44446-67

2006/10/2002

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OCT 29 2002

Mr. Bill Schmidt Product Manager Quest Chemical Corporation 12255 FM 529 Houston, TX 77041

Subject:

Concept Hospital Disinfectant Deodorant

EPA Registration Number 44446-67 Application Dated September 6, 2002

Dear Mr. Schmidt:

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

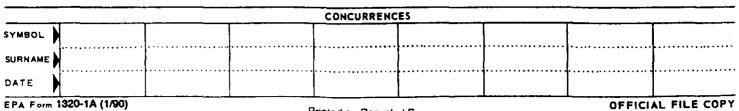
Proposed Amendment:

revised First Aid statement PR Notice 2001-1

General Comments:

In accordance with PR Notice 94-4, the following paragraph must be added to the label.

"This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into 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."



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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely

Adam Heyward

Product Manager (34)

Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosure

Virucidal* • Tuberculocidal
Fungicidal • Bactericidal
Pseudomonicidal • Staphylocidal
Sanitizes Fabric and Leather
Controls Mold/Mildew Fungi
(Specific species/agents listed on backpanel.)

DEODORANT

HOSPITAL-USE AND BROAD-SPECTRUM DISINFECTANT AND ANTIMICROBIAL AGENT

KILLS HIV-1 (AIDS VIRUS) AND HERPES SIMPLEX TYPES 1 & 2 VIRUSES ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS.

FOR USE ON PRECLEANED, HARD, NONPOROUS, NONFOOD-CONTACT SURFACES IN/ON INDUSTRIAL, INSTITUTIONAL, COMMERCIAL, MEDICAL, AND RESIDENTIAL FACILITIES, EQUIPMENT, AND VEHICLES.

Authorized by USDA for use in Federally inspected meat and poultry plants.

ACTIVE INGREDIENTS: 2-Phenylphenol		ć
4-tert-Amylphenol	0.0465	ί
Ethanol	53.0009	6
INERT INGREDIENTS	46.7559	Ĺ
TOTAL	7	6
EPA Reg. No. 44446-6	7 EPA Est. No. 44446-TX-1	

NET WT. 16.5 OZ. (468 g)

KEEP OUT OF REACH OF CHILDREN

SEE ADDITIONAL PRECAUTIONARY AND FIRST AID STATEMENTS ON BACK PANEL.

MANUFACTURED BY:
QUEST CHEMICAL CORPORATION
HOUSTON, TX 77041

FE ES, CLAIMS, AND USES

An excellen. Infectent, antimicrobial agent and two-way deodorizer for use on pre-cleaned, hard, nonporous surfaces, including toilets, urinals, bath-tubs, shower stalls, seats, benches, lockers, partitions, counters, fixtures, knobs, handles, railings, telephones, furniture, equipment and many other similar public and private items and surfaces which could harbor hazardous microorganisms.

VIRUCIDAL* - kills Human Immunodeficiency virus Type 1 (HIV-1; a retrovirus that causes *AIDS* (Acquired Immune Deficiency Syndromel), Herpes simplex Types 3 and 2, Influenza A2/Hong Kong, Adenovirus Type 5, Vaccinia, Infectious canine hepatitis, Canine distemper, and Feline pneumonitis.

BACTERICIDAL - kills Escherichia coli, Pseudomonas aeruginosa, Salmonella choleraesuis, Salmonella schottmuelleri (paratyphoid B), Shigella dysenteriae, Staphylococcus aureus, and Streptococcus pyogenes.

TUBERCULOCIDAL - kills Mycobacterium tuberculosis (Tubercle bacilli).

FUNGICIDAL - kills Trichophyton mentagrophytes ("athlete's foot" fungi; formerly T. interdigitale) in appropriate areas, such as on shower room floors, locker room benches and bath mats.

CONTROLS MOLD/MILDEW - completely inhibits the growth of Aspergillus niger and Penicillium variable fungi on cloth.

SANITIZES - controls Staphylococcus aureus and Klebsiella pneumoniae on porous fabric and leather surfaces, such as on shoes, athletic mets, athletic shoes and other athletic equipment:

DEODORIZES TWO WAYS - plassant fragrance quickly suppresses existing unpleasant odors from many sources. Controls microorganisms that could continue to create foul putrefactive odors.

