

Mr. John Wigand
Canberra Corporation
3610 Holland-Sylvania Rd
Toledo, OH 43615

OCT 16 2002

Subject: High Dilution Quaternary Husky 801 Germicidal Cleaner
EPA Registration No. 8155-11
Amendment Date: July 16, 2002
EPA Receipt Date: July 24, 2002

Dear Mr. Wigand,

The amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Update the First Aid Statements per PR Notice 2001-1
- Add additional uses

Conditions

Revise the label as follows:

1. On page 2, delete the claim, "this product is designed to help prevent cross contamination that can lead to nosocomial infections."
2. Under the Mildewstat directions, add the statement, "Preclean surfaces," as the first sentence for these directions.
3. Under "Veterinary Practice/Animal Care/Animal Laboratories/Zoos/Kennel/Pet Shop, add the statement, "Immerse all halters, ropes, and other types of equipment used to handle or restrain animals as well as forks, shovels, and scraper used to remove litter and manure." This statement should appear after the use dilution and contact time statement.

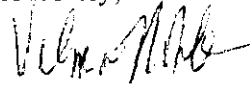
CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

General 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 regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

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***HIGH DILUTION QUATERNARY HUSKY 801 H/D/Q
GERMICIDAL CLEANER**

**ANTIBACTERIAL, ANTI-MICROBIAL GERMICIDE CONCENTRATE BASED ON A UNIQUE BLEND OF
QUATERNARIES WITH ORGANIC SOIL LOAD TOLERANCE
ONE-STEP DISINFECTANT-CLEANER-SANITIZER-FUNGICIDE-MILDEWSTAT-VIRUCIDE*-
DEODORIZER FOR HOSPITAL, INSTITUTIONAL AND INDUSTRIAL USE
EFFECTIVE IN THE PRESENCE OF 5% SERUM CONTAMINATION**

PICTOGRAM

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chlorides.....	003.75%
Didecyl dimethyl ammonium chlorides.....	001.50%
Diocetyl dimethyl ammonium chlorides.....	002.25%
Alkyl (C14 50%, C12, 40%, C16 10%) dimethyl benzyl ammonium chlorides.....	005.00%
OTHER INGREDIENTS.....	087.50%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. **If on skin or clothing:** Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. **If swallowed:** 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor for further treatment advice.

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

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

See side panel for additional precautionary statements.

EPA REG. NO. 8155-11

EPA EST. NO. 8155-OH-1

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

NET CONTENTS: ONE GALLON

MANUFACTURED BY: CANBERRA CORPORATION

TOLEDO, OHIO 43615

OCT 16 2002

BACK PANEL (Note to reviewer: The following is considered optional marketing language.)

...by the Federal Insecticide,
...for the pesticide,
...under EPA Reg. No. **8155-11**

Contains no phosphorous.

Cleans Disinfects Deodorizes.

Disinfectant Deodorizer

This product will deodorize surfaces in restrooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and other places where bacterial growth can cause malodors.

This product will deliver non-acid disinfectant performance in an economical concentrate.

This product is an economical concentrate.

This product can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.

This product is formulated for use in daily maintenance programs to deliver effective disinfecting and malodor control.

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This product will not leave grit or soap scum.

This product is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-*virucide in the presence of moderate amounts of organic soil.

This product is a versatile disinfectant.

This product inhibits bacterial growth on moist surfaces.

This product deodorizes by killing microorganisms that cause offensive odors.

This product is a complete, chemically balanced disinfectant-cleaner, sanitizer that provides clear use solutions even in the presence of hard water.

Cross-contamination is of major housekeeping concern.

This product has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions and industry. This product is designed to help prevent cross-contamination that can lead to nosocomial infections.

