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5 9/9/2002 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP - 9 2002

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

8155-

Subject: General Purpose/Non-Acid Husky G/P Disinfectant Cleaner EPA Registration No. 8155-5 Amendment Date: June 13, 2002 EPA Receipt Date: June 20, 2002

Dear Mr. Wigand

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

- Update organism nomenclature
- Revised first aid statements based on toxicology profile

Conditions

Revise the label as follows:

1. Under Mold and Mildewstat directions, add the step, "pre-clean surfaces."

2. For the fungicidal directions, set the directions apart by adding the heading, **FUNGICIDAL**" in **bold**. Also, add the statement, *"follow the disinfection directions."*

3. Under "Pesticide Storage" instructions, add the phrase, "Keep from Freezing."

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.		CONCURRENCES						
SYMBOL								
SURNAME			· ·					
DATE						· ·		

Printed on Recycled Paper

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely, ma Noble

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

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Final Label/Oct. 3, 2000/EPA Reg. No. 8155-5 RESPONSE TO AGENCY LETTER DATED SEP. 26, 2000 FINAL LABEL IN RESPONSE to AGENCY LETTER Stamped Accepted with Comments 01-03-2001

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

BACTERICIDAL TUBERCULOCIDAL *VIRUCIDAL CLEANS DISINFECTS DEODORIZES ANTIBACTERIAL ANTI-MICROBIAL NON-ACID DISINFECTANT BOWL & BATHROOM CLEANER

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 Streptococcus faecalis-Vancomycin Resistant (VRE) Cuts Through Dirt and Grease Cleans Soap Scum and Hard Water Films

GERMICIDAL/MILDEWSTAT(ON HARD INANIMATE SURFACES)/ FUNGICIDAL/THICK FOAMING FORMULA

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%
INERT INGREDIENTS	99.790%
TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN CAUTION

See reverse side for First Aid and additional precautionary statements. Net Contents: One Quart (32 Fl. Oz.) 946 ml Manufactured by: Canberra Corporation Toledo, Ohio 43615 With COMMENTS

with COMMENTS in EPA Letter Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the perificide, registered under EPA Reg. No 8155-5 375

Designed specifically for institutional cleaning and disinfection in Nursing Homes, Hospitals, Institutions, Offices, Homes, Schools, 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).

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With all the news about germs and bacteria, just <u>looking</u> 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), Streptococcus faecalis(Strep), 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 <u>completely</u> 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, Streptococcus 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.

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 ^Ainanimate surfaces. MILDEWSTAT - To control mold and mildew on hard non-porous surfaces (such as floors, walls, table tops), spray the surfaces to be treated, making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

This product is fungicidal against pathogenic fungi (T. 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 disciplention directions and the description directions are descripted as the description direction of the description directions are descripted as the description direction of the description direction direction directions are descripted as the description direction direction directions are directed as the description direction direction directions are directed as the description direction direction directions are directed as the direction direction direction directions are directed as the direction direction direction direction direction direction directions are directed as the direction directi

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

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

SEP 9 2002 Under the Federal Insecticide, Fungicide, end Rodenticide Act as amended, for the pendicide, registered under EPA Reg. No 8/55-5

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).

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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.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

Pesticide Storage -Store in a cool, dry location, in locked area inaccessible to children. Pesticide Disposal - Pesticide spray mixture or rinse water that cannot be used according to label

instructions must be disposed of according to Federal or approved state procedures under Sub-Title C of the Resource Conservation and Recovery Act. Container Disposal - Do not reuse empty container. Rinse thoroughly with water before discarding in trash.

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

> with COMMENTS in EPA Letter Dated: SEP Under the Federal Insecticide, Functicide, Circl Redenticide Act as amended, for the pepticide, registered under EPA Reg. No. 8155-5

ACCEPTED