

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 17, 2020

Juli Mann Regulatory Analyst Steptoe and Johnson, Authorized Agent to ETI H2O 1330 Connecticut Ave., NW Washington, D.C. 20036

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: SDC3A

EPA Registration Number: 72977-5 Application Date: March 11, 2020

Decision Number: 560972

Dear Ms. Mann:

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, 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),
 - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (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)
 - 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).

- 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.

Page 3 of 3 EPA Reg. No. 72977-5 Decision No. 560972

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus and Norovirus 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.

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, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

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

Enclosure: stamped label

SDC3A

[Disinfectant], [Fungicide] [& Virucide*][& Food Contact Surface Sanitizerl

[Disinfects and Deodorizes] • [Food Contact Surface Sanitizer] • [Sanitizer for Food Contact Surfaces] • [Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices] •

[Trucks] • [Trailers] • [Shipping Containers] • [Rail Cars] • [Sanitizer for food [and

beverage] processing equipment [facilities]]

Active Ingredient

Silver[†] 0.003% Citric Acid 4.846% Other Ingredients 95.151% Total 100.000%

ACCEPTED

06/17/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

72977-5

KEEP OUT OF REACH OF CHILDREN

Manufactured by ETI H2O A Division of PURE Bioscience 771 Jamacha Rd.#512 El Cajon, CA 92019 EPA REG. No. 72977-5 EPA EST. No. 72977-CA-001 Net Vol. [Batch Number - may appear on container]

[†] Electrolytically generated silver ions stabilized in citric acid as silver dihydrogen citrate

DIRECTIONS FOR USE

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

[SDC3A] [this product] is a colorless, odorless, broad spectrum antimicrobial [sanitizer], disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, [SDC3A] [this product] should be used on non-porous environmental hard surfaces in Choose from the lists below

Note: Non food contact sites

Homes [households] ambulances offices patient transfer vehicles hospitals hotels nursing homes restaurants medical clinics hars

dental clinics supermarket[grocery store] infirmary schools

blood bank[s] colleges

pharmacies dorm rooms [dormitories] laboratories churches funeral homes shelters

veterinary clinics military [installations] animal shelters [locations] day care facilities kennels daycare centers cages stables nurseries catteries playrooms

animal transport vehicles playgrounds recreational facilities laundromats prisons [jails] airports kitchens[public] restrooms school buses bathrooms cars [autos]

washrooms RV [mobile home] laundry rooms trucks bedrooms trailers

basements shipping containers

garage(s) rail cars workshops subways attics trains locker rooms airplanes exercise facilities ships gyms [gymnasium] cruise ships beauty shops or salons) busses

other public transportation barber shops spas

vehicles

smokehouses

Note:Food Contact sites

beverage plants delis food processing plants liquor [convenience] stores [facilities] eating establishments food storage areas supermarkets [grocery food [beverage] prep areas stores] institutional kitchens snack bars cafeterias dining rooms **lunchrooms** bars

fast food operations break rooms coffee [donut] [bagel]shops dairy farms [facilities]

egg processing plants meat [poultry] [fish]processing plants meat [poultry] [fish]producing establishments rendering plants [milk] [fruit] [vegetable] [wine] [ice cream] [potato] processing facilities

health clubs

[Food service] [hospitality] Cruise ship food processing [preparation] areas Dining halls

[SDC3A] [this product] has been formulated to treat hard, non-porous environmental surfaces ([painted], [glazed tile], [plastic], [nonporous vinyl], [naugahyde], [polyurethane], [plasticized PVC], [butyl rubber (EPDM)], [neoprene], [Viton®], [Teflon®], [silicone] [metal], [glass], [glazed porcelain], [acrylic], [sealed fiberglass], [sealed granite], [sealed marble], [Formica®], [linoleum]) and objects including Choose from the lists below

