

706-65

01/27/2010

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 27 2010

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

Subject: **Clair Disinfectant Bathroom Cleaner**
EPA Registration Number 706-65
Application Dated December 28, 2009
EPA Received Date December 29, 2009

Dear Ms. Davis:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:


- Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

General Comments:

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


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

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,


Velma Noble
Product Manager (31)
Regulatory Management Branch I

SYMBOL							
SURNAME							
DATE							

	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. 706-65	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Claire® Disinfectant Bathroom Cleaner	PM # 31	
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 _____
<input type="checkbox"/> 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.
--	---

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

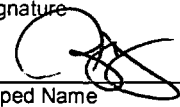
Notification of label revisions to add Pandemic 2009 H1N1 Influenza A Virus claims per PR Notice 95-2.
and
Notification of minor label revisions per PR Notice 98-10
Refer to the Reference Label for an illustration of the revisions.

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	<input type="checkbox"/> Glass
			If "Yes" Packaging Wt.	No. Per Container	<input type="checkbox"/> Paper
			<input type="checkbox"/> Other (Specify): _____		
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) (370) 353-0611 kim@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.		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		



December 28, 2009

Ms. Velma Noble, Product Manager 31
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 Ms. Noble:

Subject: Claire® Manufacturing Company
Claire® Disinfectant Bathroom Cleaner
EPA Reg. No. 706-65

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. 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
970-373-0613 Fax
Kim@regwest.com

Claire Disinfectant Bathroom Cleaner

Country Fresh Scent

Disinfects

HIV-1 (AIDS Virus)*, Influenza A₂/Japan Virus* and Herpes Simplex Virus* Types 1 and 2
on Hard Inanimate Nonporous Environmental Surfaces

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

For Use in Homes and Other Residential Dwellings, Hospitals, Nursing Homes, Clinics, Medical Facilities,
Businesses, Hotels, Motels, Restaurants, Schools, Institutions and Commercial Establishments

ANTIBACTERIAL

Kills Common Kitchen Germs
Bactericidal *Virucidal Fungicidal

Cleans and Deodorizes
Spray and Wipe Shining Clean

Active Ingredients:

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.115%
n-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈)	
dimethyl ethylbenzyl ammonium chloride	0.115%
Other Ingredients	99.770%
Total	100.000%

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

EPA Reg. No. 706-65 EPA Est. 706-IL-1

Net Wt. ____ oz. (____ grams)

{Back Panel}

Needs No Rinsing

Kills: *Aspergillus niger, Candida albicans, Escherichia coli, Klebsiella pneumoniae, *Pandemic 2009 H1N1 Influenza A Virus, Penicillium pinophilum, Penicillium variable, Pseudomonas aeruginosa, Salmonella choleraesuis, Staphylococcus aureus, Streptococcus pyogenes, Trichophyton mentagrophytes, Vancomycin-resistant Enterococcus faecalis, *Adenovirus Type 2, *Herpes Simplex Virus Types 1 and 2, *Influenza A₂/Japan Virus and Vaccinia (Poxvirus)* on hard inanimate non-porous environmental surfaces.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus*. This product, Claire Disinfectant Bathroom Cleaner, is a broad-spectrum hard surface disinfectant that has been shown to be effective

5/7

against Influenza A₂/Japan 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/Japan virus* and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called "swine flu").

Disinfects: Acts as a disinfectant on hard, non-porous environmental surfaces such as toilet seats, fixtures, glazed tile, wash bowls, shower stalls, walls, finished woodwork and countertops. The easy way to clean, disinfect and deodorize. Spray and wipe clean. Cleans and disinfects without scouring or scratching. Use in nursery and sickroom, for garbage and diaper pails, for any washable hard, non-porous environmental surface that needs disinfecting as you clean.

DIRECTIONS FOR USE

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

To Clean and Deodorize: Remove all gross filth or heavy soil from surfaces to be treated prior to using this product. **Shake Well Before Each Use.** Point valve opening toward area to be cleaned, press down firmly and spray evenly. Wipe clean with a dry cloth, turning frequently.

This product effectively controls the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Apply by holding can upright 6" to 8" from surface to be treated. Spray as to wet all surfaces completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

This product demonstrates effective fungicidal activity against pathogenic fungi, *Trichophyton mentagrophytes*, in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities, on clean hard, nonporous surfaces commonly contacted by bare feet. Follow disinfection directions.

To Disinfect: After surface is cleaned, hold can upright 6" to 8" from surface 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. When used as a disinfectant on food contact surfaces such as counter tops, tables and appliances, wash surfaces thoroughly with a potable water rinse. Do not use on utensils, dishes or glasses.

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 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.

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

Storage and Disposal

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. **Disposal:** Replace cap, wrap container in several layers of newspaper and dispose in trash collection. Do not incinerate or puncture.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin. Avoid contact with eyes, skin or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately 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 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

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 (49°C) may cause bursting. Incineration of container may cause explosion.



{Aerosol Can Pictograms}

[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}

7/7

A Product of



Claire Manufacturing Company

[500 Vista Avenue]

Addison, IL 60101

www.clairemfg.com

[] Indicates optional/alternate language

{ } Indicates language that does not appear on market labeling