FOR USE IN: Industrial, Institutional, Commercial, Medical, and Residential facilities, equipment, and vehicles, including hospitals; ambulances; nusterinary offices and dental offices and clinics; veterinary offices and animal areas; schools; laboratories; hotels and motels; restaurants and cafeterias; food storage, processing, packaging, handling, and serving establishments and equipment; offices; stores; factories and manufacturing plants; and apartment buildings and homes.

FOR USE ON: Most glass, porcelain, ceramic, enemeled, painted, plastic (such as ABS, acrylic, latex rubber, phenolic rasin, polyamide, polycarbonate, polyester, polyethylene, polyclefin, polypropylene, polystyrene, polytetrafluorethylene, polyurethane, and vinyl), rubber, metal, sealed leather, wood, grout, and concrete, and similar nonporous surfaces.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes eye irritation; do not get in eyes, on skin, or on clothing. May be harmful if swallowed. Avoid breathing spray mist or vapors.

if inhaled:

- 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.

If on skin or clothing:

- . 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 in eyes:

- Hold eye 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 eye.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vorniting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when celling a poison control center or doctor, or going for treatment.

PHYSIGAL/CHEMICAL HAZARDS: Flammable. Contents under pressure. Keep away from heat, sparks, pilot lights, and flames. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

DIRECTIONS FOR USE

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

GENERAL: Shake container well before each use and hold it upright while spraying. For use on precleaned, hard nonporous surfaces; not for use on humans or animals. Do not contaminate foods/drinks/feeds. Not recommended for use on waxed/polished surfaces, water-based "latex" paint, shellac, cellulose (such as rayon) or other alcohol-sensitive materials.

TO KILL HIV-1 (Human Immunodeficiency virus Type 1; AIDS virus) ON PRECLEANED SURFACES/OBJECTS in health care or other settings with inanimate environmental surfaces/objects associated with the potential for transmission of HIV-1 and likely to be soiled with blood/body fluids, follow these additional SPE-CIAL INSTRUCTIONS FOR CLEANING AND DECON-TAMINATING AGAINST HIV-1 ON SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PER-SONAL PROTECTION - Barrier protection items such as disposable latex gloves, gowns, masks, and eye coverings should be worn when handling items soiled with blood/body fluids. CLEANING PROCEDURE - Blood/ body fluids must be thoroughly cleaned from surfaces/ objects before application of this product as a disinfectant, CONTACT TIME - Same as for disinfecting, DIS-

POSAL OF INFECTIOUS MATERIALS - Blood/body fluids and other materials removed from or used to clean surfaces/objects should be autoclayed and disposed of according to federal, state and local regulations for infectious waste disposal.

FOR DISINFECTING, MILDEW CONTROL, SANITIZING, AND DEODORIZING OF CLEAN, NON-FOOD CONTACT SURFACES: Hold container upright about 6 to 8" (1/5 m) from surface and spray until target area is thoroughly wetted. Complete disinfection and tuberculocidal activity require a contact time of 10 minutes at approximately 68" (20°C). Sanitization requires a 5 minute contact time at about 72" f (22°C). For mildew control, repeat application when necessary.

TO DEODORIZE AND FRESHEN ROOM AIR: Spray upward toward center and comers of room, keeping spray opening at least 3 ft. (1m) from surfaces.

STORAGE AND DISPOSAL

GENERAL: Do not contaminate other materials (including foods/drinks/feeds/water) during transport, use, storage, and disposal. If damaged or leaking, soak up and wrap any waste, then dispose of as below.

STORAGE: Keep in a cool, dry, locked area inaccessible to children and away from sources of heat and ignition (including flames, sparks, hot surfaces, and sunlight).

DISPOSAL: Refasten protective cap on container, securely wrap in several layers of newspaper and discard in trash. Do not incinerate or puncture.

INGREDIENTS (CAS#): Ethyl Alcohol (64-17-5), Water (7732-18-5), Propane/n-Butane (68476-86-8).

HMIS Ratings: Health - 1, Flammability - 3, Reactivity - 1, Personal Protection - A.

NOTE: Section below includes optional/additional claims that can be made for product.

FEATURES, CLAIMS, AND USES

This unique product was issued U.S. Patent No. 3,832,459.

