

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 27, 2020

Catherine Kickham Director of Strategic Development Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: Ready To Use Thymo-Cide

EPA Registration Number: 34810-25

Application Date: 03/15/2020 Decision Number: 561111

Dear Ms. Kickham:

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 are large non-enveloped and 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.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus [surrogate for 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 <a href="mailto:disinfectantslist@epa.gov">disinfectantslist@epa.gov</a>.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: stamped label

## [READY TO USE THYMO-CIDE]

<b>ACTI</b>	VF.	IN	IGF	2F	וח	FΝ	JΤ·

Thymol [†]	
	99.949%
TOTAL:	100.00%

[†][present as a component of [Thyme] oil[s]]
[†][Includes detergents, perfume and water]

# KEEP OUT OF REACH OF CHILDREN [CAUTION]

[See [left] [side] [right] [back] [bottom] panel for Precautionary Statements and First Aid]

## [PRECAUTIONARY STATEMENTS] [HAZARD TO HUMANS AND DOMESTIC ANIMALS]

**[CAUTION:** Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.]

## [FIRST AID]

[IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.]

Net Contents:
[Batch Code : for non-refillable containers]
EPA Reg. No. 34810- <b>25</b> EPA Est. No. [insert Est. No. here]
[Barcode] [DOT Symbols] [QR Code] [Country of origin (insert country)] [Manufactured/Made in (insert country)]
[SDS #: [insert SDS number here]] [Reorder #: [insert reorder number here]

Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122

## ACCEPTED

04/27/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 34810-25

## LIST OF ORGANISMS THAT MAY BE INCLUDED ON LABEL

[DACTEDICIDAL] [Dactoricidal [Activity]][ACAC Use Dilution	
[BACTERICIDAL] [Bactericidal [Activity]][ AOAC Use Dilution Confirmation][In the presence of 5 % blood serum,][at 20°C] [is	ATCC and/or Strain
effective against]	Arcc and/or strain
10 minutes	
Pseudomonas aeruginosa [Ps. Aeruginosa]	[ATCC 15442]
Staphylococcus aureus [S. aureus]	[ATCC 15442]
Salmonella enterica [S. enterica]	[ATCC 10708]
Methicillin resistant Staphylococcus aureus (MRSA)][**] [**Clinical Isolate]	[///66 10/00]
Methicillin resistant Staphylococcus epidermidis (MRSE)[**] [**Clinical Isolate]	
Tetracycline Novobiocin Streptomycin resistant Staphylococcus aureus [TNSR]	[ATCC 27659]
Gentamicin Methicillin resistant Staphylococcus aureus [GMR]	[ATCC 33592]
Penicillin resistant Staphylococcus aureus[PR]	[ATCC 11631]
Vancomycin Resistant Enterococcus faecalis [VRE]	[ATCC 51575]
[VIRUCIDAL*] [AOAC Use Dilution Confirmation][In the presence of 5 % blood serum,][at 20°C] [is effective against]  10 minutes	ATCC and/or Strain
Human Adenovirus 5	[Strain Adenoid 75] [ATCC VR-5]
Influenza A Virus [Pandemic 2009 H1N1 Influenza A Virus [formerly called swine flu]	[H1N1][Strain A/PR/8/34][ATCC VR-1469]
Influenza A3 Virus ]	[Strain Hong Kong][H3N2]
Feline calicivirus [surrogate for][Norovirus]	[Strain F-9][ATCC VR-782]
Herpes Simplex Virus Type 2	
Vaccinia Virus	
Human Rotavirus	
Respiratory Syncytial Virus	[ATCC VR 26]
Human immunodeficiency virus[HIV][Type 1][AIDS Virus]	
[in the presence of 10% serum] [at 20° C] [in <b>1 minute</b> .]	

