

706-69

12-3-2007

1/8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 3, 2007

Kim Davis
Agent for Claire Manufacturing Co.
RegWest Company, LLC
30856 Rocky Rd.
Greeley, CO 80631

Subject: Claire® Disinfectant Spray
EPA Registration No.: 706-69
Application Date: November 23, 2007
Receipt Date: November 26, 2007

Dear Ms. Davis,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- List previously approved organisms on front page of label.

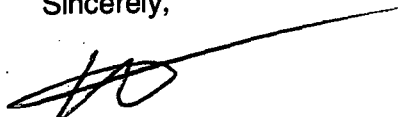
General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email at heyward.adam@epa.gov.

Sincerely,



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

CONCURRENCES

SYMBOL	7510 P							
SURNAME	Graham							
DATE	12/3/07							

2/8

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number Notification
--	--	--

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 706-69	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Claire® Disinfectant Spray	PM # 34	
5. Name and Address of Applicant (Include ZIP Code) Claire Manufacturing Company c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Check if this is a new address

Section – II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 03/20/2007 <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
--	--

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Submit Non-PRIA label revision notification per PR Notice 98-10 and final printed labeling per the EPA letter dated March 20, 2007

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____	
*Certification must be submitted		If "Yes" Unit Packaging Wt.	No. Per Container	If "Yes" Packaging Wt.	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Kim Davis, CC, APC, Manager	Title Consultant/Agent	Telephone No. (Include Area Code) (970) 353-0611 kim@regwest.com
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 		3. Title Kim Davis, CC, APC, Manager
4. Typed Name Kim Davis, CC, APC, Manager		5. Date November 23, 2007

November 23, 2007



Mr. Adam Heyward, Product Manager 13
Document Processing Desk – **NOTIF/FPL**
Office of Pesticide Programs – **7504P**
U.S. Environmental Protection Agency
2777 South Crystal Drive
One Potomac Yard, Room S-4900
Washington, DC 20460

Dear Mr. Heyward:

Subject: Claire® Manufacturing Company
Claire® Disinfectant Spray
EPA Reg. No. 706-69

On behalf of **Claire Manufacturing Company**, RegWest Company, LLC is submitting the attached materials as notification of a Non-PRIA label revision for subject product per PR Notice 98-10. RegWest will act as sole agent in this endeavor.

Attached are the following:

- 1. Application for Pesticide: Other (Notification)
- 2. One draft label illustrating the changes
- 3. Two final printed labels incorporating the changes

We are adding two microorganisms to the front panel marketing claims which are currently listed in the "General Information" section of the Directions for Use". We are also adding their acronyms "MRSA" and "VRE" as part of the front panel marketing claims and in the "General Information" section of the Directions for Use".

We are also submitting the final printed labeling in response to the Agency letter of March 20, 2007, even though we were not specifically required to do so by the letter.

Please contact me at (970) 353-0611 or kim@regwest.com if you have any questions or require additional information.

Regards,
RegWest Company, LLC

Kim Davis, CC, APC, Manager
Consultant/Agent

Attachments

pc: CMC – Cempa, R.

30850 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

4/8

Claire Disinfectant Spray

[For Hospital Use]

Country Fresh {or other descriptive term} Scent

Disinfects

HIV-1 (AIDS Virus), Methicillin Resistant *Staphylococcus aureus* (MRSA),
Vancomycin Resistant *Enterococcus faecalis* (VRE),
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

Bactericidal Staphylocidal
Tuberculocidal
Fungicidal Pseudomonicidal
Virucidal

NOTIFICATION
Date Reviewed: 11-3-07
Reviewed By: [Signature]

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)

5/8

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

DIRECTIONS FOR USE

It is 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-733) and Type 2 (ATCC VR-540), Human Immunodeficiency Virus Type 1 [HIV-1 (AIDS virus)], Influenza A₂/Hong Kong Virus, Methicillin Resistant *Staphylococcus aureus* (MRSA) (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* (VRE) (ATCC 51299) on hard, nonporous, inanimate environmental surfaces.

Disinfects: Disinfects on such bacterial- and viral-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. **Disinfects** hard, non-porous surfaces of 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.

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

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.

For Skate, Ski and Snowboard Boots

To Deodorize and Control Mildew on Shoes and Boots: After shoe/boot surface is cleaned, hold can upright with opening pointed away from face and 6" to 8" from shoe/boot surface to be treated. Spray interior and exterior of shoe/boot for 3-5 seconds or until surface is wet. Allow shoe/boot 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. [Note: This product contains a chemical(s) known to the state of California to cause cancer.] [Not for sale or distribution in California.]

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.
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 eye.
<p>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.</p>	

{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.

EPA Reg. No. 706-69

EPA Est. 706-IL-1

{Aerosol Can Pictogram}
[Point spray pattern toward dot {or similar instructional text}]
Aerosol Spray

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

{Mobius Loop logo}
{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

[500 Vista Avenue]
Addison, IL 60101
www.clairemfg.com

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

