



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 14, 2020

Maureen Purcell
EPA Registrations Manager
PLZ Aeroscience Corporation
1000 Integram Drive
Pacific, MO 63069

Subject: Label Amendment – Emerging Viral Pathogen Claim
Product Name: Claire Disinfectant Bathroom Cleaner
EPA Registration Number: 706-65
Application Date: March 6, 2020
Decision Number: 560782

Dear Maureen:

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 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 Adenovirus Type 2 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 disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

Claire Disinfectant Bathroom Cleaner

[[Select marketing claims from "Marketing Claims" section]]

Active Ingredients:

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.115%
n-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈)	
dimethyl ethylbenzyl ammonium chloride	0.115%
Other Ingredients	<u>99.770%</u>
Total	100.000%

Keep Out of Reach of Children

CAUTION

See back panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 706-65

Refer to the bottom of container for production facility

Net Wt. ____ oz. (____ grams)

{Back Panel}

Kills: *Aspergillus niger*, *Candida albicans*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pandemic 2009 H1N1 Influenza A Virus*, *Penicillium pinophilum*, *Penicillium variable*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Trichophyton mentagrophytes*, Vancomycin-resistant *Enterococcus faecalis*, *Adenovirus Type 2, *Herpes Simplex Virus Types 1 and 2, *Influenza A2/Japan Virus* and *Vaccinia* (*Poxvirus) on hard, inanimate, non-porous environmental surfaces.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus*. This product, Claire Disinfectant Bathroom Cleaner, is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A2/Japan virus* and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 (formerly called "swine flu").

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*.

This product has demonstrated effectiveness against Avian Influenza A2/Japan virus* and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 (formerly called "swine flu").

This product effectively controls the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces.

This product demonstrates effective fungicidal activity against pathogenic fungi, *Trichophyton mentagrophytes*, in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities and on clean hard, non-porous surfaces commonly contacted by bare feet.

Disinfects: Acts as a disinfectant on hard, non-porous environmental surfaces such as toilet seats, fixtures, glazed tile, wash bowls, shower stalls, walls, finished woodwork, counter tops, kitchen counter tops, tables and outside surfaces of appliances.

The easy way to clean, disinfect and deodorize. Cleans and disinfects without scouring or scratching. Use in nursery and sickroom, for garbage and diaper pails, for any washable hard, non-porous environmental surface that needs disinfecting as you clean.

DIRECTIONS FOR USE

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

To Clean and Deodorize: Pre-clean surface prior to use. **Shake Well Before Each Use.** Point valve opening toward area to be cleaned, press down firmly and spray evenly. Wipe clean with a dry cloth, turning frequently.

For Control of Mold and Mildew: Apply by holding can upright 6" to 8" from surface to be treated. Spray until surface is completely wet. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

To Disinfect: After surface is cleaned, hold can upright 6" to 8" from surface to be treated. Spray until surface is thoroughly wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. When used as a disinfectant on food contact surfaces such as counter tops, tables and appliances, thoroughly rinse surfaces with potable water. Do not use on utensils, dishes or glasses.

Kills HIV on Pre-Cleaned Environmental Surfaces 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 human immunodeficiency virus* Type 1 (HIV) (associated with AIDS): **Special Instructions for Cleaning and Decontamination Against HIV on Surfaces/Objects Soiled with Blood/Body Fluids: Personal Protection:** When handling items soiled with blood or body fluids, use barrier protection: disposable 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:** Spray surface to be treated 3-4 seconds, from a distance of 6-8 inches, until surface is wet. Allow spray to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. **Disposal of Infectious Materials:** Autoclave blood and other body fluids and disposed of according to federal, state and local regulations for infectious waste disposal.

This product is not for use on medical devices or medical equipment surfaces.

<< EMERGING VIRAL PATHOGENS CLAIMS – Hard, non-porous surface >>

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

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 2

{Product name} has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [porous and/or 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, porous/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, porous/non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

Storage and Disposal

Product Storage: Store in a cool, dry (preferably locked) place inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition. **Product Disposal:** Wastes resulting from the use of this product may be disposed on site or at an approved waste disposal facility. **Container Disposal:** Non-refillable container; do not refill or reuse this container. Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

{Batch Code/Lot Number will appear either on the label or the container per PR Notice 2007-4.}

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

First Aid

If in Eyes	<ul style="list-style-type: none"> 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 eyes.
If on Skin or Clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
If Inhaled	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
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. You may also contact 1-866-836-8855 {or other appropriate number} for emergency medical treatment information.	

{Note: The grid format for the First Aid statements will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Contents under pressure. Do not use or store near fire, sparks or heated surfaces. Do not store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F (49°C) may cause bursting. Incineration of container may cause explosion.



[Point spray pattern toward dot {or similar instructional text}]

Aerosol Spray



Contains no CFCs or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.



{Package display}

HMIS®: Health {Number} Fire: {Number} Reactivity/Physical Hazard: {Number} Personal Protection: {Code}
Hazard Index: 4 = Severe; 3 = Serious; 2 = Moderate; 1 = Slight; 0 = Minimal

NFPA: Health: {Number} Fire: {Number} Reactivity/Instability: {Number}

A Product of



Claire Manufacturing Company

1000 Integram Drive
Pacific, MO 63069

[www.clairemfg.com]



Nonfood Compounds
(Category Code)

{Note: The (Category Code) will contain the specific registration number for the product.}



Made in the USA with globally sourced materials

Not for sale or distribution in California

{Marketing Claims}

Antibacterial

Bactericidal *Virucidal Fungicidal

Cleans and Deodorizes

Country Fresh Scent

Country Garden Scent

Disinfects

For Use in Homes and Other Residential Dwellings, Hospitals, Nursing Homes, Clinics, Medical Facilities, Businesses, Hotels, Motels, Restaurants, Schools, Institutions and Commercial Establishments

Disinfects HIV-1 (AIDS Virus)*, Influenza A2/Japan Virus* and Herpes Simplex Virus* Types 1 and 2 on Hard, Inanimate, Non-porous Environmental Surfaces

Kills HIV-1 (AIDS Virus)*, Influenza A2/Japan Virus* and Herpes Simplex Virus* Types 1 and 2 on Hard, Inanimate, Non-porous Environmental Surfaces Kills Common Kitchen Germs

Kills Pandemic 2009 H1N1 Influenza A Virus* (formerly called "swine flu")

Kills 99.9% Germs

Kills 99.9% viruses* & bacteria

All Purpose Cleaner

Foaming Action

Tough on Grease, Soap Scum & Grime

Restroom care

{End of Marketing Claims}

{Alternate Brand Names}

Claire Germicidal Cleaner

Claire Germicidal Cleaner Country Fresh Scent

{End of Alternate Brand Names}

[] Indicates optional/alternate language

{ } Indicates language that does not appear on market labeling