Use this product:

- as a disinfectant on hard nonporous surfaces.
- as a broad spectrum disinfectant.
- to sanitize and disinfect salon/barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- to disinfect sinks and tubs.
- in kitchens, bathrooms and other areas.
- for (non-scratch) cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use in hospitals, medical and dental offices, nursing homes, day care centers, nurseries, convenience stores, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, camp grounds, public facilities, kennels, pet quarters, pet shops, zoos, animal laboratories, veterinary offices, transportation terminals, airports, hotels and motels, factories, business and office buildings, barber shops and salons, tanning salons and tattoo parlors, boats, cruise ships, recreational vehicles, buses, trains, subways, taxis, airplanes, cars and trucks

Use on washable hard nonporous surfaces: such as walls, floors, countertops, stovetops, sinks, appliances, refrigerators, cabinets, tables, chairs, desks, telephones, door knobs, garbage cans, shower stalls, tubs and glazed tiles, whirlpool bathtubs, toilets bowls and other bathroom surfaces, kennel runs, cages, coils and drain pans and other hard nonporous surfaces of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, fiberglass, plastic, enameled surfaces, vinyl and plastic furniture.

A concentrated one-step(Hospital) disinfectant that is effective against a broad spectrum of bacteria, is virucidal*, fungicidal and eliminates odor causing bacteria when used as directed.

A hospital disinfectant at (1:256 dilution)(0.5 oz. per gallon of water); this product kills:

Bacteria: (Note to reviewer: *Enterococcus faecalis* replaces archaic name *Streptococcus faecalis*)

<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i> (Staph)	<i>Salmonella choleraesuis</i>
<i>Brevibacterium ammoniagenes</i>	<i>Escherichia coli</i> (E.coli)	<i>Salmonella schottmuellerii</i>
<i>Klebsiella pneumoniae</i>	<i>Shigella dysenteriae</i>	<i>Enterococcus faecalis</i>

Enterobacter aerogenes

Viruses:

- *Herpes Simplex Type 1
- *Herpes Simplex Type 2
- *Influenza A2/Hong Kong
- *Vaccinia (Pox Virus)
- *HIV-1 (Human Immunodeficiency Virus)

Fungi:

Trichophyton mentagrophytes (Athlete's Foot Fungus)

This product meets AOAC Use-Dilution Test Standards for hospital disinfectants.

This product meets EPA's Sanitizer Test standards for non-food contact surface sanitizers. At 1/3 oz. per 2 gallons of water, in waters up to 600 ppm hardness, it is an effective one-step sanitizer in the presence of 5% serum by eliminating 99.9% of *Staphylococcus aureus* and *Klebsiella pneumoniae* in 30 seconds.

U.S. Letter Head

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NOTE TO REVIEWER – USE DIRECTION LANGUAGE IN () IS CONSIDERED OPTIONAL. (7-15-02) Pg. 3 of 5

Dilution:

Disinfection (1:256) 0.5 oz. per gallon of water
Sanitizer (1:768) 1 oz. (30ml) of product per 6 gallons (22.68 liters) (1/3 oz. per 2 gallons of water) (or equivalent dilution)

DIRECTION FOR USE

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

DISINFECTATION/VIRUCIDAL* DIRECTIONS

Add 0.5 oz of product per gallon of water (or equivalent dilution) to disinfect hard, nonporous surfaces. Apply use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray. **Note:** For spray applications, cover or remove all food products. Treated surfaces must remain wet for 10 minutes. Wipe dry with a clean cloth, sponge or mop or allow to air dry. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled. Rinse food contact surfaces such as countertops, tables, picnic tables, appliances and/or stove tops with potable water prior to reuse. Do not use on glasses, dishes or utensils. For heavily soiled areas, a preliminary cleaning is recommended. This product is not for use on medical device surfaces.

FUNGICIDAL DIRECTIONS

This product is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker room, dressing rooms, shower and bath areas, exercise facilities. Follow disinfection directions.