pacifiers

NOTE: Non-food contact surfaces

walls appliances floors stove tops counters bed frames cabinets [cabinet handles] wheelchairs over-bed tables sinks tubs examination tables exterior toilet [urinal] waste containers surfaces tables faucet handles chairs showers patio furniture doorknobs equipment tables handrails lab benches light switch covers [AC] [heating] vents telephones children's toys remote controls toys

toy boxes play tables jungle gyms playhouses baby furniture child car seats, hard surfaces only booster chairs [seats] strollers [stroller handles] cribs playpens activity centers diaper pails diaper changing tables

bathroom counters kitchen counters grocery carts desks computer keyboards tanning beds cat litter boxes animal cages [carriers] pet bowls [dishes] animal feeding dishes non-porous athletic mats

potty[training] seats

laundry hampers

NOTE: Food Contact Surfaces

counters [countertops]
dish racks
drainboards
highchairs [trays]
breast pump [parts]
lunch boxes[pails]
picnic tables
drinking fountains
kitchen surfaces
food processing equipment

food processing equipmer bottling equipment pre-mixing equipment blenders [food] processors

beverage bars [equipment] buffet counters salad bars snack counters cutting boards

plastic and other nonporous chopping blocks coolers

ice[machines] chests ice cream machines [equipment] yogurt machines

[equipment]refrigerator bins used for meat, vegetables, fruit and eggs

[refrigerated] food display equipment

food cases dairy cases food contact surfaces food travs

stovetops blenders meat cutting machines

bread slicing machines mixing equipment [mixers] kitchen appliances [meat], [fish], [poultry]

washers blanchers dicers slicers grinders shredders stuffers scalders pickers shackles saws trolleys hooks tables hoists sorters scales cones deboners separators carts
racks
chiller tanks
conveyor systems
labeling machines
packaging equipment
canning equipment

descalers
skinning equipment
filleting machines
homogenizers
evaporators
dryers
clarifiers
storage tanks

cheese making equipment processing vessels

pumps pasteurizers

filling line equipment

Tanks Kettles

filling, seaming, sealing and capping equipment

pulpers juicers millers grinders ovens extractors blanchers refrigerators freezers microwaves toasters

cooking equipment

ovens ranges grills fryers choppers crispers cutters shelving bins cabinets sinks basins faucets

bakery equipment coffee and tea equipment

steam tables

warming equipment concession equipment [processing] vacuums [processing] hand [power]

tools

General Information

[SDC3A] [this product] successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):

Organism	Kill Time
‡Pseudomonas aeruginosa	30 seconds
‡ Salmonella enterica	30 seconds
‡ Staphylococcus aureus	2 minutes
‡Listeria monocytogenes	2 minutes
Vancomycin resistant Enterococcus faecium (VRE)	2 minutes
Methicillin resistant Staphylococcus aureus (MRSA)	2 minutes
Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA)	2 minutes
Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-PVL)	2 minutes
Escherichia coli O157:H7	2 minutes
Acinetobacter baumannii	2 minutes
Campylobacter jejuni	2 minutes
Carbapenem resistant Escherichia coli	2 minutes
Carbapenem resistant Klebsiella pneumoniae	2 minutes
Carbapenem resistant Klebsiella pneumonia, NDM-1 +	2 minutes
Trichophyton mentagrophytes (Athlete's Foot Fungus)	5 minutes
[‡]*HIV type 1[Strain HTLV IIIB]	30 seconds
[‡]*Rotavirus	30 seconds
[‡]*Human Coronavirus	30 seconds
[‡]*Influenza A (H1N1)	30 seconds
[‡]*Swine Influenza A (H1N1)	30 seconds
[‡]*Respiratory Syncytial Virus [RSV]	30 seconds
[‡]*Adenovirus Type 2	30 seconds
[‡]*Avian Influenza A	30 seconds
[‡]*Influenza A [VR-544, Hong Kong strain]	30 seconds
Hepatitis B Virus (HBV) [as Duck Hepatitis B Virus]	1 minute [60 seconds]
Hepatitis C Virus (HCV) [as Bovine Diarrhea Virus]	1 minute [60 seconds]
*Murine Norovirus [MNV-1]	1 minute [60 seconds]
* Norovirus [as Feline Calicivirus]	1 minute [60 seconds]
*Herpes Simplex Type 1 [VR-733 F(1) Strain]	1 minute [60 seconds]
*Rhinovirus [R37 VR-1147, Strain 151-1]	1 minute [60 seconds]
*Polio Type 2 [VR-1002, Lansing Strain]	1 minute [60 seconds]

