

PM 31

8155-18

8-31-99

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 31 1999

Canberra Corporation
3610 Holland Sylvania Rd.
Toledo, Ohio 43615

Subject: No. 800 Husky Germicidal Cleaner
EPA Registration No. 8155-18
Your Amendment Dated: 5/26/99
EPA Receive Date: 6/11/99

Attention: Mr. John Wiegand
Director of Research and Development

The amendment referenced above, submitted in connection with registration under FIFRA, as amended, will be acceptable provided you address the following label recommendations before you release this product for shipment.

1. Under the "Directions For Use" for both labels, the disclaimer statement, This product must not be used to clean/disinfect the following food contact surfaces: eating utensils, glassware, and dishes", should appear after the food contact surface disinfection sentence.
2. The MOU statement from PR Notice 94-4 is required on the Hospital/Institutional Disinfectant label because this product is approved for use in hospitals and nursing homes on non-specific hard nonporous environmental surfaces made of metal, stainless steel, and plastic. The "unqualified "stainless steel and metal surfaces" require the language because of the possible association with non-critical devices or equipment surfaces. The following MOU should be added to the "Directions for Use" section, preferably before the disinfection directions.

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

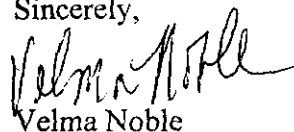
SYMBOL		CONCURRENCES					
SURNAME	75700						
DATE	Campbell						
	AUG 31 1999						

If your label changes are handled through word processing, you should go ahead and address the following comments in addition to the above comments. Please submit a revised label to the Agency for review. However, if you are in the process of printing labels, you will need to submit a label amendment addressing these comments prior to your next label printing.

- a. The use sites, commercial and industrial institutions need to be clarified or deleted.
- b. Specific use directions will need to be developed for the following sites you claim: veterinary clinics, pet shops, and kennels. The directions should also indicate specific surfaces for disinfection as well as the removal of the animals from the premises.

A stamped copy of the label is enclosed for your records. You should submit one (1) copy of the final printed label prior to the release of the product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510C)

No. 800
HUSKY
GERMICIDAL CLEANER

Kills Salmonella choleraesuis(Salmonella) and Escherichia coli.

Cuts through dirt and grease.

A concentrated, neutral, disinfectant-cleaner, fungicide, virucide* and deodorizer with organic soil and hard water tolerance for hospital, institutional and industrial use.

ONE STEP GERMICIDAL DETERGENT AND DEODORANT
EFFECTIVE AGAINST THE FOLLOWING ORGANISMS:

Pseudomonas aeruginosa	Pseudomonas aeruginosa(antibiotic resistant strain)
Staphylococcus aureus(Methicillin resistant)	Staphylococcus aureus
Salmonella choleraesuis	HIV-1(AIDS Virus)
Enterococcus faecalis(Vancomycin Resistant)	

Kills ·Bacteria
·Fungus
·HIV*

*See below for details and cautions

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chlorides.....2.31%
n-Alkyl(C14 50%, C12 40%, C16 10%) dimethyl benzyl ammonium chlorides.....1.54%

INERT INGREDIENTS.....96.15%
TOTAL...100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

(See back panel for precautionary statements.)

EPA REG. NO. 8155-18 EPA EST. NO. 8155-OH-1

NET CONTENTS: 1 FL. Oz.(29.5ml)

MANUFACTURED BY: CANBERRA CORPORATION
TOLEDO, OHIO 43615

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 31 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
8155-18

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A concentrated germicidal, bactericidal mildewstat and deodorant effective in hard water up to 400 ppm (calculated as CaCO₃) plus 5% organic serum.

Bacteria: Bactericidal at 1:64 dilution (2 ounces per gallon of water) against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* according to the current AOAC Use-Dilution Test Method, modified in the presence of 400ppm synthetic hard water(calculated as CaCO₃) plus 5% organic serum at 1:64 dilution. Virucidal against *HIV-1(AIDS Virus), Influenza A/Hong Kong, Herpes Simplex Type 1, Herpes Simplex Type 2, Vaccinia, Rubella, Adenovirus Type 4, Canine distemper, Feline picornavirus, Feline leukemia, Rabies, Pseudorabies, Infectious bovine rhinotracheitis and Infectious bronchitis(Avian IBV) according to the virucidal qualification, modified in the presence of 400ppm hard water plus 5% organic serum at a 1:64 dilution.

