

211-32

11/18/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FILE COPY

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 18 2009

Richard Kueser
Regulatory Compliance Director
Central Solutions, Inc.
401 Funston Road
Kansas City, KS 66115

Subject: Notification Application per PR Notice 95-2
Pheno-Cen Spray Disinfectant/Deodorant
EPA Registration Number: 211-32
Application Date: October 23, 2009
Receipt Date: October 26, 2009

Dear Mr. Kueser:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 95-2.

Proposed Notification:

- Addition of Influenza A virus (H1N1) label claim
- Update Storage and Disposal statement per PR Notice 2007-4

General Comment:

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

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)



2078



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 211-32	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pheno-Cen Spray Disinfectant/Deodorant	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) Central Solutions Inc. 401 Funston Road Kansas City, KS 66115 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

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.)

Label revisions; Storage and Disposal statement addition in conformance with PR Notice 2007-4, "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment" and label claim for effectiveness against H1N1 Virus in conformance with Guidance notice dated October 22, 2009.

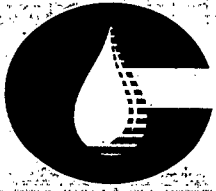
Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10,12,14,16oz		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input checked="" type="checkbox"/> Other silk screened	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Richard Kueser	Title Reg. Compliance Director	Telephone No. (Include Area Code) 913-621-6542
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.		8. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Compliance Director	
4. Typed Name Richard Kueser	5. Date 10-23-09	

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CENTRAL SOLUTIONS, INC.

913.621.6542
1.800.255.0262
Fax: 913.621.7031
401 Funston Rd.
Kansas City, Kansas 66115


Formulation • Development • Production
www.centralsolutions.com

Subject : Notification Amendment
EPA Registration number 211-32
Registered Name: Pheno-Cen Spray Disinfectant/Deodorant

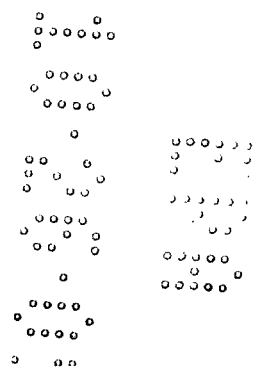
Notification of efficacy claim against H1N1 Virus and Storage and Disposal label change per PR Notice 95-2.

This notification is consistent with the provisions of PR Notice 95-2 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 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 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.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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.


Richard Kueser
Business/Regulatory Compliance Director

10-23-09
Date



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Kansas City, Kansas 66115

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Transmittal Document

1. Name and Address of Submitter: Central Solutions, Inc.
401 Funston Road
Kansas City, KS 66115
2. Product Name: Pheno-Cen Spray Disinfectant/Deodorant
3. EPA Registration Number: 211-32
4. Regulatory Action to Be Taken: Notification: Label Revision – Storage and Disposal statement addition as required by PR Notice 2007-4, "Pesticide Management and Disposal; Standards for Pesticide Containers and Containment"
Notification: Label Revision – Adding label claim for effectiveness against H1N1 Virus in conformance with "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)"
5. Transmittal Date: October 23, 2009
6. List of Submissions:
 - 1) Administrative Materials
 - Transmittal Document
 - EPA Form 8570-1
 - Statement of Compliance with PR Notice 95-2
 - 2) One (1) copy of proposed labeling
7. Company Official: Richard Kueser
- Signature:  Date: 10/23/09
8. Company Name: Central Solutions, Inc.
401 Funston Road
PO Box 15276
Kansas City, KS 66115



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(Front Panel)

Medical Device Uses
510(k) Reviewed

PHENO-CEN SPRAY

NOTIFICATION 11/18/09
Date Reviewed: 11/18/09
Reviewed By: H. Garvie

DISINFECTANT / DEODORANT

Tuberculocidal
Staphylocidal
Bactericidal

Virucidal Against HIV-1 (AIDS Virus)*
Fungicidal **Pseudomonacidal**
Salmonellacidal

ACTIVE INGREDIENTS:

O-Phenylphenol.....0.210%
Ethel Alcohol.....69.623%
INTER INGREDIENTS.....30.167%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

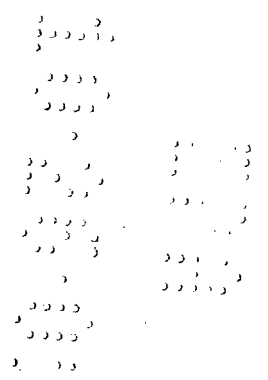
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

CENTRAL SOLUTIONS, Inc.

P.O. BOX 15276
401 FUNSTON ROAD
KANSAS CITY, KS 66115

EPA REG. NO. 211-32
EPA EST. NO. XXX-XX

NET WT: XXOZ. (XXGRAMS)



0018

(Back Panel)

PHENO-CEN SPRAY is a general purpose disinfectant/deodorant that is Bactericidal, Tuberculocidal, Fungicidal, and *Virucidal. **PHENO-SPRAY's** pleasant fragrance keeps air smelling fresh by counter acting objectionable odors.

