

PM 34

211-32

3-26-98

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 26 1998

Central Solutions, Inc
3130 Brinkerhoff Road
P O Box 15276
Kansas City, Kansas 66115

Attention c/o Olivia Laird - Laird's Regulatory Consultant
c/o Paul Nobrega
Director, Regulatory Affairs

Subject Pheno-Cen Spray Disinfectant Deodorant
EPA Registration Number 211-32
Agency's letter dated November 18, 1997
Your Letter Dated December 30, 1997

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable provided that you include the following statements on your proposed labeling dated December 30, 1997

Under the heading "NOTE", revise the statement, "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" to read, "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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection" A copy of our Efficacy Evaluation review dated March 21, 1998 is enclosed for your records

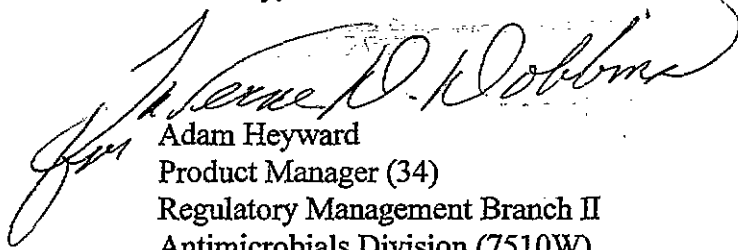
A stamped copy is enclosed for your records One copy of the finished labeling must be submitted prior to releasing the product for shipment

CONCURRENCES

SYMBOL	<i>[Signature]</i>					
SURNAME	<i>[Signature]</i>					
DATE	3/26/98					

If you have any further questions, please contact LaVerne Dobbins at (703) 6378.

Sincerely,

A handwritten signature in cursive script, appearing to read "Adam Heyward".

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:

cc: Olivia Laird
Laird's Regulatory Consultant

3015

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 26 1998

(front panel)

• Medical Device Uses
510(k) Reviewed

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

211-32

PHENO-CEN SPRAY

DISINFECTANT / DEODORANT

Tuberculocidal	*Virucidal
Staphylocidal	Fungicidal
Pseudomonacidal	Bactericidal
Salmonellacidal	

ACTIVE INGREDIENTS:

o-Phenylphenol	0.21%
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
3130 BRINKERHOFF ROAD
KANSAS CITY, KS 66115

EPA REG. NO. 211-32
EPA EST. NO. 11694-KS-1

NET WT: 16 OZ. (454 GRAMS)

MAR 26 1998

405

(Back Panel) Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,

registered under EPA Reg. No. 211-32
and "Virucidal."

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

The broad spectrum germicidal efficacy of **PHENO-CEN SPRAY** has been established, with a ten (10) minute contact time @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 virus on hard, nonporous, inanimate surfaces.

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, locker rooms, and other areas and surfaces frequently contacted by bare feet.

PHENO-CEN SPRAY has been formulated for use on hard, nonporous, inanimate surfaces commonly found in facilities and areas such as: hospitals, nursing homes, medical and dental offices, blood banks, laboratories, emergency treatment facilities, veterinary 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, other institutions and industrial facilities that need to control the hazards of cross contamination.

PHENO-CEN SPRAY is an effective disinfectant on hard, nonporous, inanimate surfaces and objects such as walls, floors, sinks, exterior bowl surfaces and exterior urinal surfaces, cabinets, tubs, showers, door handles, light switch covers, bed frames, wheelchairs, IV stands, over-bed tables, examination tables and chairs, bassinets, linen carts, medicine carts, hampers, counter tops, telephones, waste containers, lockers, desks, tables, chairs, file cabinets, accessible surfaces of hydrotherapy 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.

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 DEODORANT: 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 the can upright 6 to 8 inches from the 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 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/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 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: 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

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING

Avoid contact with skin, eyes, or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. Avoid contamination of food.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperature above 130°F may cause bursting.

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry area away from heat or open flame.

DISPOSAL: Pesticide: Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container: Replace cap and discard in trash. Do not incinerate or puncture.

5045

(Alternative Text for Back Panel)

[Statements to be added only to labels of containers destined for aseptic controlled environments (clean rooms)]

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 the 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 26 1998

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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211-32