<b>[FUNGICIDAL]</b> [In the presence of 5 % blood serum,] [is effective against]	ATCC and/or Strain
10 minutes	
Trichophyton interdigitale	[ATCC 9533]
[TUBERCULOCIDAL[**]][At 20°C / 68°F] [**]on previously cleaned hard non-porous inanimate surfaces.	ATCC and/or Strain
10 minutes	
[Mycobacterium bovis][Mycobacterium tuberculosis] [BCG] [Organon Teknika Corp.] [M. bovis] [TB]	
SANITIZING	
[FOOD CONTACT SANITIZER]	ATCC and/or Strain
60 seconds	
Staphylococcus aureus	[ATCC 6538]
Escherichia coli	[ATCC 11229]

## [ALLERGENS]

- [Spray][Wipes](s) away dirt [and] [and][allergens]
- This product removes the following allergens: [cat dander], [cockroach debris/matter/particles], [dog dander], [dust mite debris/matter/particles], [pet dander], [pollen particles] [from timothy grass], [grass].

#### OPTIONAL MARKETING CLAIMS

#### **DISINFECTION CLAIMS**

- [Cleans][Disinfects][Deodorizes][Germicidal]
- [Tuberculocidal][Fungicidal][Virucidal\*][Bactericidal]
- [Germicide] [Tuberculocide] [Fungicide] [Virucide\*][Bactericide]
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)
- Effective One-Step Germicidal Detergent
- [Antibacterial] kitchen cleaner
- [Antibacterial] bathroom cleaner
- [Antibacterial] household cleaner
- [Antibacterial] formula
- Disinfects while you clean
- Clean and disinfect in one step
- Disinfects & deodorizes
- Kills [99.9% of] (household) germs
- Kills [99.99] % of (household) germs§ §Staphylococcus aureus and/or Escherichia coli
- [Eliminates][Fights] [Effective Against] [Kills] 99.99 % of Bacteria<sup>§</sup> §Staphylococcus aureus and/or Escherichia coli
- Disinfecting Spray
- Disinfectant [formula][cleaner]
- Disinfectant Spray
- [Eliminates][Fights] [Effective Against] [Kills] 99.9 % of Bacteria
- [Eliminates][Fights] [Effective Against] [Kills] 99.9 % of Viruses\*
- Broad Spectrum [Hospital] [Disinfectant] [Germicide][Cleaner]
- [Eliminates][Kills] over 99.9% of bacteria & viruses\* [including flu virus\*]
- Broad spectrum germicidal
- [Kills] cold & flu
- [Kills] [cold] [&] [flu] viruses\*
- [Kill[s]] [Remove[s]] [Effective against] [the following] [organisms:]
  - o [include any organism listed under "Efficacy Claims"]
- One step [cleaning] [and] [disinfecting] [and] [deodorizing]
- [Disinfect -and/or- touch-up clean] [Cleans -and/or- disinfects -and/or- deodorizes] [In one easy step]
- Kills [over] [99.9] % of [household germs] [kitchen germs] [bathroom germs] [germs\*] [,] [botanically] [on hard, non[-]porous surfaces]
- Wipe away germs and allergens
- Wipe away germs and allergens\* \*even on toys
- One step disinfectant
- Helps reduce the risk of cross-contamination on treated surfaces
- Antibac Bathroom Spray
- Antibac MultiPurpose Spray
- Hospital Disinfectant
- [This product has demonstrated effectiveness against influenza A3 virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).]
- [This product] is a [germicidal detergent] [with broad spectrum kill of gram positive and gram
  negative microorganisms] formulated to clean, disinfect and deodorize in a simple one-step
  process[\*] [\*]when used according to disinfection directions. [It is an effective [one-step] cleaner
  [disinfectant] for working surfaces, including stainless steel, chrome, glass and vinyl]. [It
  effectively controls odors produced by odor causing bacteria and leaves a fresh citrus scent.]

[Passes AOAC Use Dilution Confirmation in the presence of 5% organic soil load at 20° C for 10 minutes.]