- No mixing ... comes ready-to-use ... instantly!
- . Won't spill, evaporate, or become contaminated.
- Sprays on ... hands never touch hazardous contaminated surfaces.
- Leaves surfaces thoroughly disinfected and deodorized.
- Kills the viruses that cause AIDS, genital Herpes, and Hong Kong Flu.
- Documented germicidal activity ... kills Staph, Strep, TB, and other listed bacteria and fungi.
- . Kills fungi that cause "Athlete's Foot".
- . Controls fungi that cause mold/mildew.
- Has dual-mode, long-lasting deodorizing action.
- Does not affect sense of smell (will not cause anosmia).
- Destroys microorganism-caused putrefactive
- Attacks chemical malodors at the molecular level.

READY-TO-USE MICRO-MIST HIGH-SOLVENT SPRAY wets surfaces thoroughly and penetrates into cracks and crevices that many low-solvent liquids cannot reach. Dries quickly; leaves no stains.

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This convenient, pressurized, pleasant, hospital-use and broad-spectrum disinfectant and antimicrobial agent disinfects and deodorizes surfaces after a 10 minute exposure time. Eliminates dilution errors, product contamination, and other problems common to non-pressurized products and those that require dilution and mixing.

VIRUCIDAL" - killa these agents: Adonotiruo Type 5 (on adenovirus that couses a type of "tonsilitis" and may allect the adenoids): Canine distemper (a myxovirus that causes "distemper" in doos: reline oneumonitis (a Chlamydia psittaci that affects the lungs of cats): Herpes simplex Type 1 (a herpes virus that causes "cold sores" and π av affart the brain): Heroes simplex Type 2 to herpes virus that causes genital lesions and may effect the brain); Human immunodeficiency virus 'vpa 1 (HIV-1; a recrovirus that causes "AIDS" (Acquired Immune Deficiency Syndrome). which destroys the hody's ability to fight diseasel: Infectious canine hepatitis (an adenovirus that causes a type of hepatitis in dogs); Influenza A2/Hong Kong (a myxovirus typical of many that cause "flu"); and Vaccinia (a poxvirus that causes "cowpox").

BACTERICIDAL – kills these species: Escherichia coli; Pseudomonas aeruginosa; Salmonella choleraesuis; Salmonella schottmuelleri (paratyphoid B); Shigella dysenteriae; Staphylococcus aureus; and Streptococcus pyogenes.

TUBERCULOCIDAL - kills Mycobacterium tuberculosis (var. bovis [8CG]; Tubercle bacilli).

FUNGICIDAL – kills Trichophyton mentagrophytes ('athlete's foot' fung; formerly T. interdigitale) in appropriate areas, such as on shower room floors, locker room benches, and bath mats.

CONTROLS MOLD/MILDEW - completely inhibits the growth of Aspergillus niger and Penicillium variabile fungi on cloth.

SANITIZES NONFOOD-CONTACT SURFACES - controls Staphylococcus aureus and Klebsiella pneumoniae on fabric and leather. Effective in the presence of 5% organic soil. For use on shoes, athletic mats, athletic shoes, other athletic equipment, and on similar items with porous fabric and leather surfaces. Sanitizes against odor-causing organisms on most porous surfaces.

TWO-WAY SURFACE/SPACE DECODRIZING ACTION: Its fresh, pleasant scent acts quickly and remains effective for long periods on unpleasant odors from many sources. Quickly counteracts "CHEMICAL" MALDORS such as garlic, onion, tobacco smoke, stale odors, musty smells, fish, gas, and urine; in kitchens, bathrooms, basements, and many other occasionally malodorous, unpleasant areas and situations. Controls many odor-causing microorganisms that generate the "BIOLOGICAL" MALODORS associated with surgical drassings, estomy pouches (post-colestomy/post-lieostomy dressings and bags), malignant disasses, excised organs and tissue, fecal matter, burns, perspiration, mold/mildew, garbage, and other decaying, putrefying organic matter.

AIR DEODORIZING ACTION: It is also a nonspecific odor suppressant for space odor conditioning. Molecular deodorant attacks melodors at the source. Suppresses and eliminates odors by chemically neutralizing odor producing materials. Does not cause anosmia.

IN MEDICAL FACILITIES

This full-strength product has been used successfully for many years in hospitals and other medical facilities to help control the hazard of cross-contamination on hard surfaces in operating and delivery rooms, obstetric wards, and other critical patient care areas.

IN HOMES AND APARTMENTS

Now you can use this same product for household areas, such as in homes, apartments, cars, vans, trucks, boats, campers, garages, and storage buildings; on and around toilet seats, sinks, bathrubs, shower stalls, telephones, diaper pails, trash compactors, garbage cans, and pet areas; wherever contaminated areas and odor-causing bacteria are a problem.

