-

step] disinfectant 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
Cleanrooms	Controlled Areas	Pharmaceutical Manufacturing Facilities
Biotechnology 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		
Cereal Processors	Grain Processors	Milling Operations
Dry Food Ingredient Blending Operations	Dairies	Dairy Farms
Breweries	Wineries	Beverage Processing Plants
Protein	Food Processing Plants	Produce Pack Houses

Use on hard, non-porous [food] [or] [non-food contact] 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
Conveyors	Chairs	Benches
Troughs	Forklifts	Tires
Pallet Jacks	Pallets	Water dispensing units

Offices	Cafeteria	Breakrooms
Restrooms	Tools	Office spaces
Locker rooms	Coolers^	Freezers^
Extruders	Driers^	Hoppers
Ovens^	Mixers	Conveyors
Packaging Equipment	Pipelines	Tanks
Vats	Fillers	Evaporators^
Pasteurizers	Sorting equipment	Work boots
Proofers	Bakery equipment	Scale baggers

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

^allow surfaces to come to room temperature prior to treatment

[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

GENERAL CLEANING

This product is ready to use. Do not dilute. This product (insert name) is recommended for (daily) cleaning of washable hard non-porous (environmental) surfaces including surfaces where cleaning could be done.

Apply this product without dilution to clean surfaces. Apply (by) (pouring) (squirting) (or) with a cloth, disposable wipe, mop, or sprayer (device) (or) [with a circulation technique] wetting the surface. Allow to air dry. (No (water) rinse required). (A water rinse is not required).

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 visibly 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 visibly 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 visibly 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 visibly soiled areas, a pre-cleaning step is required. Apply solution to hard, non-porous [food contact,] [or] [non-food contact] surfaces [in cleanrooms and controlled areas] with a mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to visibly 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 visibly 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 [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)

VIRUCIDAL* in 1 minute against SARS-CoV-2 [(BEI Resources NR-52281) (Strain Isolate USA-WA 1/2020)] [modified in the presence of 5% blood serum].

FUNGICIDAL in 10 minutes against *Trichophyton interdigitale* (ATCC 9533) on hard, nonporous 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].

SANITIZING NON-FOOD CONTACT SURFACES

This product is ready to use. Do not dilute. This product is a hard surface sanitizer for precleaned, hard, non-porous, non-food contact surfaces in cleanrooms and controlled areas. [Visible soil must be removed prior to sanitizing (by) (pre-cleaning, pre-flushing, (and) (or) pre-scraping (the surface) (or when necessary, pre-soaking) (with) (this product) (insert product name).] Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking, so as to visibly 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 the required contact time indicated in the directions for use. Allow to air dry [or if desired wipe dry with a [sterilized] cloth or wiper].

When used as directed at a 10 second contact time, this product is effective against:

Staphylococcus aureus (ATCC 6538)

Klebsiella aerogenes (ATCC 13048)

When used as directed at a 3 minute contact time, this product is effective against:

Klebsiella pneumoniae (ATCC 4352)

FOOTWEAR SANITIZER:

This product is recommended as a sanitizer for use on outside surfaces of [waterproof] footwear [such as] [boots] (and) [work boots]. This product may be used to preclean this surface.

Remove visible soils from [waterproof] footwear before sanitizing. Apply this product without dilution by spray to ensure exposure to sanitizer for at least 10 seconds, allow surface to remain visibly wet for required contact time. Allow surfaces to air dry. Do not rinse.

SANITIZING HARD, NON-POROUS FOOD CONTACT SURFACES:

This product is ready to use. Do not dilute. Visible soil must be removed prior to sanitizing by [chose one (pre-cleaning), (pre-flushing), (and) (or) (pre-scraping) (the surface) (or when necessary, pre-soaking)] (with) (this product) (insert product name).