#### **SANITIZATION CLAIMS**

- Food contact sanitizer
- No rinse required when sanitizing food contact surfaces
- Food service surface sanitizer
- No rinse, food contact surface sanitizer and cleaner
- Formulated to sanitize food contact surfaces

#### **CLEANING AND DEODORIZING CLAIMS**

- Instrument PreSoak
- · Quick and easy cleaning
- Effectively controls odor
- [Eliminates] odor-causing bacteria
- [Eliminates] odor
- Multi-Purpose
- Multi-Purpose Cleaner
- Multi-Surface [formulation]
- Carpet Cleaner and Deodorizer
- Bathroom Cleaner
- Everyday Cleaner
- One Step
- Deodorizes
- Cleans
- Clean without a [harsh] [strong] chemical[s]
- Removes allergens

#### SURFACE COMPATIBILITY AND USAGE CLAIMS

- No haze
- [Virtually] [haze-free] [film-free] [residue-free shine [clean]
- [Low-haze] [Low-Residue] [Low-Film] [No-Film [Clear-Drying] [Formula] [Spray] clean[s] thoroughly
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- [This product or product name] will not harm most surfaces: including acrylic, sealed fiberglass and vinyl.
- Do not use on unpainted wood.
- Note: Do not use on unpainted wood or natural marble or brass.
- For plastic and painted surfaces, spot test on an inconspicuous area before use.
- Will not damage hard, non[-]porous surfaces
- Dries clear on mirrors and glass
- No streak
- Residue free
- Streak free
- Dries clear
- Leaves no residue

#### **INGREDIENT CLAIMS**

- Non-corrosive ingredients
- Bleach Free
- Botanical
- Botanical Cleaning
- Botanical surface cleaner with natural essential oil[s]
- Botanical ingredient[s]
- Botanically derived ingredient[s]
- Botanical active ingredient
- Botanically derived active ingredient
- [Botanically based] product]
- Plant-based
- Effective plant-powered formula
- Plant-based cleaning power
- Compostable, plant-based cleaning power
- Dye free [formula]
- Bleach[-]free
- Paraben[-]free
- · Free of glycol solvents
- Free of chlorine of formaldehyde
- Free of gluten
- Free of phosphate
- Free of formaldehyde
- Free from harsh chemicals
- [Contains no][No] [Does not contain] [bleach,] [added dyes,] [added colors,] [perfumes,] [(volatile organic compounds)], [ammonia], [phosphates], [phosphorus], [chlorine bleach], [dyes], [synthetic fragrances,] [volatile solvents,] [known or suspected endocrine disruptors,] [glycol ethers,][chlorinated compounds,] [or] [chlorine] [MIT][BIT]
- Does not contain [bleach] [ammonia] [chlorine]
- Does not contain [Triclosan] [Parabens]
- Made without Parabens and Phthalates
- [Free of][no] dye and/or perfumes
- Free of [glycol solvents] [chlorine of formaldehyde] [gluten] [phosphate]
- No harsh chemicals
- No artificial fragrance
- Powered by botanical actives [and essential oils]
- [made] [formulated][using] [with] essential oils
- Effective botanical [formula][spray]
- [Sanitizes] [disinfects] with [botanically-derived ingredients] [plant-powered ingredients]

### **MISCELLANEOUS CLAIMS**

- Non-Irritating
- Non-corrosive
- Inspired by nature
- No Rinse required [even on [children's] [toys]]
- Rinse free [formula]
- No Rinse
- No Rinse Formula
- Rinse Free Formula
- No Rinse Disinfectant

- Tough on [dirt] [germs]
- [Can be used] around kids and pets
- Good for use around cats and dogs
- Made in USA
- Proven effective on most hard surfaces
- No harsh fumes
- Powered by compressed air§ §non-aerosol
- Non-flammable
- Contains no CFCs which deplete the ozone layer
- No CFCs
- Safely store out of reach of children
- [Please rinse toys][Rinse toys with potable water]
- Store safely out of reach of children
- [Please rinse toys][Rinse toys with potable water]
- [Made from [x]% [recycled plastic] [post consumer resin]]
- No rinse or wipe required
- No mixing [required]
- No Warning Labels or First Aid Statements [required]