[Fungicidal Activity: [SDC3A] [this product] is effective against *Trichophyton mentagrophytes*, the Athlete's foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

[Deodorizes: When used as directed, [SDC3A] [this product] reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.]

[**SANITIZATION: SDC3A is a food contact surface sanitizer proven to kill 99.999% of the following bacteria in 60 seconds:

Escherichia coli Staphylococcus aureus

See application instructions for proper use.]

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product. [You may use this product for pre-cleaning.]

[General Cleaning: Apply to surface until thoroughly wet then wipe the surface clean.]

General Disinfection:

For general disinfection and control of the bacteria *Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica, Listeria monocytogenes,* Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA-PVL), *Escherichia coli* O157:H7, *Acinetobacter baumannii, Campylobacter jejuni*, Carbapenem resistant *Escherichia coli*, Carbapenem resistant *Klebsiella pneumonia*, and Carbapenem resistant *Klebsiella pneumoniae* (NDM-1 [positive] [+]) the surface must be completely wet with [SDC3A] [this product] for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, [SDC3A] [this product] provides residual protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and

Salmonella enterica up to 24 hours after initial application. Do not [touch] [contact] treated surface after application if residual protection is to be maintained.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill bacteria, [apply] [spray] [mist] [SDC 3A] [this product] to the surface until thoroughly wet for 2 minutes. The surface may then be wiped dry with a clean towel. When used as directed, [SDC3A] [this product] provides residual protection from *Pseudomonas aeruginosa, Staphylococcus aureus* and *Salmonella enterica* up to 24 hours after initial application. Do not [touch] [contact] treated surface after application if residual protection is to be maintained.

Fungus Control:

For effective control of the fungus *Trichophyton mentagrophytes*, the surface must be completely wet with [SDC3A] [this product] for 5 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill fungus, [apply] [spray] [mist] [SDC3A] [this product] to the surface until thoroughly wet for 5 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

*Viral Control:

To kill Herpes Simplex Type 1 [F(1) Strain], Rotavirus, Human Coronavirus, Influenza A (H1N1), Swine Influenza A (H1N1), Adenovirus Type 2, Respiratory Syncytial Virus [RSV], Murine Norovirus [MNV-1], Norovirus [as Feline Calicivirus], Avian Influenza A, Influenza A Virus [Hong Kong strain], Rhinovirus [R37 Strain 151-1] and Polio Virus Type 2 [Lansing Strain] the surface must be completely wet with [SDC3A] [this product] for 1 minute. The surface may then be wiped dry with a clean towel

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill viruses, [apply] [spray] [mist] [SDC3A] [this product] to the surface until thoroughly wet for 1 minute. The surface may then be wiped dry with a clean towel.

Note to Reviewer: The following are optional phrases as outlined in the EPA's Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)

[Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. [SDC3A] [This product] is a broad-spectrum hard surface disinfectant that has been shown to be effective against [Influenza A Virus (H1N1)], [Influenza A Virus], [Avian Influenza A Virus] and [Swine Influenza A Virus (H1N1)] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]

[SDC3A] [[This product] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.]

Kills HIV-1, HBV and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV HBV or HCV): Instructions for Cleaning and Decontamination Against HIV, HBV and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: Personal Protection: When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks and eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. Contact Time: Apply [SDC3A] [this product] to area to be treated. Allow the surface to remain wet for 30 seconds to kill HIV-1. Use 1 minute for HBV and HCV. The surface may then be wiped dry with a clean towel. These contact times will not control all organisms listed on this label. Refer to application instructions for other organisms. Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Sanitization [of food contact surfaces]

Do not use this product on utensils, dishes or glassware.

