

8155-5

10/1/2008

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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

OCT 1 2008

John Wiegand
V.P. Research and Development
Canberra Corporation
3610 Holland-Sylvania Rd
Toledo, Ohio 43615

Subject: General Purpose/Non-Acid Husky *G/P Disinfectant Cleaner
EPA Registration 8155-5
Amendment Dated: June 20, 2008
EPA Received Date: July 03, 2008

Dear John Wiegand,

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

- Revised Container Disposal Per PR Notice 2007-4

Conditions

Revise label as follows :

- 1) Revise the 2nd statement on page two to be in agreement with PR Notice 2000-5 which requires mandatory language by deleting the term, "Recommended". Revise to state: "This product is for use as a..."
- 2) Revise the "Container Disposal" statements for containers greater than 1 gallon to read: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling if available. Otherwise, dispose in a sanitary landfill or by incineration if allowed by state and local authorities. If burned, stay out of smoke.

General Comments

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

SYMBOL	Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6239					
SURNAME						
DATE						

Sincerely,

Velma Noble

Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510P)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

*GENERAL PURPOSE/NON-ACID HUSKY *G/P DISINFECTANT CLEANER

BACTERICIDAL TUBERCULOCIDAL *VIRUCIDAL
CLEANS DISINFECTS DEODORIZES
ANTIBACTERIAL ANTI-MICROBIAL
NON-ACID DISINFECTANT BOWL & BATHROOM CLEANER
Showers Sinks Tubs Washrooms Toilet Bowls
Ships Boats Cruise Lines
HARD SURFACE DISINFECTANT ONE-STEP CLEANER DISINFECTANT
DEODORIZER READY-TO-USE

Kills Herpes Simplex Type 2*
Kills HIV-1(AIDS VIRUS) on precleaned environmental surfaces*
Kills Methicillin Resistant Staphylococcus aureus (MRSA)
Kills Glycopeptide Resistant Staphylococcus aureus(GRSA)
Kills Escherichia coli (O157:H7)
Kills Enterococcus faecalis-Vancomycin Resistant (VRE)
Cuts Through Dirt and Grease Cleans Soap Scum and Hard Water Films
[(Clean)(Ocean)(Minty)(Lemon)(FreshScent)]
GERMICIDAL/MILDEWSTAT (ON HARD INANIMATE SURFACES)/
FUNGICIDAL/[THICK] FOAMING FORMULA

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 1 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the
*registered under
8185-5

ACTIVE INGREDIENTS

n-Alkyl(60% C14, 30%C16, 5%C12, 5%C18)	
dimethyl benzyl ammonium chlorides	0.105%
n-Alkyl(68%C12, 32%C14) dimethyl ethylbenzyl ammonium chlorides	0.105%
OTHER INGREDIENTS	<u>99.790%</u>
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. NO. 8155-5 EPA EST. NO. 8155-OH-1 U.S. PATENT NO. 5,444,094

See reverse side for First Aid and additional precautionary statements.

Net Contents: One Quart (32 Fl. Oz.) 946 ml

Manufactured by: **Canberra Corporation**
3610 Holland-Sylvania Rd.
Toledo, Ohio 43615

Note to Reveiwer - Copy in brackets | | is optional marketing information. Italicized is new copy.
June 20, 2008 Amendment 8155-5 Compliance with PR Notice 2007-4

BACK PANEL

Designed specifically for institutional cleaning and disinfection in Nursing Homes, Hospitals, Institutions, Offices, Homes, Schools, Hotels and Motels. This product is ~~not for use~~ for use in hospitals, medical and dental offices, nursing homes, rest rooms, institutions, schools, colleges, athletic facilities, airports, boats, ships, cruise lines, transportation terminals, hotels and motels.

When used as directed, it will disinfect inanimate hard surfaces such as walls, sink tops, tables, chairs, telephones, door knobs, light switches, shower stalls, hampers and cabinets. Use on washable hard nonporous surfaces: such as walls, floors, countertops, sinks, appliance exteriors, cabinets, tables, chairs, desks, telephones, door knobs, garbage cans, shower stalls, tubs and glazed tiles, wash basins, hard nonporous surfaces of ships, cruise lines, boats and other hard nonporous surfaces of metal, glazed porcelain, glazed ceramic, plastic, and enameled surfaces.]

