

211-63

5-22-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY 22 2003

Bob MacDonald
Agent for Central Solutions, Inc.
Central Solutions, Inc.
3130 Brinkerhoff Road
Kansas City, KS 66115

Subject: PRO-TECH Disinfectant Cleaner
EPA Registration No. 211-63
Application Date: February 24, 2003
EPA Received Date: February 27, 2003

Dear Mr. MacDonald:

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

Proposed Amendment

- Revised labeling in response to Agency letter dated January 9, 2003

General Comments

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

Should you have any questions or comments concerning this letter, please contact me at 703-308-6345.

Sincerely,
Joseph L. Noble
Velma Noble
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510 C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	Schay						
DATE	5-12-03						

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(front panel)

PRO-TECH

**DISINFECTANT CLEANER
DETERGENT DISINFECTANT**

TUBERCULOCIDAL - READY TO USE

**BACTERICIDE – FUNGICIDE – MILDEWSTAT – DEODORIZER
CLEANER – DISINFECTANT - FUNGICIDE (against pathogenic fungi) - *VIRUCIDAL**

Effective Bactericide, Fungicide, and Virucide* in the presence of organic soil (5% blood serum)

**Non-Critical Medical Device Uses

Ready-To-Use on Stainless Steel and Other Hard, Non-Porous Surfaces
Effective Against Canine Parvovirus

Active Ingredients:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	0.105%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	0.105%
Other Ingredients:	99.790%
	Total: 100.000%

KEEP OUT OF REACH OF CHILDREN

WARNING

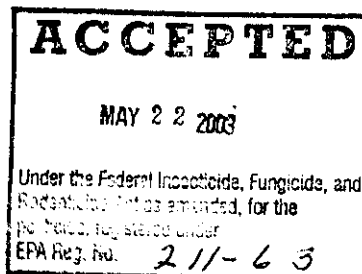
SEE BACK/SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Central Solutions, Inc.

P.O. Box 15276
Kansas City, KS 66115

Net Contents: ()

EPA Reg. No. 211-63
EPA Est. No. 211-KS-1



(back panel – required)

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. Wear protective eyewear. Harmful if swallowed. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with plenty of water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment 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 treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
HOTLINE NUMBER	
For emergency medical advice, call your local poison control center or a doctor Have the product container or label with you when seeking medical advice or treatment.	
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

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

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

("Container Disposal" text for containers ≤ one (1) gallon):

CONTAINER DISPOSAL: Do not reuse empty container. Wrap container and put in trash.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest Regional Office for guidance.

("Environmental Hazards" text for containers ≥ five (5) gallons):

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. This product is toxic to fish and aquatic organisms.

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 degrees C with a 10 minute contact time.

BACTERICIDAL ACTIVITY: When used as directed, this product exhibits effective disinfectant activity against the organisms *Mycobacterium bovis* (BCG) at 20 degrees C, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* (meeting the requirements for hospital use), *Escherichia coli*.

FUNGICIDAL ACTIVITY: This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus) when used as directed on hard surfaces in areas such as dressing rooms, locker room benches, shower room floors, bath mats, and exercise facilities.

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard, non-porous surfaces, spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

***VIRUCIDAL ACTIVITY:** This product, when used on environmental, inanimate, non-porous surfaces, exhibits effective activity against Hepatitis B Virus (HBV), HIV-1 (associated with AIDS), Poliovirus Type 1 and Canine Parvo Virus.

KILLS HIV-1 AND HBV 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 or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS) and Hepatitis B Virus (HBV).

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 latex gloves, gowns, 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 Federal, State, and local regulations for infectious disposal.

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DIRECTIONS FOR USE

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

PRO-TECH is designed as a general cleaner and disinfectant for use in nursing homes, hospitals, schools, hotels, and homes. It is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as walls, sink tops, table, chairs, telephones, glazed ceramic tile in bathrooms, shower stalls, and bathtubs, cabinets, and bed springs.

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 the hazards of microbial cross contamination.

PRO-TECH may be used in kitchens and dining rooms on counters, sinks, cabinets, appliances, stove tops, exhaust hoods, tables, and chairs. When using **PRO-TECH** as a disinfectant on hard, non-porous food contact surfaces such as kitchen counters, sinks, kitchen & dining room tables, and appliances, thoroughly rinse all wetted and cleaned surfaces with potable (tap) water. This product should not be used to clean silverware, glassware, and dishes.

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 non-critical medical and dental equipment.

PRO-TECH is a general purpose disinfectant cleaner for use in veterinary clinics, animal shelters, kennels, and other facilities that need to control microbial contamination.

PRO-TECH is a general purpose disinfectant cleaner formulated to clean and disinfect hard, non-porous, inanimate objects such as tables, chairs, counter tops, sinks, and floors, stations, footbaths and surfaces such as stainless steel, Formica™, glazed porcelain, glass, glazed ceramic tile, most plastics, and other surfaces not harmed by water-based cleaners. **PRO-TECH** is effective against a broad spectrum of bacteria, is virucidal*, fungicidal, and controls the growth of mold and mildew and their odors, when used as directed.

****Non-Critical Medical Device Uses:** This product is a general purpose disinfectant cleaner that may be used to clean and reprocess non-critical medical and dental equipment and surfaces.

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 penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may also be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

PRO-TECH when used as a ready-to-use spray and wipe cleaner or as a 10 minute disinfectant cleaner may be used on hard, nonporous surfaces, materials, and components such as:

Metals: Stainless Steel, Chrome Plated Steel, Brass, Copper, and Aluminum

Plastics: Fiberglass™, Formica™, Nylon, ABS, Acrylics, and Vinyl;

Glazed Porcelain, Glass, & Glazed Ceramic Tile; Enamel & Epoxy Painted Surfaces; Vinyl, Rubber, Terrazzo, Marble, Glazed Quarry Tile Surfaces; and other surfaces not harmed by water based cleaners.

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

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

(OR)

DISINFECTION, CLEANING, AND DEODORIZING: Remove gross filth or heavy soil prior to application of the product. Hold container six to eight inches above the surface to be treated. Spray area until it is covered with the solution. Allow product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop, or sponge. This product will not leave grit or soap scum.

Cleaning and Disinfection of Toilets and Urinals: Remove water from toilet bowl and urinal by forcing water over the trap with a bowl swab. 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 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.

Vehicles (For general purpose disinfectant and cleaning of hard, non-porous, inanimate environmental surfaces): Remove heavy soil or organic material from the surface. Hold container six to eight inches above the surface and spray area until thoroughly wet with product. For disinfection, allow to remain wet for 10 minutes, then wipe clean with a clean cloth or sponge.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS

DISINFECTANT DIRECTIONS: For cleaning and disinfecting the following hard non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with product, spraying surface and allow it to remain wet for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Text in (..) and italicized is in explanation of labeling panels alternate container sizes etc. It will not appear in actual labeling.