NOTE TO REVIEWER: Products labeled only for consumer/residential/ non-food-processing area use will include the following directions for use:

[To] Sanitize Food Contact Surfaces

Spray, pour or spread [SDC3A] [this product] on surface until thoroughly wet. Let stand for 60 seconds [one minute] and wipe with a clean towel or allow to air dry. No rinsing is required.

** [SDC3A] [This product] kills 99.999% of Escherichia coli [E. coli] and Staphylococcus aureus.

NOTE TO REVIEWER: Products labeled for professional/commercial/industrial/food processing area use will include the following directions for use:

To sanitize food contact surfaces

NOTE: [Bracketed] text is optional wording. Bold/italicized test is information only and not part of the label. Page 5 of 13

O

To sanitize food processing equipment and other hard surfaces in food processing locations, dairies, restaurants and bars:

[Recommended] for sanitizing food processing equipment, dairy equipment, sink tops, countertops, refrigerated storage and display equipment, and other hard nonporous surfaces. Recommended for use in restaurants, dairies, food processing plants [establishments] [facilities] and bars.

[Clean, Rinse Sanitize]

Prior to application, remove gross food particles and soil by pre-flush or pre-scrape and when necessary, pre-soak. Thoroughly wash objects to be sanitized with a good detergent or cleaner followed by a potable water rinse prior to applying sanitizer. No potable water rinse is allowed after application as a sanitizer.

Apply [SDC3A] [this product] by spraying or by total immersion. Surfaces must remain wet for 60 seconds [1 minute].

If the [article] surface] cannot be washed and rinsed, clean thoroughly in an appropriate fashion prior to sanitizing.

**[SDC3A] [This product] is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds: Escherichia coli Staphylococcus aureus

-OR-

Prior to use in a federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected. A potable water rinse is not permitted following the use of this product as a sanitizer on previously cleaned hard, non-porous surfaces, provided that the surfaces are adequately drained before contact with food so that little or no residue remains.

Apply [SDC3A] [product] to pre-cleaned hard surfaces by thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Surfaces should remain wet for 1 minute followed by adequate draining and air drying.

**[SDC3A] [This product] is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds: Escherichia coli (ATCC 11229) Staphylococcus aureus

[DIRECTIONS FOR SANITZING FOOD PROCESSING EQUIPMENT AND FOOD CONTACT ARTICLES REGULATED BY 21CFR Sec. 178.1010: b(22), c(17)

- 1. Scrape flush or presoak articles to remove gross food particles and soil.
- 2. Thoroughly wash articles in an appropriate detergent or cleaner.
- 3. Rinse articles thoroughly with potable water.
- 4. Sanitize articles by immersion in **[SDC3A]** [this product] for 60 seconds. Articles too large for immersion should be thoroughly wetted with **[SDC3A]** [this product] by rinsing, spraying or swabbing.
- 5. Remove immersed items from solution to drain and air dry. Non-immersed items should also be allowed to air dry.] [U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS CLEANING AND SANITIZING: Equipment shall be thoroughly pre-flushed or pre-scraped and pre-soaked when necessary to remove gross food particles and soil.
- 1. Thoroughly wash equipment in a hot detergent solution. Rinse equipment thoroughly with potable water.
- Sanitize equipment by immersion for 60 seconds at a temperature of 75°.
- 3. For equipment that is too large to immerse, apply [SDC3A] [this product] by rinsing, spraying or swabbing until thoroughly wetted.
- 4. Allow sanitized surfaces to drain and air dry. No potable water rinse is allowed.]

[BEVERAGE DISPENSING EQUIPMENT SANITIZER DIRECTIONS

For sanitizing of bottling or pre-mixed dispensing equipment after cleaning thoroughly rinse equipment with a potable water rinse. Fill equipment with [SDC3A] [this product] and allow to remain in the equipment for at least 60 seconds. Sanitizing solution should be drained from the system. To insure the removal of flavors, it is suggested that during changeover between products the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Drain thoroughly and allow to air dry before reuse. No potable water rinse is allowed.]