MILDEWSTAT DIRECTIONS

A solution of 0.5 oz. of product with a gallon of water (or equivalent dilution) will effectively control or inhibit the growth of mold or mildew and the odors caused by them when applied to hard, nonporous, environmental surfaces. Allow to dry on surface and repeat when mildew growth re-appears.

***KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/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 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.”**

Personal Protection: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection. **Cleaning Procedure:** Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Leave surface wet for 2 minutes with 2 ounces per gallon use-solution. Use a 10 minute contact time for disinfection against all other virus, bacteria and fungi claimed. **Disposal of Contaminated Material:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste material.

NON-ACID TOILET BOWL CLEANER/DISINFECTANT DIRECTIONS

Flush toilet. Then add 0.5 oz. of product to the toilet bowl (0.75 gallons) and mix. Brush thoroughly over exposed surfaces and under the rim. Allow to stand for ten (10) minutes and flush. For heavy soil, a preliminary cleaning is recommended.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTATION DIRECTIONS:

Mix 0.5 oz. of product with a gallon of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled. **Note:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to instruments.

OCT 16 2002
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Washington, D.C. 20460
8155-11

NOTE TO REVIEWER – USE DIRECTION LANGUAGE IN () IS CONSIDERED OPTIONAL.(7-15-02) pg. 4 of 5

WHIRLPOOL BATH DISINFECTANT DIRECTIONS:

After using whirlpool unit, drain and fill with a use solution of 0.5 oz. of product with a gallon of water (or equivalent dilution) to just cover the intake valve. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift, and any related equipment with a clean swap, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly disinfected, drain the solution from the unit and rinse disinfected surfaces with fresh water. Repeat for heavily soiled units.

TO SANITIZE NON-FOOD CONTACT SURFACES:

Add 1 oz. (30ml) of product per 6 gallons (22.68 liters) of water (0.33 oz. per two gallons of water) (or equivalent dilution) to sanitize hard nonporous surfaces. Apply sanitizer use-solution with a cloth, mop sponge, sprayer or by immersion, thoroughly wetting surfaces. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray.

Treated surfaces must remain wet for 30 seconds. Wipe dry with sponge, mop or cloth or allow to air dry. Prepare fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

TO SANITIZE SALON (BARBER) INSTRUMENTS AND TOOLS:

Immerse pre-cleaned salon (barber) instruments and tools (such as combs, brushes, rollers, razors, scissors, blades, manicure instruments) in a use-solution of 1 oz. (30ml) of product per 6 gallons (22.68 liters) of water (0.33 oz. per two gallons of water) (or equivalent dilution) for at least 30 seconds. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the use solution becomes visibly diluted, cloudy or soiled. Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to instruments.

VETERINARY PRACTICE/ANIMAL CARE/ANIMAL LABORATORY/ZOO/PET SHOP/KENNEL DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, and catteries. Remove all animals and 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 and detergent and rinse with water. Saturate surfaces with a use-solution of 0.5 oz of product per gallon of water (or equivalent dilution) for a period of ten (10) minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

VEHICLES:

Clean all vehicles including mats, crates, cabs and wheels with high pressure water and this product. Use 0.5 oz of product per gallon of water (or equivalent dilution) to treat all vehicles. Leave treated surfaces wet for ten (10) minutes or more. Allow to air dry.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Harmful if swallowed or absorbed through the skin. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

FOR CONTAINERS LESS THAN 1 GALLON:

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

ACCEPTED
EPA Letter Dated
OCT 16 2002
EPA
Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered under EPA Reg. No. 8155-11

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FOR CONTAINERS OVER 1 GALLON:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE Do not store on side. Avoid creasing or impacting of side walls.

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 directions, contact your State Pesticide or Environmental Control Agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

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

FOR CONTAINERS OVER 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. (7-15-02)

ACCEPTED
BY GOVERNMENT
OFFICIAL

OCT 16 2002

State of Florida
Department of Agriculture
Bureau of Pesticides
EPA Reg No

8155-11