Disinfection: Effective against the following pathogenic bacteria according to the AOAC Use-Dilution, current edition, modified in the presence of 400ppm synthetic hard water (calculated as CaCO₃) plus 5% organic serum:

<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Salmonella choleraesuis</i>
<i>Bordetella bronchiseptica</i>	<i>Chlamydia psittaci</i>	<i>Escherichia coli</i>
<i>Escherichia coli</i> (Antibiotic Resistant)	<i>Enterobacter aerogenes</i>	<i>Enterobacter cloacae</i>
<i>Fusobacterium necrophorum</i>	<i>Klebsiella pneumoniae</i> (Antibiotic Resistant)	<i>Klebsiella pneumoniae</i>
<i>Pasteurella multocida</i>	<i>Pseudomonas aeruginosa</i> (Antibiotic Resistant)	<i>Proteus mirabilis</i>
<i>Proteus vulgaris</i>	<i>Salmonella typhi</i>	<i>Salmonella typhimurium</i>
<i>Serratia marcescens</i>	<i>Shigella flexneri</i>	<i>Shigella sonnei</i>
<i>Staphylococcus aureus</i> (Antibiotic Resistant)	<i>Staphylococcus epidermidis</i> (Antibiotic Resistant)	
<i>Enterococcus faecalis</i> (Antibiotic Resistant)	<i>Enterococcus faecalis</i>	<i>Streptococcus pyogenes</i>

Fungus: Effective against *Trichophyton mentagrophytes* and *Candida albicans* according to the AOAC fungicidal test modified in the presence of 400ppm hard water (calculated as CaCO₃) plus 5% organic serum at a 1:64 dilution.

Mildew: Will effectively control the growth of mold and mildew plus the odors caused by them when used on non-porous surfaces. Soak (1 ounce per 2 quarts of water) for 10 minutes and let air dry. Repeat application weekly or when mildew growth reappears.

This product cuts through greasy soils and tough food stains to clean most kitchen surfaces. It also kills many household germs found in the kitchen, like *Escherichia coli*(*E. coli*), *Salmonella choleraesuis* (*Salmonella*), *Staphylococcus aureus* (*Staph*) and *Streptococcus pyogenes* (*Strep*) on hard non-porous surfaces such as floors, walls, metal or plastic surfaces, such as kitchen appliances. It also helps to control the hazards of cross-contamination of many germs on kitchen surfaces.

SINK STOVE GARBAGE CAN FLOOR

P I C T O G R A M S

(For retail disinfectant-cleaner label)

DIRECTIONS FOR USE:

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

Recommended for household use to **clean, disinfect and deodorize** hard non-porous surfaces (such as tables, countertops, floors, walls, appliances, waste baskets and sinks), use 2 ounces per gallon of water for a minimum contact time of 10 minutes for each application. The product can be applied with a mop, sponge, or cloth to wet all surfaces thoroughly. Prepare a fresh solution for each use, then discard. For food contact surfaces (countertops, tables, appliances, stoves) thoroughly rinse all wetted and cleaned surfaces with potable(tap) water. Rinsing of floors and walls is not necessary unless floors are to be waxed or polished. Pre-clean to remove heavy soil before disinfection. **General Directions for Anti-Bacterial Implement Soak:** For use on hard non-porous surfaces such as metal, stainless steel, porcelain and plastic. Clean surfaces of dirt and build-up. Use 1/4 ounce per 16 oz. of water and soak metal and non-porous hard surfaces for at least 10 minutes. Prepare a fresh solution for each use, then discard excess. Rinsing is not necessary. Disinfects, cleans and deodorizes in one step.

