

PM 31 211-63

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Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
220125

Application for Pesticide - Section I

1. Company/Product Number 211-63	2. EPA Product Manager Marion J. Johnson, Jr.	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Pro-Tech Disinfectant Cleaner	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Central Solutions, Inc. P.O. Box 15276 3130 Brinkerhoff Rd. Kansas City, KS 66115 <input 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: 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. NOV 6 1996
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of Addition of Indoor, Nonfood Sites for Antimicrobial Product. This notification is consistent w/ the provision of PR Notice 95-2 & EPA Regs at 40 CFR 152.46 & no other changes have been made to the labeling or the CSF of the product. I understand that it's a violation of 18 USC Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification isn't consistent w/ PR 95-2 & 40 CFR 152.46, this product may be in violation of FIFRA & I may be subject to enforcement action & penalties under sect. 12 & 14 Section - III of FIFRA.

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input 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	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1,2,4,8,16 32 64 oz.; 5,6,15,30,55 gal bulk	5. Location of Label Directions on label
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6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled	<input checked="" type="checkbox"/> Other silk-screened; sleeve labels
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Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Paul Nobrega	Title Director, Regulatory Affairs	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.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Director, Regulatory Affairs
4. Typed Name Paul J. Nobrega	5. Date 10-25-96

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(front panel)

- Medical Device Uses
510(K) Reviewed

PRO-TECH

TUBERCULOCIDAL DISINFECTANT CLEANER

NOTIFICATION

READY TO USE

BACTERICIDE • FUNGICIDE • *VIRUCIDE • MILDEWSTAT • DEODORIZER

Effective in the presence of organic soil (5% blood serum)

Active Ingredients:

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) dimethyl benzyl ammonium chlorides105%

n-Alkyl (68% C₁₂, 32% C₁₄) dimethyl ethylbenzyl ammonium chlorides105%

Inactive Ingredients: 99.79%

KEEP OUT OF THE REACH OF CHILDREN

WARNING

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS



CENTRAL SOLUTIONS, INC.

P.O. BOX 15276
KANSAS CITY, KANSAS 66115

EPA REG. NO. 211-63
EPA EST. NO. 211-KS-1

NET CONTENTS
1 Quart

REORDER NO. 17054
(REV. 10/25/96)

(back panel)

DIRECTIONS FOR USE

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

PRO-TECH is a general purpose disinfectant cleaner for use in hospitals, nursing homes, blood banks, medical & dental clinics, laboratories, emergency rooms, ambulances & patient transfer vehicles, police vehicles, prisons & jails, funeral homes, hotels, motels, restaurants, schools, day care facilities, offices, veterinary clinics, animal shelters, kennels, restrooms, and other facilities that need to control microbial contamination.

PRO-TECH may be used in kitchens and dining rooms on counters, sinks, cabinets, appliances, stove tops, exhaust hoods, tables, and chairs.

Do not use on eating utensils, plates, glasses or other food contact surfaces unless followed by a potable water rinse.

PRO-TECH is formulated to clean and disinfect hard, non-porous, inanimate environmental surfaces and objects such as walls, floors, sinks, toilets, urinals, cabinets, tubs, showers, door handles, light switch covers, bed frames, wheelchairs, IV stands, over-bed tables, examination tables and chairs, linen and medicine carts, counter tops, telephones, bassinets, waste containers, lockers, desks, tables, chairs, file cabinets, and other medical and dental equipment.

- **Medical Device Uses**

PRO-TECH is a general purpose disinfectant cleaner that may be used to clean and reprocess non-critical medical and dental equipment and surfaces. **PRO-TECH** may also be used to preclean 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.

PRO-TECH when used as a READY-TO-USE spray and wipe cleaner or as a 10 minute disinfectant cleaner may be used on surfaces, materials, and components such as:

Metals: Stainless Steel, Chrome Plated Steel, Brass, Copper, & Aluminum)

Plastics: Fiberglas™, Formica™, Nylon, ABS, Acrylics and Vinyl

Porcelain, Glass, & Ceramic Tile

Enamel & Epoxy Painted Surfaces

Vinyl, Rubber, Terrazzo, Marble, Quarry Tile Floor Surfaces

Other surfaces not harmed by water based cleaners.

*Caution: Use on floor finish, latex paint, vinyl, Lexan™, or Plexiglas™ may cause softening, hazing, or other harmful effects with repeated or long exposures.

(back panel continued)

DIRECTIONS FOR USE continued

DISINFECTION, CLEANING, AND DEODORIZING: Remove heavy soil or organic material from the surface. Hold the container six to eight inches above the surface and spray area until thoroughly wet with the product. For disinfection allow to remain wet for **10 minutes** then wipe clean with a clean cloth or sponge.

Cleaning and Disinfection of Toilets and Urinals: Remove water from toilet bowl and urinal by forcing water over the trap with a bowl swap. Press bowl swab against side of the bowl or urinal to remove excess water from the applicator. Spray product evenly and thoroughly covering entire exterior and interior surface of bowl or urinal. Swab or brush the interior surface of the fixture thoroughly, making sure to get under the rim. For disinfection allow to stand for 10 minutes then flush and wipe exterior surfaces with a cloth or sponge.

EFFICACY PERFORMANCE: The broad spectrum efficacy of PRO-TECH as a bactericide, fungicide, and virucide* on hard, non-porous, inanimate surfaces has been confirmed in the presence of 5% blood serum (used to simulate organic soil load) at 20°C with a 10 minute contact time.

BACTERICIDAL ACTIVITY has been confirmed against: *Mycobacterium tuberculosis* (BCG), *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*, meeting the requirements for hospital use.

FUNGICIDAL ACTIVITY has been confirmed against the pathogenic fungi, *Trichophyton mentagrophytes* (Athletes Foot Fungus).

***VIRUCIDAL ACTIVITY** has been tested against the HIV-1 virus (associated with AIDS) and Canine Parvovirus.

KILLS HIV-1 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 likely to be soiled with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or 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-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable gloves, gown, masks, or eye protection.

CLEANING PROCEDURES: Blood and other fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface and objects to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

WARNING

Keep out of reach of children. Causes eye and skin irritation. Do not get in eyes on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

If **IN EYES** or **ON SKIN**, flush with plenty of water for 15 minutes.
If **SWALLOWED**, drink egg whites, gelatin solution or large quantities of water.
Consult a physician when swallowed or if irritation occurs or persists.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

CONTAINER DISPOSAL: Do not reuse container. Rinse thoroughly before discarding in trash.

STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F.