

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 27 2001

Ms. Kim Davis
Agent for Claire Manufacturing Company
REGWEST COMPANY
30856 Rocky Road
Greeley, CO 80631-9375

Dear Ms. Davis:

Subject: Amended Label - Response to the Agency's Letter Dated September 21, 2001
CLAIRE DISINFECTANT SPRAY
EPA Registration Number 706-69
Amended Application Dated September 29, 2001

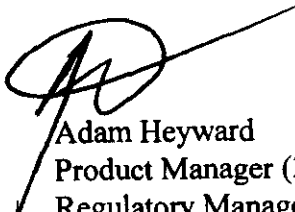
The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following comments:

1. The appropriate signal word is "CAUTION" for the subject product..
2. With respect to comment #12 of your letter of the subject date referred to above, we have no objections to the statement, "Solvents in spray may damage, etc....." be placed under the subheading "General Precautions and Restrictions".

A stamped copy is enclosed for your records.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or LaVerne Dobbins at (703) 308-6378.

Sincerely,



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

Enclosure:

CONCURRENCES

SYMBOL	7510C							
SURNAME	L. Dobbins							
DATE	12-27-01							



[For Hospital Use]



Disinfects

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

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

[For use in Health Care Settings such as Hospitals, Nursing Homes, Schools and Institutions]

For Skate, Ski & Snowboard Boots

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

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

DEC 27 2001

**Bactericidal Staphylocidal
Tuberculocidal
Fungicidal Pseudomonicidal
*Virucidal**

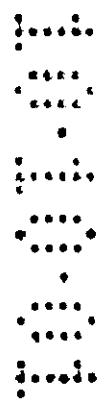
**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 706-69**

Active Ingredients:

Orthophenylphenol (CAS No. 90-43-7).....	0.176%	
Para-tertiary Amylphenol (CAS No. 80-46-6).....	0.045%	
Ethanol (CAS No. 64-17-5).....	49.950%	
+Other Ingredients	49.829%	
Total	100.000%	
+Contains Sodium Nitrite.		

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

Net Wt. ____ oz. (____ grams)



ACCOUNTED
with COMMENTS
in EPA Letter Dated:
DEC 27 2001

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

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

DIRECTIONS FOR USE

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

General Information

Kills: *Aspergillus niger* (ATCC 16404), *Human Herpes Simplex Virus Type 1 (ATCC VR-733F) and Type 2 (ATCC VR-540), *Human Immunodeficiency Virus Type 1 [HIV-1 (AIDS virus)], *Influenza A₂/Hong Kong Virus, Methicillin Resistant *Staphylococcus aureus* (ATCC 33591), *Mycobacterium tuberculosis var bovis* (BCG), *Polio Virus Types 1 and 2, *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), *Trichophyton mentagrophytes* (ATCC 9972) and Vancomycin Resistant *Enterococcus faecalis* (ATCC 51299) on hard, nonporous, inanimate environmental surfaces.

Disinfects: Disinfects 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.

General Precautions and Restrictions

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.
{The following paragraph will be included in this section when the product is labeled for use in hospitals and other medical environments;} 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 contact with the bloodstream or normally sterile areas of the body, or (2) contact 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 medical devices prior to sterilization or high level disinfection.

Application Instructions

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 and Disposal

Pesticide Storage: Store in a cool, dry (preferably locked) storage area away from direct sunlight, windows, flames and other sources of heat or ignition. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed on site or at an approved waste disposal facility. **Container Disposal:** Replace cap, wrap container and put in trash. Do not incinerate or puncture.
{Alternate Container Disposal Directions: **Disposal:** This container may be recycled. Before offering for recycling, completely empty can according to label directions (DO NOT PUNCTURE!) and replace cap. If recycling is not available, completely empty can, replace cap and put in trash.}

{The following storage and disposal directions will be used for products marketed solely for residential use:}

[Storage and Disposal]

Storage: Store in a cool, dry (preferably locked) storage area inaccessible to children and pets and away from direct sunlight, windows, flames and other sources of heat or ignition. **Disposal:** Replace cap, wrap container and put in trash. Do not incinerate or puncture.
{Alternate Disposal Directions: **Disposal:** This container may be recycled. Before offering for recycling, completely empty can according to label directions (DO NOT PUNCTURE!) and replace cap. If recycling is not available, completely empty can, replace cap and put in trash.}

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid

If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes.
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 eye.

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 1-800-228-5635, Ext. 009 for emergency medical treatment information.

{Note: The First Aid statements' grid format 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 store in direct sunlight. Do not smoke while using this product. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 27 2001

EPA Reg. No. 706-69

EPA Est. 706-IL-1

A Product of



Claire Manufacturing Company

500 Vista Avenue
Addison, IL 60101

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

[] Indicates alternate/optional language
{ } Indicates language that does not appear on market labeling