[FOR SANITIZING IN FISHERIES, MILK, WINE, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS: For use as a sanitizer on conveyor belts and equipment [to reduce or eliminate odors in the processing area]. Also for use on filling equipment to reduce bacteria. Follow directions for sanitizing food contact surfaces.]

[WISCONSIN STATE DIVISION OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

- Scrape and pre-wash articles whenever possible.
- 2. Wash with a good detergent or compatible cleaner.

- 3. Rinse with potable water
- 4. Sanitize in [SDC3A] [this product] without diluting. Immerse all articles for at least one minute or for contact time specified by governing sanitary code.
- 5. Place sanitized articles on a rack or drain board to air dry.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.]

NOTE: Optional refill instructions

To refill [spray bottles]:

- 1. [REMOVE] Remove trigger sprayer [or cap] from empty bottle
- 2. [POUR] Remove cap from refill and pour contents directly into empty [bottle].
- 3. [USE] Replace trigger sprayer and use as you normally would.

NOTE: The following language will be printed on the label of products intended to be sold to health facilities:

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.

NOTE: The following may only be used on the back or side panel of the label if a supplemental registrant obtains an NSF listing:



OR-

[NSF Listed]
[Include NSF Listing Number]

This statement will be used on NONREFILLABEL CONTAINERS.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing.

Pesticide Disposal: Nonrefillable Container. Do not reuse or refill this container –or- [Refill only with this product. Do not reuse or refill except as described in the directions for use.]. If empty: Place in trash or offer for recycling if available. Rinse thoroughly before discarding in trash or recycling.

This statement will be used on REFILLABLE CONTAINERS (typically 55 gallons or larger).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

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 the 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.

Container Handling: Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container before final disposal, empty the remaining contents from this container into a mix tank or storage tank. Fill the container about 1/4 full with solvent used in the end use product. Replace and tighten closures. Agitate vigorously or recirculate water with a pump for 2 minutes. Pour or pump rinsate into mix tank or rinsate collection system for later use or disposal. Repeat this rinsing procedure two more times

IN CASE OF EMERGENCY

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact [CHEMTREC 1-800-424-9300] or [the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 9 a.m. to 5 p.m] for emergency medical treatment information.

Optional marketing phrases

[Kills] [Eliminates] [Effective against] [Defends against] Choose one or more from the list below:

Salmonella enterica [in 30 seconds[‡]]

Pseudomonas aeruginosa [in 30 seconds[‡]]

Staphylococcus aureus

Listeria monocytogenes

Acinetobacter baumannii [in 2 minutes]

Campylobacter jejuni [in 2 minutes]

MRSA or [Methicillin Resistant Staph] or [Methicillin Resistant Staphylococcus aureus]

CA-MRSA or [Community Associated MRSA] or [Community Associated Methicillin Resistant Staphylococcus aureus]

CA-MRSA-PVL

VRE or [Vanocomycin-resistant Enterococcus] or [Vancomycin resistant Enterococcus faecium]

Escherichia coli O157:H7 [E. coli]

Carbapenem resistant Escherichia coli [in 2 minutes]

Carbapenem resistant Klebsiella pneumoniae [in 2 minutes]

Carbapenem resistant Klebsiella pneumoniae [(NDM-1 [+] [positive])] [in 2 minutes]

Tricophyton mentagrophytes

HIV [in 30 seconds[‡]]

Herpes Simplex Virus [in 1 minute]

Influenza A Virus [in 30 seconds[‡]]

Rhinovirus [in 1 minute]

Polio Virus Type 1 [in 1 minute]

Rotavirus [in 30 seconds[‡]]

Human Coronavirus [in 30 seconds[‡]]

Norovirus [as Feline Calicivirus] [in 1 minute]

Avian Influenza A on pre-cleaned environmental hard surfaces [in 30 seconds[‡]]

