



000706-00069-061099

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Systems Integration Group, Inc.

PM34

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 of 5

706-69

6/10/99

JUN 10 1999

Ms. Kim Davis
Consultant/Agent
Claire Manufacturing Company
c/o RegWest Company
P. O. Box 2220
Greeley, CO 80632-2220

Dear Ms. Davis:

Subject *Confirmatory Efficacy Data for Additional Organism Claims and Revised Labeling for Claire Disinfectant Spray
EPA Registration Number 706-69
Your Amended Application Dated December 11, 1998*

We have completed a review of the efficacy data (MRID No(s) 447200-01 and 447200-02) submitted in support of additional label claims against Methicillin Resistant Staphylococcus aureus (ATCC 33591) and Vancomycin Resistant (VRE) Enterococcus faecalis (ATCC 51299) and conclude that the data is acceptable.

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

1. *Change "Trichophyton interdigitale" to read; Trichophyton mentagrophytes"*
2. *Revised the "IF IN EYES" statement to read; Flush with water for 15 minutes . Get medical attention if irritation develops or persists.*

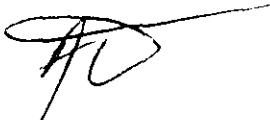
Submit three copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

CONCURRENCES

SYMBOL	7518C						
SURNAME	J. W. H. Jones						
DATE	6/10/99						

For detailed information and consideration, please refer to the enclosed EPA's Risk Assessment and Science Support Branch (RASSB) review dated April 7, 1999. If you have any questions concerning this letter, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,



*Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)*

Enclosure:

**CLAIRE
DISINFECTANT SPRAY**

FOR HOSPITAL USE



**Disinfects
HIV-1 (AIDS Virus), Polio Virus Types 1 and 2,
Influenza A₂/Hong Kong Virus and Herpes Simplex Virus Types 1 and 2
On Inanimate Environmental Surfaces**

**For Use in Homes, Hospitals, Nursing Homes, Businesses, Hotels, Motels,
Restaurants, Schools, Institutions and Commercial Establishments**

For Skate, Ski & Snowboard Boots

**Kills Most Germs
Controls Mold and Mildew
Eliminates Odors**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 10 1999**

**Bactericidal Staphylocidal
Tuberculocidal
Fungicidal Pseudomonocidal
*Virucidal**

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 706-69

ACTIVE INGREDIENTS:

Orthophenylphenol	0.176%
Para-tertiary Amylphenol	0.045%
Ethanol	49.950%
+INERT INGREDIENTS	49.829%

+Contains Sodium Nitrite.

**Keep Out of Reach of Children
CAUTION
See back panel for additional precautionary statements.**

NET WT. ____ OZ. (____ GRAMS)

4075

For Use in Homes, Hospitals, Nursing Homes, Businesses, Hotels, Motels

Kills: *Aspergillus niger*, *Herpes Simplex Virus Types 1 and 2, *Human Immunodeficiency Virus Type 1 [HIV-1 (AIDS virus)], *Influenza A₂/Hong Kong Virus, Methicillin Resistant *Staphylococcus aureus*, *Polio Virus Types 1 and 2, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Trichophyton interdigitale*, *Tubercule bacilli*, and Vancomycin Resistant *Enterococcus faecalis* on inanimate environmental surfaces.

Disinfects: Acts as a powerful disinfectant on such bacteria carrying surfaces as toilet seats, telephones, garbage and refuse cans, urinals, athletic equipment, light switches, bed pans, empty hampers and other out of the way places.

Sanitizes: Shoes and slippers. **Controls Mold and Mildew** on mattresses, awnings, shower curtains, leather goods. **Controls** mildew and mold growth on painted or finished walls, ceilings and woodwork in closets, basements, attics, storage areas, summer cottages, damp and musty corners.

Deodorizes: Reduces annoying odors. Use to control odors in hospitals and nursing homes. In private homes, use in kitchen, bathroom, sick rooms, basements. Effectively suppresses odors caused by mold and mildew.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 10 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

706-69

DIRECTIONS FOR USE

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

Shake well before using and occasionally while spraying. Clean surface thoroughly with an effective cleaning compound prior to treatment. Remove all gross filth or heavy soil from all surfaces to be treated.

To Disinfect and for Tuberculocidal Activity: After surface is cleaned, hold can upright 6" to 8" from surface to be treated. Spray 3-4 seconds until surface is wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. For Herpes Simplex Virus Types 1 and 2 spray 8-10 seconds until the surface is wet. Allow to dry without wiping or allow spray to contact treated surface for a minimum of ten minutes prior to wiping. Tuberculocidal in 10 minutes at 25°C.

To Deodorize: Hold can upright and point opening away from face. Spray into the air for 3 to 5 seconds directing spray toward center of room.

To Control Surface Mildew: After surface is cleaned, cover surface with mist. Repeat treatment every week for effective control.

To Sanitize, Deodorize and Control Mildew on Shoes: After shoe surface is cleaned, hold can upright with opening pointed away from face and 6" to 8" from shoe surface to be treated. Spray interior and exterior of shoe for 3-5 seconds or until surface is wet. Allow shoe to air dry without wiping.

Special Instructions for Cleaning and Decontamination Against HIV on Surfaces/Objects Soiled with Blood/Body Fluids on pre-cleaned environmental surfaces/objects 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 HIV): **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as disposable latex gloves, gowns, masks or 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:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

Storage: Store in a cool, dry place (preferably locked) inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition. **Disposal:** Replace cap, wrap container in several layers of newspaper and discard in trash. Do not incinerate or puncture.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. Do not spray on or near exposed food. Cover food handling surfaces and utensils before spraying or wash thoroughly after using spray. Do not use on humans, domestic animals or pets.

Statement of Practical Treatment

If in Eyes: Flush eyes with plenty of water. Contact a physician if irritation persists.

24 HOUR MEDICAL EMERGENCY: 1-800-228-5635, EXT. 009

Physical or Chemical Hazards

Flammable. 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. Incineration of container may cause explosion. Exposure to temperatures above 120°F may cause bursting. Do not spray on polished wood surfaces, rayon fabrics or on acrylic plastics. Solvents in spray may cause damage to some plastics, coatings and other materials if sprayed until wet.

EPA Reg. No. 706-69 EPA Est. 706-IL-1

A Product of



CLAIRE MANUFACTURING COMPANY

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Addison, IL 60101