



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 20, 2020

Sherri Gray
Authorized Representative of Envirocleanse LLC
Envirocleanse LLC
15616 Plain Dealing Place
Manassas, VA 20112

Subject: Label Amendment: Adding the Emerging Viral Pathogens claim
Product Name: Envirocleanse A
EPA Registration Number: 85134-1
Application Date: 03/09/2020
Decision Number: 560850

Dear Ms. Gray:

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

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus 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 Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,



John Hebert, Chief
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Envirocleanse A

Ready to Use Disinfectant and Sanitizer for Hard Non-Porous Surfaces

For Commercial and Household Use

Active Ingredient:

Hypochlorous Acid.....0.025%
Other Ingredients.....99.975%
Total.....100.000%

Contains 338 ppm FAC

Date produced: _____

If the product is not used immediately after production, the product should be tested with a chlorine test kit. The product should contain 338 ppm FAC. Do not use product if less than 338 ppm of available chlorine.

KEEP OUT OF REACH OF CHILDREN

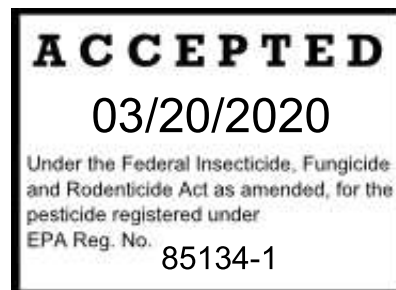
CAUTION

EPA Reg. No: 85134-1
EPA Est. No.: [85134-TX-001]

Net Contents:

Manufactured For:
Envirocleanse LLC
12621 W. Airport Road
Sugar Land, TX 77478

Batch Code:



PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with other household or industrial chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia. To do so will release hazardous, irritating gas. Prolonged contact with metal may cause pitting or discoloration.

DIRECTIONS FOR USE

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

(Envirocleanse A) (This product) is a disinfectant for use on hard non-porous inanimate surfaces. Envirocleanse A is an oxidized, pH-neutral water based solution that is ready-to-use. When used according to the directions for use, this product disinfects hard, non-porous surfaces.

Cleaning and General Use Applications

(Envirocleanse A) (This product) can be used to clean surfaces and floors. To clean, spray soiled area then wipe clean. For spot cleaning, spray and wipe clean with damp sponge (or mop) (or cloth).

Deodorization Applications

To deodorize, spray surface or item until thoroughly wet. Let stand for 10 minutes to kill odor causing bacteria, then wipe clean. For heavily soiled areas, a precleaning step is required.

Disinfection of Hard, Non-porous Surfaces

(Envirocleanse A) (This product) can be used to disinfect hard, non-porous surfaces. To disinfect, apply (Envirocleanse A) (this product) to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. Remove visible soil from surfaces before applying this product. Small non-porous objects can also be soaked in Envirocleanse A without dilution. Allow objects to soak for 10 minutes.

Disinfection of Carbapenem Resistant *Klebsiella Pneumoniae* on Hard, Non-porous Surfaces

Spray Directions

(Envirocleanse A)(This product) is used as a spray to disinfect against Carbapenem Resistant *Klebsiella Pneumoniae* on hard, non-porous surfaces. Upon opening this container, record the date on the container. Immediately transfer (Envirocleanse A)(this product) to the white HDPE spray bottle. To fill spray bottle, remove trigger sprayer from empty bottle. Pour (Envirocleanse A)(this product) directly into empty spray bottle. Pour product into spray bottle over sink or tub basin. Use a funnel to minimize product spills or waste. Replace trigger sprayer. When the transfer of the product to the white HDPE spray bottle is complete, record the date on the bottle. Remove visible soil from surfaces before applying this product. To disinfect, spray (Envirocleanse A)(this product) on any hard, non-porous surface. Spray product 6-8 inches from surface until surface is thoroughly wet. Allow surface to remain wet for 10 minutes. Allow treated surface to air dry.

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 direct 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 devices prior to sterilization or high level disinfection.

Sanitization of Hard Non-porous Food Contact Surfaces

(Envirocleanse A) (This product) is an effective sanitizer against gram positive and gram negative bacteria (vegetative forms) such as *Staphylococcus aureus* and *Escherichia coli*.

(Envirocleanse A) (this product) is a sanitizer for use on pre-cleaned non-porous, food contact surfaces including food preparation and storage areas, and all hard non-porous surfaces.

