

211-32

02-19-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 19 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Melissa Schnake, Agent for
Central Solutions, Inc.
3130 Brinkerhoff Road
Kansas City, KS 66115

Subject: Pheno-Cen Spray
EPA Registration Number: 211-32
Application Date: July 10, 2009
Receipt Date: July 21, 2009

Dear Ms. Schnake:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment:

Add Methicillin- Resistant Staphylococcus aureus MRSA claim

Data Summary

Data Requirement	Means of Support	Status
AOAC Germicidal Spray Method- MRSA	Submitted study, MRID 47873502	Acceptable, RTU with 10 minute contact time.

General Comments

A stamped accepted label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have further questions concerning this letter, please contact me at 703-308-6416 of 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,

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

SYMBOL						
SURNAME						
DATE						

(Front Panel)

Medical Device Uses
510(k) Reviewed

PHENO-CEN SPRAY

DISINFECTANT /DEODORANT

**Tuberculocidal
Staphylocidal
Bactericidal**

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

ACTIVE INGREDIENTS:

O-Phenylphenol.....0.210%
Ethyl Alcohol.....69.623%
INERT INGREDIENTS.....30.167%
TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

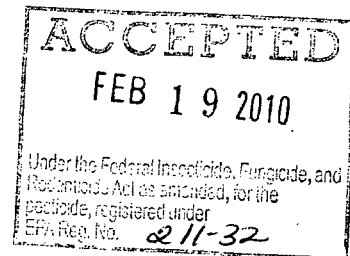
WARNING

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)

(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, Pseudomonas aeruginosa, and Methicillin-Resistant Staphylococcus Aureus (MRSA).

***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.

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.

To Disinfect Veterinary Clinics, Animal Shelters, and Kennels: Remove all animals and feed from premises, vehicles, cages, kennels, etc.

Remove all litter, droppings, and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Empty all feeding and water appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Hold container upright about 6-8" from surface. Spray to thoroughly wet hard, nonporous surfaces. Treated surfaces must remain wet for 10 minutes. Allow to air dry. Immerse all halters, collars, leashes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, vehicles, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub feeding and watering equipment with soap or detergent, and rinse with potable water before reuse.

- **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.

To Clean/Deodorize: Hold can 6-8 inches from surface. Spray surfaces. Then wipe.

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 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, and 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 must 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 of 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	
<p>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.</p>	

(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. Store in a cool, dry place away from heat or open flame. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If not, 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 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, glazed porcelain, glass and chrome.