

11525-30

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JAN 06 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Kim Davis, CC, APC, Manager
KIK Custom Products, Inc.
C/o Reg West Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

Subject: Notification per PR Notice 95-2
Disinfectant Spray "G"
EPA Registration Number: 11525-30
Application Date: December 16, 2009
Receipt Date: December 17, 2009

Dear Ms. Davis:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 95-2

Proposed Notification:

Notification to add Pandemic 2009 H1N1 Influenza A label claims per PR Notice 95-2.

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 that reads "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="text-align: center;">Notification</h2>
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Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 11525-30	2. EPA Product Manager Tracy Lantz	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/ Product (Name) Disinfectant Spray "G"	PM # 34	
5. Name and Address of Applicant (Include ZIP Code) KIK Custom Products, Inc. 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"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

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

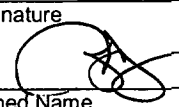
Notification of label revisions to add Pandemic 2009 H1N1 Influenza A Virus claims per PR Notice 95-2.
and
Notification of label revisions for CDPR per PR Notice 98-10.
Refer to Reference Label for an illustration of the revisions.

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 Notices 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:			
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	2. Type of Container <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) kim@regwest.com (970) 353-0611
Certification		6. Date Application Received (Stamped)
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.		
2. Signature 	3. Title Consultant/Agent	
4. Typed Name Kim Davis, CC, APC, Manager	5. Date December 16, 2009	

Non-PRIA Label Revision (H1N1) Notification*



December 16, 2009

Ms. Tracy Lantz, 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
Arlington, VA 22202



Dear Ms. Lantz:

Subject: KIK Custom Products, Inc.
Disinfectant Spray "G"
EPA Reg. No. 11525-30

On behalf of **KIK Custom Products, Inc.**, RegWest Company, LLC is submitting the attached materials as a notification of label revision per PR Notices 95-2 (H1N1) and 98-10* (DPR-requested changes). RegWest will act as sole agent in this endeavor.

Attached are the following:

- 1. Application for Pesticide: 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 referenced 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) as required for CDPR. 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

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

Attachments

cc: KIK - Muczynski, M.

Disinfectant Spray "G"

For Use in [in and/or on] {select from listed use sites}

Kills Many Household Germs [Bacteria, Viruses*, Mold & Mildew]

Kills [Effective Against] {select from listed microorganisms}

Prevents Mold and Mildew Growth

Kills [Eliminates] [Destroys] 99.9% of [Common] [Household] Germs [in 50 Seconds**]

Kills [the] Flu Virus Fights Germs and Odors

Kills ~~antibiotic-resistant~~ Methicillin-resistant Bacteria (Staphylococcus aureus) [(MRSA)]

Kills [the] Avian Influenza A virus on pre-cleaned environmental surfaces

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

Eliminates [Removes] [tough] Odors [caused by bacteria [mold] [mildew] [germs]

Antibacterial Disinfectant/Cleaner for Use In and On Microwave Ovens

[and Other] Hard, Nonporous Environmental [Inanimate] Surfaces

[Grime Scrubbing Cap]

Active Ingredients:

n-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chloride	0.072%
n-alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride	0.072%
Ethanol	53.088%
Other Ingredients	46.768%
Contains sodium nitrite	
Total	100.000%

Keep Out of Reach of Children

CAUTION

See side [back] panel for additional precautionary statements.

Net Wt. ___ oz.

NOTIFICATION
Date Reviewed: 1/5/10
Reviewed By: K. Swift

{Side Panels or Back Panel}

DIRECTIONS FOR USE

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

DISINFECTS [DISINFECTANT] • VIRUCIDAL* • FUNGICIDAL • STREPTOCIDAL
• TUBERCULOCIDAL • STAPHYLOCIDAL • PSEUDOMONACIDAL • SANITIZER**
• ANTIBACTERIAL

[[Packaging Claims:] Bonus [pocket] [purse] [travel] [trial] [value] [mini]
[portable] [on-the-go] [to go] size [pack]]

Product Information

Fresh [[for other descriptive term]] Scent • Kills Bacteria and Viruses*
Kills {Select from listed microorganisms}!

**Sanitizes: Kills 99.9% of *Staphylococcus aureus* (Staph) and *Klebsiella pneumoniae* (K. pneumoniae)
on hard, nonporous surfaces in 50 seconds!