Asterisk (\*) used when referring to multiple viruses

### FRAGRANCE DESCRIPTORS

{Note to reviewer: each scent list in "Fragrance Descriptors" section may also be represented by a graphic depicting the corresponding scent, except when referring to a type of food, in this case the graphic will be submitted to the Agency for review.}

- [Herbal]
- [Citrus]
- [Scent]
- [Cranberry]
- [Rose]
- [Fresh]
- [Modern][Citrus][Lime]
- [Clean][Kitchen]
- [Lemon]
- [Citrus][Sparkle]
- [Fragrance free]
- [Unscented]
- [Essential Oil fragrance]
- [Clean]
- [Peppermint][Mint]

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. [Product is ready to use.] [DO NOT DILUTE.] [Gross filth and] Visible soil must be removed before applying cleaning solution.

[CLEANING AND DISINFECTING DIRECTIONS: Apply to hard, nonporous surfaces by [cloth], [sponge], [brush], [coarse spray] or [by immersing equipment using normal cleaning methods]. All hard surfaces must be wet thoroughly, and remain wet for at least 10 minutes and allowed to air dry. [Thoroughly rinse all wetted and cleaned food contact surfaces with potable water]. [As the solution becomes dirty discard and replace with fresh solution.] [This is a complete product.] [DO NOT MIX WITH OTHER CHEMICALS.]

or

## [TO [CLEAN]/[DEODORIZE]] [Cleaning Instructions]:

[Apply [this product] undiluted to hard, non-porous surfaces by spraying, wiping with a cloth or towel until clean.] [Spot check to test for compatibility]

[Apply to surfaces as needed.] [Spray] [apply to] surface and wipe clean]

[ODOR CONTROL: It effectively controls odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance.] [Follow "CLEANING AND DISINFECTING DIRECTIONS".]

**[TO SANITIZE:** Wet [the] [all] surface[s][with the product]. Let stand for [60 seconds][one minute] [on hard, non-porous, [food contact] surfaces]. [Wipe or let air dry.] [No rinsing or wiping is required], [even on food contact surfaces] ]

#### [TO DISINFECT] or [Disinfecting Instructions]:

[Apply the [this product] [product] [undiluted] to hard, non-porous surfaces with [a] [sprayer], [cloth], [mop] or [brush], or [by immersing equipment [item] to be disinfected].] Wet all surfaces thoroughly. The surface must remain visibly wet [with this product] [for at least] [Leave for] 10 minutes. [Wipe or let air dry.] [No rinsing or wiping is required.]

Or

Spray and wet hard, non-porous surface or item to be disinfected thoroughly. Leave for 10 minutes. Wipe or let air dry. No rinse required after using.

Or

Wet the hard, non-porous surface. Allow surface to remain visibly wet for 10 minutes. Allow to air dry. No rinsing or wiping is required.

Or

Use to disinfect hard, nonporous areas. Spray surface to be disinfected. Allow treated surface to remain visibly wet for 10 minutes.[No rinsing or wiping is required]

### Optional:

[FUNGICIDAL DIRECTION: This product is effective against Trichophyton interdigitale (athlete's foot fungus and a cause of ringworm) on inanimate surfaces [in locker rooms, dressing rooms, exercise facilities, and shower and bath areas]. [Follow disinfection directions.]

## TO CLEAN, DEODORIZE AND REMOVE DEBRIS FROM CARPETS AND FABRICS

**To Spot Clean:** Blot or scrub area to be treated with [*Brand name*] Disinfectant Solution to remove soiling. Wipe dry with clean cloth or towel.