The broad spectrum germicidal efficacy of **PHENO-CEN SPRAY** has been established, with a ten (10) minute contact time at 25*C, against the following organisms.

BACTERICIDAL: Mycobacterium tuberculosis, Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa.

***VIRUCIDAL:** HIV-1 (AIDS Virus), Herpes Simplex Virus (Type 2), Influenza A2 Virus (Hong Kong), Avian influenza virus, Avian bronchitis virus, Avian laryngotracheitis virus, Hog cholera virus, and Pseudorabies on hard, nonporous, inanimate surfaces.

(Optional copy for claim against H1N1 Virus - Swine Flu)

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. **Pheno-Cen Spray** is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

or

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.

or

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

or

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

or

Kills Pandemic 2009 H1N1 influenza A virus.

FUNGICIDAL: Trichophyton mentagrophytes pathogenic fungi: PHENO-CEN SPRAY can be used to clean and disinfect floors, benches, and other hard, nonporous surfaces commonly found in bathrooms, shower rooms, and locker rooms.

PHENO-CEN SPRAY has been formulated for use on hard, nonporous inanimate surfaces commonly found in areas such as: hospitals, nursing homes, medical and dental offices, blood banks, laboratories, emergency treatment facilities, veterinarian clinics, animal shelters, kennels, ambulance and patient transfer vehicles, police and law enforcement vehicles, prisons and jails, prisoner holding areas, offices, funeral homes, restrooms, hotels, motels, restaurants, schools, day care facilities, hair care shops, and salons.

Handwritten scribbles and marks in the bottom right corner of the page.

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PHENO-CEN SPRAY is an effective disinfectant on hard, nonporous, inanimate surfaces and objects such as walls, floors, sinks, exterior bowl surfaces and exterior surfaces, cabinets, tubs, showers, door handles, light switch covers, bed frames, wheel chairs, IV stands, over bed tables, examination tables and chairs, bassinets, linen carts, medicine carts, hampers, counter tops, telephones, waste containers, lockers, desk, tables, chairs, file cabinets, accessible surfaces of hydro therapy bathing units, patient transfer lifts, clippers, combs, scissors, barber and salon chairs, trays, racks, carts, vehicle door handles, vehicle steering wheels, rubber floor mats, shovels, scrapers, nonporous rubber boots, nonporous rubber shoe covers, and nonporous rubber gloves.

• **Medical Device Uses**

PHENO-CEN SPRAY is a general purpose disinfectant that may be used to clean and reprocess non-critical medical and dental equipment and surfaces. **PHENO-CEN SPRAY** may also be used to prepare or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection. NOTE: 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) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. The product may be used to pre clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Shake well before using.

As a DEODERANT: Hold the can upright, then spray toward the center of the room for 3 to 5 seconds.

As a MILDEW PREVENTATIVE: Spray surface until moist.

As a DISINFECTANT: Thoroughly clean all surfaces with soap or detergent and rinse with water. Hold can upright 6 to 8 inches from surface. Saturate all surfaces with the recommended disinfecting solution, allowing to remain wet for 10 minutes before wiping if wiping is required.

Kills HIV-1(AIDS VIRUS) ON PRE CLEANED ENVIRONMENTAL SURFACE/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUID in health care settings or other settings in which there is an expectant likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surface/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUID.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use appropriate barrier protection such as disposable latex gloves, gowns, mask, or eye coverings.

CLEANING PROCEDURE: Blood or other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

CONTACT TIME: 10 minutes

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.

DO NOT USE ON POLISHED WOOD FURNITURE OR RAYON FABRICS.



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Administrative Note: The following text is required on all labeling)

**PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS**

WARNING

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin and clothing. Wash hand before eating, drinking, chewing gum, using tobacco, or using the toilet. If on clothing remove contaminated clothing and wash before reuse.

FIRST AID

If in eyes	<ul style="list-style-type: none"> • Hold eyes 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 eyes. • Call a poison control center or doctor for treatment for further advice.
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 further treatment advice

HOTLINE NUMBER

In case of emergency, call your local Poison Control Center or doctor. Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

(Administrative Note: The First Aid Statement's 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 smoke while using this product. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting,

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Pesticide Storage: Store in a cool, dry place away from heat or open flame.

Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

(Administrative Note: The following text is required for labels only on containers being sold and/or distributed in California)

NOTICE: California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals.

(Administrative Note: The following text is optional for containers destined for pharmaceutical or biotechnology clean room markets).

(Front Panel): Product and container sterilized and distributed by:
Sterile Pharmaceutical Clean Room Formula

(Back Panel):

PHENO-CEN SPRAY is recommended for use by pharmaceutical and biotechnology industries, medical device manufactures, hospitals and health care institutions that are dedicated to controlling hazards of cross contamination in their establishments. For use on hard, inanimate surfaces in aseptic filling and gowning rooms general manufacturing areas on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, porcelain, glass and chrome.