[With all the news about germs and bacteria, just looking clean isn't good enough. This product does it all -- cleans, disinfects and deodorizes your bathroom and toilet bowl, even under the rim. Antibacterial formula kills common household germs such as Staphylococcus aureus(Staph), Enterococcus faecalis, Escherichia coli(E. coli) and Salmonella choleraesuis(Salmonella) and quickly eliminates annoying odors, leaves a light fresh scent. Will not harm plumbing or septic tanks. This product is a combination of effective cleaners, plus antibacterial disinfectants, so you can be sure your bowl is completely clean.]

Bactericidal Activity - When used as directed this product exhibits effective disinfectant activity against the organisms: Mycobacterium tuberculosis (BCG) at 20° C, Staphylococcus aureus, Staphylococcus aureus-Methicillin Resistant(MRSA), Salmonella choleraesuis, Pseudomonas aeruginosa, Enterococcus faecalis-Vancomycin Resistant(VRE), Staphylococcus aureus-Glycopeptide Resistant(GRSA), and Escherichia coli(O157:H7)

Efficacy tests have demonstrated it to be an effective one-step cleaner-disinfectant in the presence of organic soil(5% blood serum).

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 for use on critical or semi-critical medical device surfaces.*

FOR CLEANING AND DEODORIZATION: To clean light soil from hard surfaces, dilute one part product with seven parts water. Spray and wipe clean.

DISINFECTION AND CLEANING: To disinfect, clean and deodorize hard non-porous surfaces such as toilet seats, bathroom tiles, fixtures, shower stalls, tables hand rails, walls and sinks, proceed as indicated below: Spray area until it is covered with solution. Allow the product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum. For disinfection, remove heavy soil before treatment.

One step cleaning and disinfection of toilet bowls and urinals: Remove water from bowl or urinal. Apply one to two ounces of this product evenly, allowing sufficient time for product to cover entire surface of bowl for best cleaning results. Swab bowl completely using brush or bowl mop, making sure to get under the rim. Let stand for 10 minutes and flush.

MOLD AND MILDEWSTAT - Prevents and controls mold and mildew on hard non-porous pre-cleaned inanimate surfaces. **MILDEWSTAT** - To control mold and mildew on hard non-porous surfaces (such as floors, walls, table tops), pre-clean surfaces, then spray the surfaces to be treated, making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

FUNGICIDAL - This product is fungicidal against pathogenic fungi (Trichophyton mentagrophytes) when used as directed on hard surfaces found in the restroom, shower stall and locker room or other clean hard non-porous surfaces commonly contacted by bare feet. Follow disinfection directions.

EFFECTIVE AGAINST HERPES SIMPLEX TYPE 2 (on hard inanimate surfaces).

EFFECTIVE AGAINST HIV-1 (AIDS VIRUS): Product was evaluated and found to be an effective virucide in the presence of 5% serum against the virus HIV-1(Human Immunodeficiency Virus 1, commonly referred to as "AIDS VIRUS" on inanimate surfaces.

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare settings (Hospitals, Nursing Homes) 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 or 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 ON SURFACES/OBJECTS SOILED WITH BLOOD /BODY FLUIDS:

Personal Protection: Disposable latex gloves, gowns, masks and splash resistant goggles must be worn when handling items soiled with blood or body fluids. **Cleaning Procedures:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Leave surface wet for 10 minutes. **Disposal of Infectious Material:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if absorbed through the skin and/or if inhaled. Avoid contact with eyes, skin and clothing. Avoid breathing spray mist. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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.

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

FOR CONTAINERS 1 GALLON or LESS:

STORAGE AND DISPOSAL: Store in an area inaccessible to children. *Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Otherwise,* wrap empty container in plastic bag and discard in trash.

(For Industrial and Institutional Use Only) *LOT CODE Designating Batch*

FOR CONTAINERS OVER 1 GALLON:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store in an area inaccessible to children.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of 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: *Nonrefillable container. Do not reuse or refill this container.* ~~Offer for recycling or~~ *Triple rinse container (or equivalent) promptly after emptying.* Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

FOR CONTAINERS OVER 5 GALLONS:

ENVIRONMENTAL HAZARD

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.