**To Deep Clean Carpets, Upholstery and Fabrics:** Vacuum to remove loose dirt and soiling. Thoroughly moisten with product using coarse tip pressure sprayer and rake or brush into nap. Clean treated areas using clean water extraction method, such as portable or truck-mounted carpet cleaning machine or upholstery cleaning machine. Allow to dry thoroughly prior to using. Always spot test in inconspicuous area prior to application for compatibility.

## **Deodorizing and Cleaning of Carpet/Fabrics**

To Deodorize and Clean Carpets, Fabrics, and other Materials: [Product name] can be used on most fabrics that can be cleaned with water-based cleaners. [Not for use on wool, silk, or suede.] Always test for color fastness and material compatibility in an inconspicuous area prior to use. Apply by sprayer, to ensure even coverage [and allow for 10 minute contact time]. Do not rinse, use hot water extraction wand to remove product from treated surfaces and then dry stroke carpet to remove excess moisture. Carpet can be air dried or fans may be used if carpet needs to dry more quickly.

#### **USAGE CLAIMS**

[This product] is [suitable] [intended] [for] [use] [on] [in] all disinfection of hard, non-porous surfaces[([floors] [walls] [tables] [etc.])] in

[Ambulances]	[Kitchens]
[[Dental] and [Medical] Offices]	[Laboratories or other small animal facilities]
[Athletic facilities]	[Locker Rooms]
[Bathrooms]	[Medical Offices]
[by Police and EMS]	[Military installations]
[Cafeterias]	[Nurseries]
[Classrooms]	[Nursing homes]
[Coils and drain pans** of HVAC & R equipment]	[Operating Rooms]
[Day care centers]	[Oral Healthcare Facilities]
[Dental Labs]	[Oral Surgery Centers]
[Dental Operatories]	[Prisons]
[Dental Schools]	[Public areas]
[Emergency Areas]	[Public restrooms]
[Grocery Stores]	[Residential]
[Grooming Facilities]	[Restaurants]
[Gyms]	[Schools]
[Healthcare Facilities] [including]	
[Hospitals]	[Shopping Centers]
[Hotels and motels]	[Shower and bath areas]
[Institutional facilities]	[Spas]
[Institutional kitchens]	[Veterinary Clinics]
[Institutions]	[Zoos]
[Intensive Care]	
[Kennels]	
[as well as other areas/facilities concerned with reducing cr	oss contamination between treated surfaces]

<sup>\*\*</sup>Drain pans must be pre-cleaned and dry before applying this product and coils must be at room temperature

## [TYPES OF SURFACES/USE SITES:] [Graphic –depicting surface]

[Use for one-step cleaning, disinfecting and deodorizing of devices and surfaces potentially contaminated with microorganisms and other items made of]

[When used as directed, [this product] effectively cleans and disinfects hard, non-porous environmental surfaces such as]