Respiratory Syncytial Virus [RSV] [in 30 seconds[‡]]

Adenovirus [type 2] [in 30 seconds[‡]]

Influenza A (H1N1) [in 30 seconds[‡]]

Swine Influenza A (H1N1) [in 30 seconds[‡]]

Murine Norovirus [in 1 minute]

Hepatitis B Virus [HBV] [in 1 minute]

Hepatitis C Virus [HCV] [in 1 minute]

Kills germs in 30 seconds[‡]

Kills common household germs

Kills germs [on surfaces you touch most]

Kills common household germs including [Salmonella enteric], [Staphylococcus aureus], [Listeria monocytogenes], and [E. coli].

Kills [Salmonella], [Staphylococcus], [Listeria], and [E. coli].

Kills - Bacteria, Fungus and Virus*

Disinfects [Defends against] common household surfaces

Kills [Defends against] [common] [cold] and [flu] virus[s]

Defends against germs that can make you sick

Disinfectant, Fungicidal & Virucidal* Spray

Can help reduce the risk [danger] of cross contamination

[Effective against] [Kills] multiple drug resistant bacterium

Fast acting disinfectant

Designed for practical use

Designed to save you time

Inspired by how you want [need] to disinfect

Invented to disinfect the way you want [need]

Your time is important so our kill times are fast

Meets EPA requirements for Toxicity Category IV

[Patented] Silver [Ion] Formula

No dulling residue

[Compatible with] [Safe for use on] [most] hard non-porous surfaces

Disinfects without bleaching

No harsh chemical smell

Odorless

Fragrance free

Contains no [dyes] or [artificial fragrances]

Contains [no] [non] VOC emitting ingredients

Ammonia free [formula]

Bleach free [formula]

Alcohol free [formula]

Phenol free [formula]

Contains no phosphates

Does not contain [chlorine] bleach [or] [ammonia] [alcohol] [phenols]

[This product] contains no [chlorine] bleach [alcohol] [phosphates] [or ammonia]

Colorless

Ready-to-Use [Formula]

No mixing required

Eliminates odors caused by bacteria

Disinfects household surfaces

No Mixing Required

Powered by [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]

For daily use

Refill

[Worldwide] Patented formula

[U.S. Patent(s) 6,197,814; 6,583,176, 7,261,905, [additional patent numbers as issued]

Other patents pending

Use for a [fresh] [home] [environment] [kitchen]

Commercial [Line] [Disinfectant]

Industrial [Line] [Disinfectant]

Hospital [Line] [Disinfectant]

Consumer [Line] [Disinfectant]

Retail [Line] [Disinfectant]

Freight [Line] [Disinfectant]

Janitorial [Line]

Janitorial Disinfectant

Cruise Line Disinfectant

[FAST], [EASY], [EFFECTIVE]

[Antimicrobial] [antibacterial] disinfectant

Leaves surfaces disinfected

For use on high touch surfaces

Travel size

For use in (insert use site from label)

For use on (insert use surface from label)

[Ideal for] [Formulated for] [Hospitality Environment(s)] [Institutional] [Childcare Environment(s)] [Medical Environment(s)] [Nursing Environment(s)] [Healthcare Environment(s)] [Athletic Environment(s)] [Educational Environment(s)]

A New Generation of Protection

A New Generation Disinfectant

As seen on TV may include graphic



Made in the USA [may include graphic of American flag]

[SDC3A] [This product] has demonstrated effectiveness against Influenza A Virus [Avian Influenza A Virus] [Swine Influenza A Virus] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.

