

4446-67

12-3-2003

14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 3, 2003

Mitch Whitney
Vice President
Quest Chemical Corporation
12255 FM 529
Houston, TX 77041

Subject: Concept Hospital Disinfectant Deodorant
EPA Registration No. 44446-67
Application Date: September 30, 2003
EPA Received Date: October 8, 2003

Dear Mr. Whitney:

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

Proposed Amendment

- First Aid Statements per PR Notice 2001-1
- Revised Storage and Disposal Statements per PR Notice 2001-6

Conditions

1. Revise the Directions for Use by including bactericidal directions as listed on your last stamped label, dated October 29, 2002, to read:

BACTERICIDAL - Kills these species: Escherichia coli; Psuedomonas aeruginosa; Salmonella choleraesuis; Salmonella schottmuelleri (paratyphoid B); Shigella dysenteriae; Staphylococcus aureus; and Streptococcus pyogenes.

CONCURRENCES							
SYMBOL	7510c						
SURNAME	Whitney						
DATE	12-3-03						

2. Revise the Directions for Use by including the fungicidal directions as listed on your last stamped label, dated October 29, 2002, to read:

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

3. Delete the phrase "...and many other similar public and private items." from the product label. Use sites must be specific and this phrase is too broad.

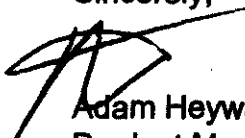
General Comments

Note that it is the Agency's policy not to review additional brand name or supplemental product labeling, i.e. "Phenomenal Hospital Disinfectant Deodorant", "Phenomenal Country Garden Hospital Disinfectant Deodorant", and "Phenomenal Citrus Hospital Disinfectant Deodorant."

Other Comments

A stamped copy of the labeling accepted with conditions 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 703-308-6422.

Sincerely,



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

QUEST

CHEMICAL CORPORATION

CONCEPT HOSPITAL DISINFECTANT DEODORANT

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

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	0.199%
4-tert-Amylphenol	0.046%
Ethanol	53.000%
INERT INGREDIENTS	46.755%
TOTAL	100.000%

EPA Reg. No. 44446-67 EPA Est. No. 44446-TX-1

NET WT. 16.5 OZ. (466 g)

KEEP OUT OF REACH OF CHILDREN
WARNING:

SEE ADDITIONAL PRECAUTIONARY AND FIRST AID
STATEMENTS ON BACK PANEL.

MANUFACTURED BY:
QUEST CHEMICAL CORPORATION
HOUSTON, TX 77041

RES. CLAIMS, AND USES

An excellent disinfectant, antimicrobial agent and two-way deodorizer for use on pre-cleaned, hard, nonporous surfaces, including toilets, urinals, bathtubs, 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.

VIROCIDAL* - kills Human Immunodeficiency virus Type 1 (HIV-1; a retrovirus that causes "AIDS" [Acquired Immune Deficiency Syndrome]), Herpes simplex Types 1 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 schottnuelleri (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 mats, athletic shoes and other athletic equipment.

DEODORIZES TWO WAYS - pleasant 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; nursing homes; medical 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, enameled, painted, plastic (such as ABS, acrylic, latex rubber, phenolic resin, polyamide, polycarbonate, polyester, polyethylene, polyolefin, polypropylene, polystyrene, polytetrafluoroethylene, polyurethane, and vinyl), rubber, metal, sealed leather, wood, grout, and concrete, and similar nonporous surfaces.

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

Use this Product in accordance with the label as directed for use on humans and animals.
registered under EPA Reg. No. 44446-67

FIRST AID

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 vomiting 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 calling a poison control center or doctor, or going for treatment.

PHYSICAL/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.

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

GENERAL: Shake container well before each use and hold it upright while spraying. For use on pre-cleaned, 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 SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: PERSONAL 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. **DISPOSAL OF INFECTIOUS MATERIALS** - Blood/body fluids and other materials removed from or used to clean surfaces/objects should be autoclaved 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°F (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 corners 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: Do not puncture or incinerate! If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

INGREDIENTS (CAS#): Ethyl Alcohol (64-17-5), Water (7732-18-5), Propane/n-Butane (68476-96-8).

WARNING: This product contains a chemical(s) known to the State of California to cause cancer.

HMS 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.