For use on hard, non-porous environmental [inanimate] [environmental/inanimate] surfaces in the [your] entire house [household]. Disinfectant Spray "G" kills household germs throughout the entire house plus prevents mold and mildew growth. This effective formulation [formula] doesn't just mask odors, it eliminates them at their source, leaving behind a light fresh {or other descriptive term} scent.

For use on hard, nonporous environmental [inanimate] [environmental/inanimate] surfaces in homes, offices, hospitals, institutions, locker room facilities and food processing plants. [In Kitchens] [Use on] cabinets, counter tops, drain boards, garbage cans, [trash cans], [wastebaskets], microwaves, refrigerators, sinks, and stoves and under sinks; [In Bathrooms] [Use on] basins, closets, counter tops, drains, faucets, garbage cans, [trash cans], [wastebaskets], hampers, mirrors, plastic shower curtains, showers, tiled walls, toilet areas (seats, rims and exterior surfaces) and tubs; [Use] [Use on] chairs, closets, computer[s], counter tops, [camp storage areas], desks, diaper changing tables, diaper pails, door knobs, exercise equipment, faucet handles, filing cabinets, garbage cans, [trash cans,] [wastebaskets,] keyboards, pet areas, plastic baby toys (rinsing required), telephones and work benches. Use in patient rooms, emergency rooms, operating rooms and recovery rooms. Effective on dressing carts, laundry chutes and patient care items.

Kills household germs such as "Staph" and "Strep" as well as athlete's foot fungus on hard, nonporous environmental [inanimate] surfaces. Inhibits mold and mildew growth on hard, nonporous environmental surfaces. Disinfectant Spray "G" can be used as a herpical toilet spray. When used as directed, this formula kills Herpes Simplex Type 2 on hard, nonporous environmental [inanimate] surfaces and toilet areas (seats, rims and exterior surfaces).

{Note: CDPR requires ATCC numbers on market labels}

[Disinfects:] An effective formula that disinfects against all of the following organisms [household germs] on hard, nonporous environmental [inanimate] surfaces [kills household germs and bacteria such as:]		
Bactericidal	Fungicidal	Virucidal*
<ul style="list-style-type: none"> • <i>Escherichia coli</i> (E. coli) [ATCC 11229] • <i>Pseudomonas aeruginosa</i> [ATCC 15442] [Pseudomonas] • <i>Salmonella enterica</i> (Shottmueller) [ATCC 8759] • <i>Salmonella enterica</i> (Salmonella) [ATCC 10708] • <i>Salmonella typhimurium</i> [ATCC 13311] • <i>Shigella dysenteriae</i> [ATCC 9361] • <i>Staphylococcus aureus</i> (MRSA) [ATCC 33592] • <i>Staphylococcus aureus</i> (Staph) [ATCC 6538] • <i>Streptococcus pyogenes</i> (Strep) [ATCC 14289] 	<ul style="list-style-type: none"> • <i>Aspergillus niger</i> [ATCC 6275] [(mold and mildew)] • <i>Trichophyton mentagrophytes</i> [ATCC 9533] (athlete's foot fungus) 	<ul style="list-style-type: none"> • *Avian Influenza virus Type A H9N2 • Herpes Simplex Type 2 [ATCC VR-734] • *Human Immunodeficiency virus (HIV-1) (associated with AIDS) • *Influenza A2/Japan/305 virus [ATCC VR-100] [Flu virus]
	Tuberculocidal	Sanitizer**
	<ul style="list-style-type: none"> • <i>Mycobacterium bovis</i> (BCG) (TB) 	<ul style="list-style-type: none"> • **<i>Staphylococcus aureus</i> (Staph) [ATCC 6538] • **<i>Klebsiella pneumoniae</i> (K. pneumoniae) [ATCC 4352] <p>**Sanitizes: Kills 99.9% of these micro-organisms in 50 seconds.</p>

{Alternate presentation of kill claims:}

[[Disinfects:] An effective formula that disinfects against all of the following organisms on hard, nonporous environmental [inanimate] surfaces [kills household germs and bacteria such as]:

Avian Influenza virus Type A H9N2*, Herpes Simplex Type 2* [ATCC VR-734], *Aspergillus niger* [ATCC 6275] [(mold and mildew)], *Escherichia coli* [ATCC 11229] (E. coli), Human Immunodeficiency virus (HIV-1)* (associated with AIDS), Influenza A2/Japan/305 virus* [ATCC VR-100] [(Flu virus)], *Mycobacterium bovis* (BCG) (TB), Pandemic