Apply this product without dilution to clean surfaces. Apply product to the surface (by) (immersion), (pouring), coarse spray, (or) [with a circulation technique] with a (disposable) cloth, wipe. Allow the surface to remain visibly wet for (60 seconds) (1 minute). Allow to air dry. No (water) rinse required). (A water rinse is not required). When used as directed at a 1 minute contact time, this product is effective against:

Escherichia coli [(ATCC 11229)]

Staphylococcus aureus [(ATCC 6538)]

Cronobacter sakazakii [(ATCC 12868)]

Escherichia coli O157:H7 [(ATCC 35150)]

Escherichia coli O103:H11 (STEC) [(USDA 04-39730)]

Escherichia coli O111:NM (STEC) [(ATCC 00-4748)]
Escherichia coli O121:H19 (STEC) [(ATCC 03-2832)]
Escherichia coli O145:H18 (STEC) [(USDA 07865 Feng)]
Escherichia coli O26:H11 (STEC) [(USDA 05-6544)]
Escherichia coli O45:H2 (STEC) [(USDA 96-3285)]
Listeria monocytogenes [(ATCC 49594)]
Pseudomonas aeruginosa [(ATCC 15442)]
Salmonella enterica [(ATCC 10708)]
Salmonella typhimurium [(ATCC 13311)]
Vibrio cholerae [(ATCC 25873)]
Shigella sonnei [(ATCC 11060)]
Campylobacter jejuni [(ATCC 33291)]

SANITIZING NON-POROUS GLOVES AND WATERPROOF GLOVES:

This product is recommended as a sanitizer for use on non-porous and waterproof gloves [such as] [plastic gloves,] [rubber gloves,] [latex gloves,] [vinyl gloves,] [and] [polypropylene gloves]. Visible soil must be removed prior to sanitizing by [Chose one (pre-cleaning), (pre-flushing), (and) (or) (pre-scraping) (the surface) (or when necessary, pre-soaking)] (with) (this product) (insert product name).

Apply this product without dilution to clean and sanitize gloves. Apply by [spray,] [wipe,] [or] [total immersion] to ensure exposure to gloves for at least 60 seconds (1 minute). Allow surfaces to air dry. Do not rinse.

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. Offer recycling if available.

[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.

US EPA Reg. No. 1677-249

US EPA Est. No. 001677-GBR-001, 5389-NC-1 (G), 72806-OK-1

Canadian DIN: 02447789

Manufactured by:

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102

(Made in Great Britain)

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

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)
	18.9L (5 US gal)
	208L (55 US gal)

[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

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Optional Claims (Marketing Claims)

Claims (for cleaning):

- New (and –or- Improved) (!) **to be used for first 6 months only**
- New (and –or- Improved) Formula (!) **to be used for first 6 months only**
- (This product) (insert product name) is for (daily) cleaning of hard, non-porous (environmental) (food contact) (non-food contact) surfaces
- (Daily-Use) (Multi-Purpose) (Multi-Use) (Cleaner)
- (Fragrance Free) (Dye Free)
- (This product) (insert product name) (Removes) (Cleans) (Cuts through) (oily) (burnt-on) (dry) (soils) (and) (food) (products) (in food processing areas)
- (Quick) (Fast) drying
- Evaporates quickly (to help protect water-sensitive equipment)
- For use in dry cleaning (facilities) (manufacturing) (production)
- (Improve) (Improved) (Improves) (Increases) (Increased) operational efficiency
- (Convenient) Cleaner For (daily) (everyday) use, (light duty) (or) (hard duty)

Claims (sanitizing, disinfecting, virucidal*, antimicrobial):

