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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JAN 25 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Kim Davis, CC, APC, Manager, Consultant/Agent
Claire Manufacturing Company
c/o RegWest Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

Subject: Notification per PR Notice 98-10
Claire Disinfectant Spray
EPA Registration Number: 706-69
Application Date: December 28, 2009
Receipt Date: December 29, 2009

Dear Ms. Davis:

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

Proposed Notification:

Notification in compliance with "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)."

General Comments:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me by telephone at 703-308-6416 or by email at mcFarlane.jacqueline@epa.gov or Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline McFarlane".

Jacqueline McFarlane
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

	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 <h2 style="margin:0;">Notification</h2>
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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 type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)


**Notification of label revisions to add Pandemic 2009 H1N1 Influenza A Virus claims per PR Notice 95-2 and
and
Notification of minor label revisions per PR Notice 98-10
Refer to the Reference Label for an illustration of the revisions.**

This notification is consistent with the provisions of PR Notices 95-2 and 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 95-2 and 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
*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 kiin@regwest.com
Certification 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 December 28, 2009	

Non-PRIA Label Revision (H1N1) Notification



December 28, 2009

Mr. Adam Heyward, Product Manager 34
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504P**
U.S. Environmental Protection Agency
One Potomac Yard, South Building, Room S-4900
2777 South Crystal Drive
Washington, DC 20460

Dear Mr. Heyward:

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

One 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 Notices 95-2 (H1N1) and 98-10 (minor revisions). RegWest will act as sole agent in this endeavor.

Attached are the following:

- 1. Application for Pesticide: Other (Notification)
- 2. One **Reference Label** (illustrating the label revisions)
- 3. Two **New Labels** (incorporating the revisions)

Per the Agency's guidance document entitled "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" and the reference PR Notice 95-2, we are adding the 'labeling recommendations' as presented in the guidance document. Per PR Notice 98-10 we are also taking this opportunity to make certain minor refinements (revisions) such as adding graphics and deleting the website address. All revisions are illustrated on the **Reference Label**.

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

cc: CMC – Cepa, R.

30856 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

Claire Disinfectant Spray

[For Hospital Use]

Country Fresh {or other descriptive term} Scent

NOTIFICATION
Date Reviewed: 1/25/10
Reviewed By: [Signature]

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

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

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 Pseudomonocidal *Virucidal

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	<u>49.829%</u>
Total	100.000%

+Contains Sodium Nitrite.

Keep Out of Reach of Children
CAUTION
See back panel for First Aid and additional Precautionary Statements.

Net Wt. ____ oz. (____ grams)

{Back Panel}

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.

Product ~~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.

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

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.

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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.]

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First Aid

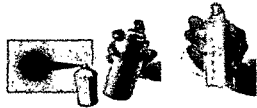
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, 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.claire.com

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