Mildewstatic Instructions: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard non-porous surfaces such as floors and walls. Pre-clean to remove heavy soil before application. Apply solution(2 ounces per gallon of water) with a cloth, mop, sponge or coarse spray. Make sure to wet all surfaces completely for at least 10 minutes. Let air dry. Repeat application weekly or when growth reappears.

ACCOUNTED
WITH COMMENTS
in EPA Letter Dated:

AUG 31 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the pesticide,
registered under EPA Reg. No.

8155-18

5046

(For hospital, institutional disinfectant label)

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO₃) in the presence of a moderate amount of soil(5% organic serum) according to the AOAC Use-Dilution

Tests. Effective against the following organisms:

Pseudomonas aeruginosa	Staphylococcus aureus	Salmonella choleraesuis
Bordetella bronchiseptica	Staphylococcus aureus(Methicillin Resistant)	
Enterobacter aerogenes	Staphylococcus epidermidis	Enterobacter cloacae
Escherichia coli	Klebsiella pneumoniae(Antibiotic Resistant)	
Escherichia coli(Antibiotic Resistant)	Pasteurella multocida	Proteus mirabilis
Chlamydia psittaci	Proteus vulgaris	Streptococcus faecalis
Shigella flexneri	Salmonella typhi	Streptococcus pyogenes
Shigella sonnei	Salmonella typhimurium	Serratia marcescens
Enterococcus faecalis(Antibiotic Resistant)	Pseudomona aeruginosa(Antibiotic Resistant)	

Enterococcus faecalis(Vancomycin Resistant) (VRE)

Staphylococcus epidermidis(Antibiotic Resistant)

*Adenovirus Type 4	*Canine distemper	*Feline leukemia
*Herpes Simplex Type 1	*HIV-1(AIDS VIRUS)	*Feline picornavirus
*Herpes Simplex Type 2	*Influenza A/Hong Kong	*Pseudorabies
*Rubella	*Vaccinia	*Rabies

*Infectious bronchitis(AvianIBV)

Candida albicans Trichophyton metagrophytes

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DIRECTIONS FOR USE:

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

General Use Instructions: Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, pet shops, kennels, hotels and motels. Disinfects, cleans and deodorizes hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, plastic surfaces, stainless steel surfaces, porcelain, glazed porcelain surfaces, bathrooms, shower stalls, bathtubs, kitchens, counters, sinks, appliances and cabinets. **Application:** Remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 ounces of concentrate per gallon of water. Solution can be applied with cloth, mop, sponge or coarse spray or by soaking. Let solution remain on surface for a minimum of 10 minutes. For food contact surfaces (countertops, tables, appliances, stoves) thoroughly rinse all wetted and cleaned surfaces with potable(tap) water. Rinsing of floors is not necessary unless they are to be waxed or polished. Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Mildewstatic Instructions: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard non-porous surfaces such as floors and walls. Pre-clean to remove heavy soil before application. Apply solution(2 ounces per gallon of water) with a cloth, mop, sponge or coarse spray. Make sure to wet all surfaces completely for at least 10 minutes. Let air dry. Repeat application weekly or when growth reappears.

***KILLS HIV-1(AIDS VIRUS) ON PRECLEANED, 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/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human immunodeficiency virus Type I (HIV-1)(associated with AIDS). **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1(AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:** **Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures. **Cleaning Procedures:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant. **Contact Time:** HIV-1(AIDS virus) is inactivated after contact time of 4 minutes at 25°C(room temperature). Use a 10 minute contact time for other viruses, fungi and bacteria listed. **Disposal of Infectious Materials:** Blood/body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

6086

Precautionary Statements

Hazard to Humans and Domestic Animals

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

Statement of Practical Treatment

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician.

(For retail label)

Storage and Disposal: Store in original container in an area inaccessible to small children. Keep container closed. Do not reuse empty container. Rinse thoroughly with water before discarding in trash.

(For institutional label)

Storage and Disposal:

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

Storage: Keep product under locked storage, inaccessible to children.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal: Do not reuse empty container. Rinse thoroughly. Securely wrap in several layers of newspaper and discard empty container in trash.

For containers larger than one gallon.

Container Disposal: Triple rinse(or equivalent). 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 five gallons and larger.

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.

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