**TWO-WAY DEODORIZING ACTION
PLEASANTLY SCENTED
ATTACKS MALODORS AT THEIR SOURCE**

- 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".

3/4

- 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 odors.
- 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.

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* - kills these agents: Adenovirus Type 5 (an adenovirus that causes a type of "tonsillitis" and may affect the adenoids); Canine distemper (a myxovirus that causes "distemper" in dogs); Feline pneumonitis (a Chlamydia psittaci that affects the lungs of cats); Herpes simplex Type 1 (a herpes virus that causes "cold sores" and may affect the brain); Herpes simplex Type 2 (a herpes virus that causes genital lesions and may affect the brain); Human immunodeficiency virus Type 1 (HIV-1; a retrovirus that causes "AIDS" [Acquired Immune Deficiency Syndrome], which destroys the body's ability to fight disease); 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").

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

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 DEODORIZING ACTION: Its fresh, pleasant scent acts quickly and remains effective for long periods on unpleasant odors from many sources. Quickly counteracts "CHEMICAL" MALODORS 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 dressings, ostomy pouches (post-colostomy/post-ileostomy dressings and bags), malignant diseases, excised organs and tissue, fecal matter, burps, 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 malodors 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, bathtubs, 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, NATURAL, FRESH SCENT: Acts quickly to eliminate (not just "cover up") cooking, bathroom, sickroom, and pet odors. Refreshes 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 pre-cleaned, hard, nonporous surfaces. Use in basements, attics, closets, laundry 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 pre-cleaned, 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 surfaces.

USE LOCATIONS, AREAS, ITEMS AND SURFACES

For use in areas and on hard, nonporous, pre-cleaned 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 cafeterias; 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; air-dries 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 cars and vans, fire cars and trucks, and other emergency vehicles; 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, living rooms, living rooms, recreation rooms, family rooms, atriums, laundry rooms, nurseries, closets, storage rooms, basements, cellars, attics, garages, sheds, outbuildings, dog-houses, and pet quarters; operating rooms, wards, sickrooms, nurseries, labs, lounges, lobbies, and ambulances; embalming rooms; and gyms, tennis courts, bowling alleys, locker rooms, and shower rooms.

ITEMS - Toilets and toilet seats, urinals, toilet and urinal tanks, bathtubs, 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; halls, hallways, stairs, and stairways; 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 gymnastic mats, shoes, and equipment; bowling, golfing, baseball, football, tennis, racquetball, 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, elastomeric, 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, phenolic-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 - Acrylonitrile-butadiene-styrene (ABS), aramid, buna (polybutadiene), butyl rubber (isobutylene-isoprene copolymer), chlorinated polyvinyl chloride (CPVC), epoxy resin, ethylene-propylene (FEP), latex rubber (natural or synthetic), neoprene (polychloroprene), nitrile rubber, phenolic resin, polyallomer (PA), polyamide (nylon), polybutylene terephthalate, polycarbonate, polyester, polyethylene (PE; P/E; LDPE; HDPE; XLPE), polyethylene terephthalate (PET), polymethylmethacrylate (PMMA), polymethylpentene (PMP), polyolefin, polyoxymethylene (acetal), polyphenylene oxide (PPO), polypropylene (PP; P/P), polystyrene (PS), polysulfone

(PSF), polytetrafluoroethylene (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), Hastelloy®, Inconel®, Kevlar® (polyamide; aramid), Lexan® (polycarbonate resin), Lucite® (acrylic resins), Melmac® (melamine-formaldehyde resin), Mylar® (polyester; polyethylene terephthalate), Nomex® (polyamide; aramid), Orion® (polyacrylonitrile), Plexiglas® (acrylic resins), Tedlar® (polyvinylfluoride), Teflon® TFE (tetrafluoroethylene), Teflon® FEP (fluorinated ethylene-propylene), Teflon® PFA (perfluoroalkoyl), Thiokol® (Polysulfide® rubber), Vitor® (vinylidene fluoride/hexafluoropropylene copolymer).

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, Lucite, Mylar, Nomex, Orion, Tedlar, Teflon, and Vitor are registered trademarks of E. I. DuPont 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.

Plexiglas is a registered trademark of Rohm & Haas 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.

0903

ACCEPTED
Made in U.S.A. ITEM 310
WITH COMMENTS

DEC 3 2003

44446-67