- Ready-to-use, no-rinse sanitizer
- No mixing or measuring required
- Ideal for sanitizing (dry) (water limited) (food) (processing) (areas) (environments)
- Ideal for sanitizing (cooler) (low) (temperature) (processing) (areas) (environments), sanitization should be done at room temperature only.
- (This product) (insert product name) is for sanitizing of (hard, non-porous) (environmental) (food contact) (non-food contact) surfaces
- Ideal for sanitizing (water) (sensitive) (electronic) (processing) (areas) (equipment) (environments)
- (No-rinse) (Sanitizes) (Food) (Non-food) (hard, non-porous) (contact) (surface) (sanitizer)
- (No-rinse) (Disinfects) (Food) (Non-food) (hard, non-porous) (contact) (surface) (sanitizer)
- Recommended for use as a sanitizer on hard, nonporous non-food contact surfaces such as (select locations, sites, and surfaces from Table 1, 2, or Table 3)
- Can be used to sanitize non-porous and waterproof gloves and outside surfaces of footwear
- Effective against (list any pathogens from Food Contact Surface Sanitizing list, the Non-Food Contact Surface Sanitizing list, or the Hard Surface Disinfection list) when used according to disinfection directions for use
- Kills 99.9% of (select from organisms in Non-Food Contact Sanitizing table) (on) (select from Use Sites list or Use Surfaces list) (in (select from Use Locations list)) on Non-Food contact Surfaces (in 10 seconds)
- Kills 99.999% of (select from organisms in Food Contact Sanitizing table) (on) (select from Use Sites list or Use Surfaces list) in (select from Use Locations list) on Food Contact Surfaces (in) (60 seconds) (1 minute)
- Kills 99.999% of (select from organisms in Food Contact Sanitizing table) that cause food borne illnesses. Please refer to food borne organisms list
- Use to (clean) (and) sanitize ((select from sites and surfaces in Table 2 or Table 3)) (in) (select from use locations in Table 1)
- Use to (clean) (and) sanitize ((select from sites and surfaces in Table 2 or Table 3)) (in) (select from use locations in Table 1)
- Use to (clean) (and) disinfect ((select from sites and surfaces in Table 2 or Table 3)) (in) (select from use locations in Table 1)
- Cleans (and) sanitizes ((select from sites and surfaces in Table 2 or Table 3)) (in) (select from use locations in Table 1)
- Cleans (and) disinfects ((select from sites and surfaces in Table 2 or Table 3)) (in) (select from use locations in Table 1)
- For use as a (cleaner) (and) sanitizer (on hard, non-porous surfaces) when used according to sanitization directions.
- For use as a (cleaner) (and) disinfectant (on hard, non-porous surfaces) when used according to disinfectant directions.
- (Antimicrobial) (Germicide) (Germicidal) (Bactericide) (Bactericidal) (Virucide*) (Virucidal*) (action)

- (This product) (insert product name) (is effective against) kills SARS-CoV-2, the virus that causes COVID-19, on (Food Contact Surfaces) (and) (Non-Food Contact Surfaces) hard, non-porous surfaces (in) (2 minutes) (on) (select locations, sites, and surfaces from Table 1, 2 or Table 3)
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus when used according to virucide directions for use on hard, non-porous surfaces
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus, the cause of COVID-19 when used according to virucide directions for use on hard, non-porous surfaces
- Kills [Eliminates] 99.9% SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19][the virus that causes COVID-19] when used according to virucide directions for use on hard, non-porous surfaces
- Effective against SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in [2] minutes] on hard, non-porous surfaces
- Disinfects surfaces by killing [99.9%] SARS-Related Coronavirus 2 [SARS-CoV- 2] [USAWA1/2020] [in One Step] when used according to virucide directions for use on hard, nonporous surfaces
- Kills [99.9% of] SARS-CoV-2, which causes COVID-19 when used according to virucide directions for use on hard, non-porous surfaces
- [Kills] [Effective against] the virus* that causes COVID-19 (*SARS-CoV-2) on hard, non-porous surfaces

Claims (general)

- (This product) (Product name) (saves) (money) (labor) (is cost efficient) (reduces operations costs) (is time efficient)
- The non-corrosive formula enables its use on hard, non-porous, food contact surfaces as a (sanitizer)
- The non-corrosive formula enables its use on hard, non-porous, food contact surfaces as a (disinfectant)
- One (product) dilution does many (things) (jobs)
- For (daily) (everyday) use
- Regular, effective cleaning and sanitizing of (equipment) (processing units) (environment) minimizes the potential for (cross-contamination) (contaminating) (lots) (food) (during food processing) between treated surfaces
- Application of effective sanitizing procedures reduces organisms which may be present on (equipment) (and) after cleaning.

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 when used according to disinfection or sanitization directions
- 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]
- 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 – wipe after contact time.
- Preclean 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)