

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 25, 2019

Maureen Purcell EPA Registration Manager Claire Manufacturing Company 1000 Integram Drive Pacific, MO 63069

Subject: PRIA Label Amendment – Add efficacy claim

Product Name: CLAIRE DISINFECTANT SPRAY Q

EPA Registration Number: 706-111 Application Date: March 13, 2019

Decision Number: 549032

Dear Ms. Purcell:

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.

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

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with FIFRA section 6. If you have any questions, please contact Mohammad Alavi by phone at (703) 347-0522, or via email at Alavi.mohammad@epa.gov.

Sincerely, E. Midelloff

Eric Miederhoff

Product Manager 31

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

Enclosure

- [] Denotes optional language
- ([]) Denotes one of the options within the brackets must be chosen
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Claire Disinfectant Spray Q

Spray Disinfectant

For Use on Hard, Non-porous Environmental Surfaces and Soft Spot Surface Sanitizer applications.

{Insert optional marketing claims from list below.}

Active Ingredients:

0.16%
0.16%
99.68%
100.00%

Keep Out of Reach of Children CAUTION

See [back][side] panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 706-111

EPA Est. XXX

Refer to bottom of container for production facility

{Optional Marketing Claims:}

Antibacterial

Bactericidal

*Virucidal

Fungicidal

Tuberculocidal

Germicidal

Country Fresh Scent

Country Garden Scent

Lavender Scent

Lemon Scent

Disinfect[s]

Deodorize[s] [Deodorizer]

Sanitize[s]

Sanitizes soft non-food contact surfaces as a spot treatment.

Kills Common Kitchen Germs

Kills Pandemic 2009 H1N1 Influenza A *virus [formerly called "swine flu"]

Kills 99.9% Germs

Kills 99.9% *viruses and bacteria

Kills flu viruses

Kills (TB) Mycobacterium bovis

Multipurpose Disinfectant

Controls Mold and Mildew

ACCEPTED

07/25/2019

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

EPA Reg. No. 706-111

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Controls mold and mildew on [mattresses], [shower curtains], [painted or finished walls], [attics and damp, musty areas].

Eliminates Odors

Multipurpose

Ready-to-use

No mixing

This [product] is effective as a [sanitizer][disinfectant] on hard, non-porous, non-food contact surfaces in: {Insert use sites from list below.}

Ambulances

Homes

Residential Dwellings

Hospitals

Healthcare

Nursing Homes

Clinics

Medical Facilities

Businesses

Hotels

Motels

Restaurants

Schools

Institutions

Housekeeping [and in-home use]

Kitchens

Bathrooms

Commercial Establishments

This [product] is for use as a [sanitizer][disinfectant] on hard, non-porous non-food contact surfaces such as: {Insert surfaces from list below.}

Doorknobs

Light switches

Toilet[s] [seats]

[Kills germs on] high-touch surfaces [such as] [{see list of surfaces}].

Sinks

Kitchen appliance surfaces

[For] Bowling shoes, skates, ski and snowboard boots

Bathtubs

Showers

Garbage cans

This [product] is effective as a disinfectant [on] food contact surfaces [in]: {Insert use

sites from list below.}

Homes

Restaurants

Kitchens

[And other] commercial establishments

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This [product] is for use as a disinfectant on food contact surfaces [such as]: {Insert surfaces from list below.}

Toys Countertops Tables Appliances

{Note to Reviewer: ATCC etc. references are optional on the label.}

[This product] kills the following bacteria, fungi and *viruses in 3 minutes on pre-cleaned hard, non-porous surfaces:

{Select claims as desired for 3 minute contact time.}

Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica (ATCC 10708)

Staphylococcus aureus (ATCC 6538)

Acinetobacter baumannii Multi Drug Resistant (ATCC 19606)

Carbapenem Resistant Escherichia coli (CDC 81371)

Carbapenem Resistant Klebsiella pneumoniae (ATCC BAA-1705)

Enterobacter aerogenes (ATCC 13048)

Enterococcus faecium (ATCC 51559)

Escherichia coli (ATCC 11229)

Klebsiella pneumoniae (ATCC 4352)

Listeria monocytogenes (ATCC 19117)

Staphylococcus aureus- MRSA (ATCC 33592)

Staphylococcus aureus- CA-MRSA Genotype USA 300 (NARSA NRS 384)

Staphylococcus aureus- CA-MRSA Genotype USA 400 (NARSA NRS 123)

Shigella dysenteriae (ATCC 11835)

Streptococcus pyogenes (ATCC 19615)

Staphylococcus aureus –VISA (CDC HIP 5836)

Enterococcus faecalis –VRE (ATCC 51575)

Campylobacter jejuni (ATCC 29428)

Candida albicans (ATCC 10231)

*Viruses:

Adenovirus Type 2*

2009-H1N1 Influenza A virus*

Influenza B virus*

Human Immunodeficiency virus type 1 (HIV-1)*

Herpes simplex virus type 1*

Herpes simplex virus type 2*

Rotavirus*

Vaccinia virus*

Rhinovirus type 37*

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[This product] kills (TB) Mycobacterium bovis (ATCC 35743) in 10 minutes at 22.5°C on pre-cleaned hard, non-porous surfaces.

[This product] kills Poliovirus type 1* in 5 minutes on pre-cleaned hard, non-porous surfaces.

[This product] sanitizes and kills 99.9% of *Staphylococcus aureus (staph)* and *Enterobacter aerogenes* in 3 minutes on pre-cleaned, hard, non-porous surfaces.

Fungus:

{State fungicidal claims as 10 minute contact time} Trichophyton interdigitale (Athlete's Foot Fungus) (ATCC 9533)

{Select claims as desired for Mildew-Fungistatic use.} Aspergillus niger (ATCC 6275)

DIRECTIONS FOR USE

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

Shake Well Before Each Use. Point valve opening toward area to be cleaned, press down firmly and spray evenly.

To Disinfect: After hard, non-porous surface is cleaned, hold can upright 6" to 8" from area 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 3 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

To Sanitize Non-Food Contact Surfaces: After hard, non-porous surface is cleaned, hold can upright 6" to 8" from area 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 3 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved.

To Kill (TB) Mycobacterium bovis: Pre-clean surfaces, hold can upright 6" to 8" from area 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 10 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

To Kill Poliovirus Type 1: After surface is cleaned, hold can upright 6" to 8" from area 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 5 minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved. When used on toys or food contact surfaces such as countertops, tables and appliances, thoroughly rinse surfaces with potable water before use. Do not use on utensils, dishes or glasses.

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For use as a fungicide [against Trichophyton interdigitale (Athlete's Foot)]: Apply to clean surface holding can upright 6" to 8" from area 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. Reapplication is necessary if surface is dried before contact time is achieved.

For Spot Sanitization of Soft Non-food Contact Surfaces: After surface is cleaned, hold can upright 6" to 8" from area 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 three minutes prior to wiping. Reapplication is necessary if surface is dried before contact time is achieved.

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.

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 three minutes except for Poliovirus Type 1 which requires five 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.

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

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CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid

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 eyes.
If on Skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
0 " '	

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

Flammable. Contents under pressure. Do not use or store near fire, sparks or heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F 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}

[Made in the USA with domestic and foreign components.]



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



{Alternate Brand Names}

Claire Disinfectant Spray Lemon Scent Claire Disinfectant Spray Country Fresh Scent Claire Disinfectant Spray Floral Scent Claire Disinfectant Spray Lavender Scent

{End of Alternate Brand Names}