[Ambulance patient care surfaces]	[Glazed tile]	[Plexiglas®]
[Anesthesia equipment surfaces]	[Handrailings]	[PPE (Personal Protective Equipment] ¶
[Appliances]	[Highchairs]	[Radiology equipment surfaces]
[Baby/infant care surfaces] ¶	[Immobilization devices	[Refrigerators (exterior surface)]
[Backboards]	[Infant care equipment] ¶	[Respirators] ¶
[Baked Enamel]	[Isolettes]	[Respiratory care equipment surfaces]
[Bathing units]	[Keyboards]	[rubber]
[Bathroom[s] [tubs] [tiles]]	[Kitchen appliances]	[Sealed Granite]
[Bed railings]	[Kitchen countertop[s]]	[Shopping carts]
[Beds] <sup>¶</sup>	[Kitchen surfaces]	[Shower floors/walls]
		-
[Blood pressure devices]¶	[Laboratory equipment/surfaces]	[Sinks]
[Cabinets]	[Light lens covers]	[Skin care equipment/surfaces] ¶
[Car Interiors]¶	[Lights]	[Smart [Phones] [Watches]]
[Chairs]	[Lumens]	[Smart Screens]
[Changing tables]	[Medical equipment surfaces/devices]	[Soaking containers]
[Children's toys] ¶	[Metal]	[Stainless Steel]
[Chrome]	[Mice/Mouse]	[Stalls]
[Computer surfaces]	[Microscopes]	[Surgical equipment surfaces] ¶
[Computers]	[Mirrors]	[Surgical microscopes]
[Counters]	[MRI equipment surfaces]	[Tables]
[Countertops]	[Neonatal/nursery surfaces] ¶	[Tablets]
[CPR manikins]	[Nonporous athletic mats][vinyl]	[Telephones]
[CT equipment/surfaces]	[Obstetrical equipment surfaces]	[Toilet Seats]
		[Toilets (rims, seats and exterior
[Curing lights]	[Operating room lights/tables]	surfaces)]
[Dental equipment surfaces/devices]	[Ophthalmic equipment surfaces/devices] ¶	[Toys]
[Desks]	[Optical wear (excluding contact lenses)]	[Training tables]
[Doorknobs]	[Oxygen hoods]	[Transportation equipment surfaces] ¶
[Exam tables]	[Patient bed surfaces] ¶	[Trash Cans]
[Exercise equipment]	[Patient stretchers] ¶	[Trays]
[Fixtures]	[Patient transport surfaces]	[Vinyl]
[Floors]	[Pet Habitats]	[Walls]
[Furniture]	[Physical therapy equipment]¶	[washable painted or varnished surfaces]
[Garbage cans]	[Plastic]	[Work stations]
[Glass]	[Play mats] <sup>¶</sup>	[Wrestling mats]¶
[Glazed porcelain]	[Play-care equipment] ¶	[X-ray equipment/surfaces]
[other areas/facilities concerned wit		
Louisi areastrasimies concerned wit	in the hazards of oloss containinatio	""]

<sup>¶</sup>indicate hard, nonporous

{Note to Reviewer: Emerging Viral Pathogen claims shall be made 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.}

### **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.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Feline Calicivirus [surrogate for Norovirus]
Large, non-enveloped virus	Feline Calicivirus [surrogate for Norovirus]

## Acceptable claim language:

[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(es) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] 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, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information."

Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4. Otherwise, the all language on this page is OPTIONAL.

**DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATION/HIGH LEVEL DISINFECTION:** 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

The following special instructions must be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household.

[This product] KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in all settings in which there is an expected likelihood of soiling of hard, non-porous 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 human immunodeficiency virus type 1 (HIV-1) (associated with AIDS virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1 (AIDS virus).

**PERSONAL PROTECTION:** Wear disposable rubber or latex gloves, gowns, face masks and eye coverings when performing manual cleaning of these surfaces.

**CONTACT TIME:** Leave surfaces wet for 1 minute. This contact time will not control other common types of viruses and bacteria.

CLEANING PROCEDURE: The solution may be used to remove and clean blood and other body fluids from surfaces and objects before disinfection. For lightly soiled areas wipe off visual soil/clean with solution, and disinfect surface with a second application of the solution. For large spills the contaminated area must be flooded with the solution before cleaning, then decontaminated with fresh solution. DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and disposed of according to Federal State and local regulations for infectious waste disposal.

## **Storage and Disposal:**

[Store airtight at room temperature. Nonrefillable container. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash.]

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

## [Pesticide Storage and Disposal]:

[Store at room temperature. Do not leave containers of this product open during storage. Store in original container in areas inaccessible to children and persons unfamiliar with its use.] [Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.]

## [Container Handling:]

*{For non-refillable container:}* Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if available.

*{For refillable container:}* 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, triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available.

Revised: 04/27/2020

### Optional graphics:







[Instagram]

[Facebook]

[Twitter]

can be displayed in black/white





## Only for use with:

[Concrobium Broad Spectrum Disinfectant II]

[Category Code: D1]

[NSF Registration No.][Listed][156456]