DESTROYS ODORS ... LEAVES A PLEASANT, NATU-RAL, FRESH SCENT: Acts quickly to eliminate (not just "cover up") cooking, bathroom, sickroom, and pet odors. Refreshens smoke-fouled rooms and fabrics. Unlike ordinary "air fresheners", it stops many odors at their source by killing odor-causing bacteria and fungi in empty trash compactors, garbage and diaper pails, and hampers; in toilet areas and damp basements: under sinks: and in similar malodorous areas.

PREVENTS MOLD/MILDEW: Fungicidal ingredients will effectively control mold/mildew and odors when applied to precleaned, hard, nonporous surfaces. Use in besements, attics, closets, leundry rooms, and storage areas. Also spray on color-fast, non-rayon items such as books, shower curtains, and shoes.

IN DENTAL FACILITIES

This effective hospital-use product disinfects and deodorizes precleaned, nonporous, inanimate surfaces on furniture, equipment, and other items, in dental facilities, including public and private area surfaces which could harbor hazardous microorganisms. Use this product to disinfect and deodorize these and many other locations in dental areas. Reduces the hazard of cross-contamination between

USE LOCATIONS, AREAS, ITEMS AND SURFACES For use in areas and on hard, nonporous, precleaned nonfood-contact surfaces not damaged by alcohol, such as the following:

LOCATIONS - Public/Private Industrial, Institutional, Commercial, Medical and Residential facilities, premises, buildings, equipment, and vehicles, such as hospitals, nursing homes, medical and dental offices and clinics, doctor's and dentist's offices, veterinary offices and animal hospitals; pet boarding facilities, household pet quarters, and zoos; schools; laboratories; auditoriums and stadiums; hotels and motels; restaurants and cafetarias; athletic and health clubs; night clubs, discos, bars, and taverns; markets, supermarkets and stores; food storage, processing, packaging, handling, and serving establishments and equipment; food processing plants, bakeries, bottling plants, and canneries; offices and office complexes; factories and manufacturing plants; laundries and dry cleaners; morgues, mortuaries, funeral homes, mausoleums, and burial vaults; apartment buildings and homes; loading ramps; autos, vans, minivans, pickups, motorcycles, motorbikes, bicycles, recreational vehicles, and boats; campers, trailers, and mobile homes; taxis, buses, trains, and public transportation; ambulances, police car- vans, fire cars and trucks, and other emergency les; trucks, trailers.

and tankers; garbage trucks and waste haulers; railroad engines and cars; aircraft; ships/barges; containerized units; shipping containers; and dispensing and vending equipment.

AREAS – Bathrooms, kitchens, bedrooms, dining rooms, living rooms, recreation rooms, family rooms, atriums, laundry rooms, nurseries, closets, storage rooms, basements, cellars, attics, garages, sheds, outbuildings, doghouses, and pet quarters; operating rooms, wards, sickrooms, nurseries, labs, lounges, lobbies, and ambulances; embalming rooms; and gyms, tennis courts, bowling elleys, locker rooms, and shower rooms.

ITEMS - Toilets and toilet seets, urinals, toilet and urinal tanks, hathtubs, shower stalls, wash basins and sinks, bathroom fixtures, tiled surfaces, and partitions: walls, baseboards, floors, window sills, and ceilings; telephones and phone booths; bed frames and springs; counter and table tops; hoods, exhaust fans, and laminar flow cabinets and hoods; railings, faucet handles, door knobs, light switches, and other fixtures; halfs, halfways, stairs, and stainways; elevators and escalators; plastic upholstery and furniture; wheelchairs and power carts; laundry, linen, dressing, clean-up, and equipment carts; laundry chutes and hampers; household and industrial trash compactors, refuse and solid waste cans/containers, garbage cans/containers, and garbage and food disposal units; portable toilets, chemical toilets, holding tanks. potties, bedpans, and diaper pails; chairs, benches, tables, counters, desks, bookcases, play pens, seating, and other furniture; cabinets, closets, and lockers: plumbing and plumbing fixtures: racks, conveyors, machinery, and appliances; sickroom utensils and medical equipment; janitorial equipment; barber and beauty shop instruments and equipment; embalming tables and instruments: athletic and ovmnastic mets. shoes, and equipment; bowling, golfing, baseball, football, tennis, recouetball, soccer, camping, and sports gear and equipment; face masks, safety goggles, face hoods, safety helmets, headphones, and other safety equipment; dental patient's and operator's chairs, operator's light, working surfaces, bracket table, evacuator reservoir, tray racks and trays, x-ray control panel and button, viewers, waiting room furniture, and lab equipment; cuspidors and spittoons; brushes, clippers, razors, and grooming instruments; and many other similar public and private items.

