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ACCEPTED

JUL 2 9 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 211-32

(front panel)

 Medical Device Uses 510(k) Reviewed

# PHENO-CEN SPRAY

### DISINFECTANT / DEODORANT

Tuberculocidal Staphylocidal Pseudomonacidal Salmonellacidal Virucidal Against HIV-1 (AIDS Virus)\* Fungicidal Bactericidal

**ACTIVE INGREDIENTS:** 

## WARNING

SEE BACK PANEL FOR ADDITIONAL PRECATIONARY STATEMENTS

Central Solutions, Inc.

EPA REG. NO. 211-32 EPA EST. NO. 11694-KS-1 P.O. BOX 15276

3130 BRINKERHOFF ROAD. KANSAS CITY, KS 66115:

NET WT: 16 OZ. (454 GRAMS)\*

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#### (Back Panel)

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 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 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, and locker rooms.

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.

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. The product may be used to preclean 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 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, alllowing 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





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

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### WARNING

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

	FIRST AID
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
	HOTLINE NUMBER

In case of emergency, call your local poison control center or a 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 use)

#### 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.

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 the hazards of cross contamination in their establishments. For use on hard, inanimate surfaces in aseptic filling and gowning general manufacturing areas on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, porcelain, glass and chrome.