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2009 H1N1 Influenza A virus*, Pseudomonas aeruginosa [ATCC 15442] [(Pseudomonas)], Salmonella enterica (Shottmuelleri) [ATCC 8759], Salmonella enterica [ATCC 10708] (Salmonella), Salmonella typhimurium [ATCC 13311], Shigella dysenteriae [ATCC 9361], Staphylococcus aureus (MRSA) [ATCC 33592], Staphylococcus aureus [ATCC 6538] (Staph), Streptococcus pyogenes [ATCC 14289] (Strep) and Trichophyton mentagrophytes [ATCC 9533] (athlete's foot fungus).

**Sanitizes: Kills 99.9% of Staphylococcus aureus [ATCC 6538] (Staph) and Klebsiella pneumoniae [ATCC 4352] (K. pneumoniae) on hard, nonporous surfaces in 50 seconds.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus*. This product, Disinfectant Spray "G", is a broad-spectrum hard surface disinfectant that has been shown to be effective against Avian Influenza virus Type A H9N2* and Influenza A2/Japan/305 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 virus Type A H9N2* and Influenza A2/Japan/305 virus* and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called "swine flu").

[This] product is for use on clean, hard, nonporous environmental [inanimate] surfaces in inedible product processing areas, non-processing areas and/or exterior areas. This product must not result in the direct or indirect contamination of food products. Do not use to mask odors resulting from unsanitary conditions. For disinfection of Avian Influenza A, use this product only for surfaces that are not conducive to treatment by immersion or excess liquid.

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

Application Instructions
SHAKE WELL BEFORE AND DURING USE

Thoroughly clean surfaces or objects prior to application of product. Remove gross filth and heavy soil deposits. [Use scrubber cap to remove hard, grimy deposits.] Safe for use on surfaces [redacted] except polished wood [redacted] or acrylic plastics.

To Disinfect: Spray 6 to 10 inches from clean surface for 3-4 seconds or until surface is thoroughly wet. Allow [redacted] spray to contact treated surfaces for a minimum of 10 minutes prior to wiping. When used in microwaves and refrigerators and on plastic baby toys and food-contact surfaces, rinse treated surfaces with a potable water rinse after the 10-minute contact time.

To Sanitize: Spray 6 to 10 inches from clean surface for 3-4 seconds or until surface is thoroughly wet. Allow [redacted] spray to contact treated surfaces for a minimum of 50 seconds prior to wiping.

For Herpes Simplex Virus Type 2*: Spray 6 to 10 inches from clean surface for 3-4 seconds or until surface is thoroughly wet. Allow [redacted] spray to contact treated surfaces for a minimum of 10 minutes prior to wiping.

For Mold and Mildew: Clean surface then spray surface until thoroughly wet. Repeat weekly.

HIV-1 Precautions: Disinfectant Spray "G" [This product] effectively inactivates HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of the human immunodeficiency virus Type 1 (HIV-1) associated with AIDS. **Special instructions for cleaning and decontamination against HIV-1 of surfaces/objects soiled with blood/body fluids: Personal Protection:** Wear appropriate barrier protection including gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** Allow the surface to remain wet for 10 minutes prior to wiping. **Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids must be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Store at temperatures below 130°F. Keep away from heat or open flame. Non-refillable container; do not reuse or refill this container. Replace cap and discard container in trash. Do not incinerate or puncture.

Batch Code [Lot Number]: See bottom of can.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid

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.
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.
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 1-800-222-1222 XXXX XXXX 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. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Made by
KIK Custom Products, Inc.
1 West Hegeler Lane
Danville, IL 61832-8398

EPA Reg. No. 11525-30
EPA Est. 11525-IL-1^A; 10744-IL-1^B; 11525-RI-1^C; 54487-GA-1^D; 13891-IN-1^E
See bottom of can for code



Contains no CFCs or other known ozone depleting substances
Federal Regulations Prohibit CFC Propellants in Aerosols

PLEASE RECYCLE
WHEN EMPTY



This can is made from an average of 25% recycled Steel (10% post-consumer)
Encourage your local authorities to establish a program to recycle this can.

Questions? Comments?



Call toll-free 1-800-xxx-xxxx

- [] Denotes alternate/optional language
- { } Denotes language that does not appear on the market labeling