The following phrases can also be used for products labeled as a food contact sanitizer

No Rinsing required

No Rinse Formula

No Rinse sanitizer

Sanitize without rinsing

For daily [use] [sanitization]

Sanitizes kitchen surfaces

Household sanitizer

Institutional sanitizer

Kills 99.999% of bacteria [in 60 seconds]**

Kills 99.999% of Escherichia coli (E. coli) [in 60 seconds]**

Kills 99.999% of Staphylococcus aureus [in 60 seconds]**

Kills 99.999% of bacteria that cause food borne illnesses [food poisoning] Effective sanitizer for food contact surfaces
For use in [insert one or more of the use sites listed on the label]
For use on [insert one or more of the use surfaces listed on the label]
For sanitizing [insert one or more of the food contact use surfaces]
No [measuring] [mixing] required
Effective sanitizer for food [and beverage] processing equipment [facilities]

KEY: *-Refer to viruses ‡-Refer to organisms controlled with 30 second kill time ** Refers to sanitizer claims

These or similar optional graphics may be used to demonstrate use sites (graphics are larger here than they will appear on the label)







THE FOLLOWING TABLE IS OPTIONAL TEXT:

Organism	ID
Pseudomonas aeruginosa	ATCC#15442
Staphylococcus aureus 1	ATCC#6538
Salmonella enterica ¹	ATCC#10708
Listeria monocytogenes ¹	ATCC#19111
Vancomycin resistant Enterococcus faecium (VRE)	ATCC#700221
Methicillin resistant Staphylococcus aureus (MRSA)	ATCC#700698
Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA)	NRS123, USA 400
Community Associated Methicillin resistant Staphylococcus aureus (CA-MRSA-PVL)	NRS 192
Escherichia coli O157:H7	ATCC#43888
Acinetobacter baumannii	ATCC#19606
Campylobacter jejuni	ATCC#29428
Carbapenem resistant Escherichia coli	BSLI#082710-EcCP1
Carbapenem resistant Klebsiella pneumoniae	BSLI#081710KPC4
Carbapenem resistant Klebsiella pneumoniae , NDM-1 +	ATCC#BAA-2146
Trichophyton mentagrophytes (Athlete's Foot Fungus)	ATCC#9533
*HIV type 1- Strain HTLV IIIB	HTLV-IIIB
*Herpes Simplex Type 1 VR-733 F(1) Strain	ATCC VR-733
*Rotavirus	Strain WA, Ottawa
*Human Coronavirus	ATCC VR-740
*Influenza A (H1N1)	ATCC VR-1469
*Swine Influenza A (H1N1)	ATCC VR-333
*Respiratory Syncytial Virus [RSV]	ATCC VR-26
*Adenovirus Type 2	ATCC VR-846
*Murine Norovirus	MNV-1.CW1
*Norovirus [as Feline Calicivirus]	ATCC VR-782
*Avian Influenza A	ATCC VR-2072
*Influenza A [VR-544, Hong Kong strain]	ATCC VR-544
*Rhinovirus [R37 VR-1147, Strain 151-1]	ATCC VR-1147
*Polio Type 2, [VR-1002, Lansing Strain]	ATCC VR-1002
Hepatitis B Virus (HBV) [as Duck Hepatitis B Virus]	Hepadnavirus Testing, Inc., Lot 7/31/07 pool
Hepatitis C Virus (HCV) [as Bovine Diarrhea Virus]	Strain Oregon C24v- genotype 1

Emerging Viral Pathogen Claims

[Product name] [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..

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category [ies]

Enveloped Viruses

Large, Nonenveloped viruses Small, Nonenveloped viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following
Print 3000 10 3021	organisms on the label:
Enveloped virus	Rhinovirus
95	Norovirus
Large, non-enveloped virus	Rhinovirus
	Norovirus
Small, non-enveloped virus	Rhinovirus
20	Norovirus

[Product name] [this product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, [product name] [this product] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, nonporous surfaces. Refer to the [CDC -or- OIE] website at [pathogen-specific website address] for additional information.

-or-

[Insert name of illness/outbreak] is caused by [insert name of emerging virus]. [Product name] [this product] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, nonporous surfaces. Refer to the [CDC -or-OIE] website at [pathogen-specific website address] for additional information.

{Note to Reviewer: These statements for claims against emerging viral pathogens shall not appear on marketed (final print) product labels.}