Prior to application, preclean all surfaces by a pre-flush or pre-scrape and when necessary, presoak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner, followed by a potable water rinse before applications of the sanitizing solution.

To sanitize, apply (Envirocleanse A) (this product) to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 60 seconds. Allow treated surface to air dry. Remove gross filth from surfaces before applying this product.

Veterinary / Animal Facilities Applications

To clean and disinfect in a veterinary application: Use to clean and disinfect hard, nonporous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces or facilities occupied or traversed by animals. Empty all feeding and watering equipment. Remove gross filth from surfaces before applying this product. Saturate surfaces with (Envirocleanse A) (this product) and let stand for 10 minutes. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before reuse. Disinfection of animal quarters and kennels: To clean and disinfect hard nonporous surfaces, remove all animals and feed from premises. Remove all litter, droppings, and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Remove gross filth from surfaces before applying this product. Saturate surfaces with (Envirocleanse A) (this product) for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters, and ropes. Allow equipment and housing to completely dry after use and before returning animals.

Agricultural Applications

For livestock or poultry facilities or dairy barns, remove all animals and feed from the premises, vehicles, coops, crates, and enclosures. Remove all litter, manure, and droppings from the floors, walls, and surfaces of barns, pens, chutes, and other facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Remove gross filth. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with (Envirocleanse A) (this product) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Rinse with potable water before reuse. For cut flowers or plants, dilute (Envirocleanse A) (this product) with water by 1:25 ratio to spray on the flowers or plants, and put in the vase to mitigate and retard the growth of non-public health microorganisms affecting the health and longevity of the flowers or plants. Repeat and change water if it gets murky.

Use Sites

Hospitals, health clinics, doctors' offices, dental offices
Veterinarian clinics and animal hospitals
Nursing homes
Day care centers
Food preparation areas
Ships
Schools
Colleges
Universities
Industrial and commercial facilities
Restaurants and bars
Office buildings

Recreational facilities
Retail and wholesale establishments
Homes
Apartments
Condos
Hotels, motels, bed & breakfasts
Fitness centers
Locker rooms
Convenience stores
Indoor playgrounds
Cafeterias
Prisons and correctional facilities
Police and fire stations
Pharmaceutical and medical device producing establishments
Transit facilities
Laboratories
Pet care facilities
Agricultural facilities
Storage areas
Public restrooms
Airports

Hard Non-porous Surfaces

Stainless steel
Chrome
Glass
Vinyl
Glazed porcelain
Non-porous plastics
Enamel
Glazed tile
Dishes
Glassware
Silverware
Eating and cooking utensils
Plastic and nonporous cutting boards
Chopping blocks
Kitchen products used in food preparation
Other utensils
Tables
Counter tops
Sinks
Shelves
Racks
Carts
Refrigerators (exterior)
Coolers (exterior)
Glazed tiles
Microwaves
Ovens
Stove tops
Appliances (exterior surfaces)
Conveyor belts
Toilets

Chair
Desks
Beds (rails, frames, headboards, footboard)
Floors
Door knobs

Oil and Gas Applications

Frac Water – For typical water treatment, mix 0.5 US gallons of (Envirocleanse A) (this product) with 1000 US gallons of frac water to 0.17 ppm FAC to slow and control the growth of odor and slime producing microorganisms such as sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 338 ppm FAC of (Envirocleanse A) (this product) into the well bore on a daily basis or weekly basis to control unwanted odor and slime producing microorganisms, reduce hydrogen gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of (Envirocleanse A) (this product) with 979 US gallons of injection water to 7.1 ppm FAC to control unwanted odor and slime causing microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 US gallons of (Envirocleanse A) (this product) at 338 ppm FAC into the water phase of the mixed hydrocarbon/water system to control odor and slime causing bacteria, reduce the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of (Envirocleanse A) (this product) with 979 US gallons of injection water to 7.1 ppm FAC to control odor and slime causing bacteria in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 210 US gallons at 338 ppm FAC of (Envirocleanse A) (this product) into the transmission line on a daily or weekly basis to control microorganisms such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and any sessile bacteria which can degrade the pipeline integrity.

Note: Upon opening this container, record the date on the container. If the product is transferred to spray bottles, record the same date on the secondary container. A white HDPE bottle is recommended.

