



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 17, 2021

Cristina Griffin
Agent
Disinfexol LLC
c/o Delta Analytical Corp.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: PRIA Label Amendment – Adding Additional Organisms; Emerging Viral Pathogen Claims
Product Name: Disinfexol
EPA Registration Number: 95747-1
Received Date: December 17, 2020
Action Case Number: 00216849

Dear Ms. Griffin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

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 (large non-enveloped, enveloped).
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus type 37 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 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.

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 Wanda Henson by phone at (703) 308-6345, or via email at henson.wanda@epa.gov

Sincerely,



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

Enclosure

DISINFEXOL

Hospital HOCl Cleaner and Disinfectant

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACTIVE INGREDIENTS:

Hypochlorous Acid0.065%

OTHER INGREDIENTS99.935%

TOTAL INGREDIENTS100.000%

[Optional format:

ACTIVE INGREDIENTS:

Hypochlorous Acid0.065%

OTHER INGREDIENTS99.935%

(Reverse osmosis water)

TOTAL INGREDIENTS100.000%]

See back [side] panel for precautionary statements [and first aid]

EPA Reg. No.: 95747-1

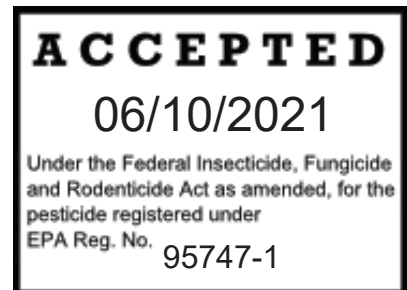
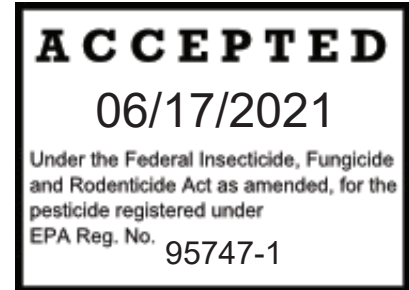
EPA Est. No.:

Manufactured by [or for]:

Disinfexol LLC

12017 Nebel Street Rockville, MD 20852

Net Contents: _____



FIRST AID: 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. You may also contact the National Pesticide Information Center (NPIC) 1-800-858-7378 for emergency medical treatment information. **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 eye.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Caution: Causes moderate eye irritation. Avoid contact with eyes. When handling this product, wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL OR CHEMICAL HAZARDS: Disinfexol is not compatible with other chemicals such as acids and hydrogen peroxide.

[List of approved organisms:]

[Reader's Note: ATCC numbers are required to be on the master label, but are not required to be listed on the marketplace label]

Bactericidal

- Pseudomonas aeruginosa [ATCC 15442]
- Staphylococcus aureus [ATCC 6358]

Fungicidal

- Trichophyton interdigitale [ATCC 9533] (the organism that causes athletes foot)

Virucidal

- Human Adenovirus Type 5 [ATCC VR-5, Strain Adenoid 75]
- Human Coronavirus [ATCC VR-740]
- Rhinovirus Type 37 [ATCC VR-1607, Strain 151-1]

[Optional Pesticidal Label Claims]

About: Disinfexol is a Hospital HOCl Cleaner and Disinfectant for hard, non-porous surfaces.

Kills the following organisms in 5 minutes *{may be listed without bullets}*:

- Human Adenovirus Type 5 [ATCC VR-5, Strain Adenoid 75]
- Human Coronavirus [ATCC VR-740]
- Pseudomonas aeruginosa [ATCC 15442]
- Staphylococcus aureus [ATCC 6358]

Kills the following organisms in 10 minutes *{may be listed without bullets}*:

- Rhinovirus Type 37 [ATCC VR-1607, Strain 151-1]
- Trichophyton interdigitale [ATCC 9533] (the organism that causes athletes foot)

Disinfects and cleans in one step+

Hospital HOCl Cleaner and Disinfectant

Kills bacteria Pseudomonas aeruginosa [ATCC 15442] and Staphylococcus aureus [ATCC 6358] on hard, non-porous surfaces in 5 minutes

Kills Human Coronavirus [ATCC VR-740] on hard, non-porous surfaces in 5 minutes

Kills Human Adenovirus Type 5 [ATCC VR-5, Strain Adenoid 75] on hard, non-porous surfaces in 5 minutes

Kills Human Rhinovirus Type 37 [ATCC VR-1607, Strain 151-1] on hard, non-porous surfaces in 10 minutes

Kills Viruses*

Kills 99.99% of Viruses*

Kills Germs**

One step cleaner [and][,] disinfectant [,][and] deodorizer+

One year shelf-life

[Text in brackets/italics is optional or instructional]

* 99.99% Rhinovirus, 99.99% Human Coronavirus, 99.99999% Adenovirus

***[In accordance with EPA guidance, for this product: The claim “germs” can be used without descriptors of the type of organism. No asterisk is required. The claim can appear on the front or back/side panel of a label. However, specific organisms must still be listed on the label.]*

+ when used in accordance with disinfection directions

[Optional Non-Pesticidal Claims]

Cleans

Deodorizes

Deodorizer

Fragrance free

No fragrances

No preservatives

Ready to Use

Ready-To-Use Product

Refill only with this product.

[These statements shall not appear on marketplace (final printed) labels:]

Emerging Viral Pathogens Claims

This product qualifies for emerging viral pathogen claims per 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 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 organism on the label:
Enveloped Virus	Rhinovirus type 37
Large Non-Enveloped Virus	Rhinovirus type 37

[Statements must adhere to one or both of the following formats:]

This product has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, nonporous surfaces. Therefore, **this product** can be used against **[name of emerging virus]** when used in accordance with the directions for use against Rhinovirus type 37 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]**. **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 Rhinovirus type 37 on hard non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

["This product" may be substituted for the product name]

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Where to use: Effective on hard, non-porous surfaces in Hospitals, Clinics, Healthcare Facilities, Schools, Government and Office Buildings. Avoid contact with painted and unfinished wood surfaces.

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For visibly soiled areas, a preliminary cleaning is required to remove all visible soil. Spray application: Hold nozzle 6-8 inches from surface. Spray until thoroughly wet. Treated surfaces must remain visibly wet for 10 minutes (5 minutes for Human Coronavirus, Adenovirus, Pseudomonas aeruginosa and Staphylococcus aureus). Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

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, 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 devices prior to sterilization or high-level disinfection.

STORAGE AND DISPOSAL

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

Storage: Store in a closed dark [or opaque] plastic container in a cool, dry area away from heat and direct sunlight. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before discarding container in trash.

Product Disposal: Product rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

[Choose the appropriate container handling instructions below. If both refillable and non-refillable handling instructions are shown on the marketplace label, the label must clearly indicate the specific container type used.]

[Institutional uses, non-refillable container 5 gallons or less]

Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Offer for recycling if available or place in trash.

[For Institutional uses, refillable container]

Container Handling: Refillable container. Refill this container with hypochlorous acid only. Do not re-use this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing the container. To clean the container before final disposal: Fill the empty container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for two minutes. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Offer for recycling if available or puncture and dispose of in a sanitary landfill.

[Optional graphics to be used anywhere on the label:]

Made in USA

Recycle icon

[Barcode]