SURFACES/MATERIALS - Ceramic/glass, electomeric, metallic, and plastic, such as ABS, acrylic, aluminum (bare and anodized), brass, cement (sealed). ceramic, chrome, concrete (sealed), copper, cork (sealed), enamel, grouting (sealed), iron (ductile and cast), leather and leatherette (sealed), nickel, phenotic-type resins (Bakelite*, Formica*, etc.), polyester, polyethylene, polypropylene, polystyrene, polyurethane, porcelain, rubber, stainless steel, steel, tile (nonporous/sealed ceramic, plastic, and quarry), varnish, vinyl, wood/woodwork (sealed/finished), zinc. Specific plastic, elastomeric, and polymeric surfaces/ materials- Acrylonitile-butadiene-styrene (ABS), aramid, buna (polybutadiene), butyl rubber (isobutyiene-isoprene copolymer), chlorinated polyvinyl chloride (CPVC), epoxy resin, ethylene-propylene (FEP), latex rubber (natural or synthetic), neoprene (polychloroprene), nitile rubber, phenolic resin, polyallomer (PA), polyamide (nylon), patroutylene terephthalate, polycarbonate, polyester.

(PE; P/E; LDPE; HDPE; XLPE), polyethylene terephthalate (PET), polymethylmethacrylate (PMMA), polymethylpentene (PMP), polyolefin, polyoxymethylene (acetal), polyphenylene oxide (PPO), polyorphylene (PF; P/P), polystyrene (PS), polysuifone (PSF), polytertafluoroethylene (PTFE; TFE), polyurethane, polyvinyl chloride (PVC), polyvinyl acetate (PVA), polyvinylidene fluoride (PVDF), silicone rubber and resin, styrene-butadiene rubber (SBR), TPA rubber, and vinylidene fluoride-hexafluoropropylene copolymers.

Registered trademarks for the materials above include: Bakelite® (phenol-formaldehyde resin and other plastics), Celcon® (acetal resin), Dacron® (polyester; polyethylene terephthalate), Delrin® (acetal resin), Dynel® (acrylonitrile-vinyl chloride copolymer), Formica® (melamine/phenolic resins), Halar® ECTFE (ethylene-chlorotrifluoroethylene copolymer). Hastellov® Inconel® Keylar® (polyamide: aramid). Lexan® (polycarbonate resin). Lucite® (acrylic resins), Melmac® (melamine-formaldehyde resin), Mylar® (polyester: polyethylene terephthalate). Nomex* (polyamide; aramid), Orlon® (polyacrylonitrile), Plexiglas® (acrylic resins), Tedlar® (polyvinytfluoride), Teflon® TFE (tetrafluoroethylene), Teflon® FEP (fluorinated ethylene-propylene), Teflon® PFA (perfluoroalkoyl), Thickol* (Polysulfide* rubber). Viton® (vinylidene fluoride/hexafluoropropylene co-

Halar is a registered trademark of Allied-Signal Corporation.

Melmac is a registered trademark of American Cyanamid Company.

Celcon is a registered trademark of Hoechst-Celanese Corporation.

Dacron, Delrin, Dynel, Kevlar, Lucita, Mylar, Nomex, Orlon, Tedlar, Teflon, and Viton are registered trademarks of E.I. DuPort de Nemours & Company.

Formica is a registered trademark of Formica Corporation.

Lexan is a registered trademark of General Electric Corporation.

Inconel is a registered trademark of International Nickel Co., Inc.

Plexigles is a registered trademark of Rohm & Haes Company.

Thiokol and Polysulfide are registered trademarks of Thiokol Chemical Corporation.

Bakelite and Hastelloy are registered trademarks of Union Carbide Corporation.

Not recommended for use on cellulose, water-based "latex" paint, fine leather, polished/waxed surfaces, cellulose/rayon, or shellac. The list above is given only as a guide; many surfaces/materials are made of chemical blends, and may be more or less resistant to damage than the pure chemicals. Pretest all house-keeping products for compatibility before using them on critical or valuable surfaces/materials.

0602

Made in U.S.A.

ITEM 310