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 through the following communication outlets: technical literature distributed exclusively to veterinarians, 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.**)

Statements shall adhere to the following format:

1. In the case of an Emerging [Large Non-Enveloped] [Enveloped] virus:

Envirocleanse A has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, Envirocleanse A can be used against [name of emerging virus] when used in accordance with directions for use against [name of supporting virus] 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	Norovirus Feline Calicivirus
Large, non-enveloped virus	Norovirus Feline Calicivirus

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal, or cleaning of equipment.

{Note to reviewer: The following text for residential/household containers.}

Storage: Store (Envirocleanse A)(this product) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{Not to reviewer: The following text for commercial/institutional products. Product is non-dilutable.}

Pesticide Storage: Store (Envirocleanse A)(this product) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. (Then) offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

WARRANTY

Envirocleanse LLC warrants that this product conforms to the product specification on this label and is reasonably fit for the purposes set forth in the Directions for Use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MECHANABILITY IS MADE.

OPTIONAL LABEL CLAIMS:

Non-corrosive

No dilution or mixing required

Ready to Use

General Cleaning and Deodorization claims

(Ideal) (Designed) for daily (use) (cleaning)

Easy to Use

Multi-Surface Cleaner

Compatible with (household) (equipment) surfaces

(Cleans) (Removes) food stains

(Cleans) (Removes) mildew stains

(Cleans) (Removes) everyday messes

Deodorizes

(Eliminates) (Removes) food odors

(Eliminates) (Removes) pet odors (like urine and feces)

Neutralizes odors

(Kills) (Neutralizes) (Removes) (Eliminates) odor-causing bacteria

Disinfection claims

Kills bacteria* on hard non-porous surfaces in 10 minutes.

**Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella enterica* (ATCC 10708), *Escherichia coli* (ATCC 11229)

Organism Name	ATCC numbers and/or strains
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Salmonella enterica</i>	ATCC 10708
<i>Escherichia coli</i>	ATCC 11229
H1 N1 A/Swine/1976/31, ATCC VR-99	ATCC VR-99
Norovirus (Feline Calicivirus and Murine Norovirus as surrogates)	Feline Calicivirus, strain F9, ATCC VR-782; Murine Norovirus, strain G, ATCC TIB-71
Carbapenem Resistant Klebsiella (CRE) Pneumoniae	ATCC BAA-2470
Hepatitis A	Strain: HM 175/18F Source: University of Ottawa
Hepatitis B	Strain: Grimaud Source: Hepadnavirus Testing
Hepatitis C	Strain: NADL Source: American Biosearch Laboratories
HIV1	Strain: IIIB Source: ZeptoMetrix

Note: ATCC numbers are not available for Hepatitis A, Hepatitis B, Hepatitis C, HIV1, Equivalent identifiers are used in above table accordingly.

(Kills) (Effective against) *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Salmonella enterica*, *Norovirus*, and *H1 N1 A/Swine/1976/31 virus* on treated surfaces.

(Kills) (Effective against) *S. aureus*, *P. aeruginosa*, *S. enterica*, *Norovirus*, and H1 N1 A/Swine/1976/31 (ATCC VR-99) virus on treated surfaces

Kills H1 N1 A/Swine/1976/31 (ATCC VR-99) virus (formerly called swine flu) on treated surfaces.

Kills H1 N1 A/Swine/1976/31 (ATCC VR-99) virus on treated surfaces.

(Kills) (Effective against) *Norovirus* (on treated surfaces)

(Kills) (Destroys)(Disinfects) (Removes) *Norovirus* in 10 minutes (on treated surfaces)

Kills Carbapenem Resistant *Klebsiella Pneumoniae* (CRE) on treated surfaces

Effective against the touch non-enveloped *Norovirus*

Antimicrobial

Bactericidal

Broad spectrum disinfectant

Multi-purpose disinfectant

Clean and disinfects hard non-porous surfaces (in 10 minutes)

Formulated with hypochlorous acid technology Tough on (bacteria) (germs), easy on surfaces

Kills Hepatitis A on treated surfaces

Kills Hepatitis B on treated surfaces

Kills Hepatitis C on treated surfaces

Kills HIV1 on treated surfaces

Sanitization claims

Kills *E.coli* and *S. aureus* on treated food contact surfaces in 60 seconds.

Kills *Escherichia coli* and *Staphylococcus aureus* on treated surfaces in 60 seconds.

An effective sanitizer for use on food contact surfaces.

(Envirocleanse A) (this product) is recommended for use as a sanitizer on dishes, glassware and utensils.