

8155-24

11/19/2008

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 19 2008

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

Subject: Husky 800 N/D
EPA Registration No.: 8155-24
Amendment Date: August 12, 2008
EPA Receipt Date: August 21, 2008

Dear Mr. Wiegand,

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

- Update Container Disposal Statements per PRN 2007-4

Conditions

Revise the label as follows:

- 1) The first statement of the 3rd paragraph under "Back Panel" on page 1 must be brought into compliance with PR Notice 2005-1, Mandatory Labeling by deleting the term, recommended.
- 2) Revise the "Disinfection/Virucidal" directions heading on page 2 to include "*Fungicidal.*"
- 3) Revise the "Cleaning" directions heading on page 3 to include "*Deodorizing.*"
- 4) Revise the "Sanitizing Non-Food Contact Surface" directions on page 3 by adding the statements, "*Thoroughly wet surfaces with a cloth, mop, sponge, or sprayer,*" as the second sentence, and "*Allow surfaces to air dry*" as the last sentence in this section.
- 5) The "Disposal of Contaminated Material" statement under the HIV directions on page 3 must be brought into compliance with PR Notice 2005-1, Mandatory Labeling by deleting the term, should, and stating "*must.*"
- 6) The "Precautionary Statements" on page 3 must be updated to be in agreement with the Precautionary Labeling in Chapter 7 of the Label Manual by stating the following:

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash clothing before reuse.

7) The "Storage and Disposal" statements for containers greater than a gallon must be revised by adding the subheading "**Pesticide Storage**" with the statement, "Store in an area inaccessible to children."

General Comments

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

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416 or Velma Noble at (703) 308-6233.

Sincerely,

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

HUSKY 800 N/D

(ANTIBACTERIAL, ANTI-MICROBIAL
DISINFECTANT-CLEANER-SANITIZER-FUNGICIDE-MILDEWSTAT-VIRUCIDE*
DEODORIZER FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE)

(EFFECTIVE IN HARD WATER UP TO 400 PPM HARDNESS(Calculated as CaCO₃)
IN THE PRESENCE OF 5% SERUM CONTAMINATION)

(WILL NOT HARM NONPOROUS PLASTIC, ACRYLIC AND FROSTED ACRYLIC SURFACES)
(CONCENTRATE)(One gallon makes 64 gallons of use-solution.)

PICTOGRAM

ACTIVE INGREDIENT:

Didecyl dimethyl ammonium chlorides.....	3.85%
OTHER INGREDIENTS.....	96.15%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

ACCEPTED
with COMMENTS
in EPA Letter Dated:
NOV 19 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
8155-24

FIRST AID

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

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. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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.

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.

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

See side panel for additional precautionary statements.

EPA REG. NO. 8155-24

EPA EST. NO. 8155-OH-1

NET CONTENTS: ONE GALLON

MANUFACTURED BY: CANBERRA CORPORATION

TOLEDO, OHIO 43615

BACK PANEL

Cross-contamination is of major housekeeping concern, not only in hospitals, but in schools, institutions and industry. This product has been formulated to aid in the reduction of cross-contamination in these areas. It is a one-step disinfectant-cleaner, that is effective against a broad spectrum of bacteria. It is virucidal* (including HIV-1), fungicidal and inhibits the growth of mold and mildew and their odors, when used as directed.

It is an effective one-step sanitizer-cleaner for use on non-food contact surfaces.

When used as directed, it will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors. It is an effective fungicide against Trichophyton mentagrophytes, (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

This product is ~~recommended~~ for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, tanning salons, massage parlors, tattoo parlors, spas, airports, boats, ships, cruise lines, transportation terminals, hotels and motels.

Note to Reveiwer - Copy in brackets [] is optional marketing information. Italicized is new copy.

August 12, 2008 Amendment 8155-24 Compliance with PR Notice 2007-4

This product contains no phosphorous. It is a no-rinse, neutral pH disinfectant-cleaner that disinfects, cleans and deodorizes in one labor saving step. It can be used with mop and bucket, trigger sprayers, sponge or by soaking. This product provides effective cleaning strength that will not dull most metal-interlock floor finishes, and does not require a rinse prior to recoat. This product is a neutral pH multi-surface cleaner, deodorizer and disinfectant.

Use it on the multi-touch surfaces responsible for cross-contamination. Use on washable hard nonporous surfaces: such as walls, floors, sinks, cabinets, tables, chairs, desks, telephones, door knobs, garbage cans, shower stalls, tubs and glazed tiles, bathroom floors and walls, hard nonporous surfaces of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, plastic, acrylic and frosted acrylic surfaces, glass and enameled surfaces, vinyl and plastic furniture. Use it on finished floors, conductive flooring, and sealed concrete flooring.

Effective against Vancomycin Resistant Enterococcus faecalis(VRE) at 2 ounces per gallon, modified in the presence of 250 ppm hard water.

This product is a hospital-use disinfectant at 2 ounces per gallon, modified in the presence of 250 ppm hard water and at 3 ounces per gallon, modified in the presence of 400 ppm hard water. It is bactericidal according to the AOAC Use-Dilution Test Method, virucidal* according to the Virucidal Qualification on hard inanimate surfaces, fungicidal according to the AOAC Fungicidal Test, and modified in the presence of 5% organic serum against:

- Staphylococcus aureus(Vancomycin Intermediate Resistant-VISA)
- Staphylococcus aureus(Methicillin Resistant-MRSA)
- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Acinetobacter baumannii
- Brevibacterium ammoniagenes
- Chlamydia psittaci
- Enterobacter aerogenes
- Enterobacter cloacae
- Escherichia coli(Methicillin Resistant)
- Enterococcus faecalis(Methicillin Resistant)
- Klebsiella pneumoniae(Methicillin Resistant)
- Aspergillus niger
- Trichophyton mentagrophytes
- *HBV Hepatitis B Virus
- *HIV-1(AIDS Virus)
- *Herpes simplex Type 1
- *Herpes simplex Type 2
- Proteus vulgaris
- Salmonella typhi
- Salmonella schottmuelleri
- Salmonella typhimurium
- Staphylococcus epidermidis
- Serratia marcescens
- Shigella dysenteriae
- Shigella flexneri
- Shigella sonnei
- Klebsiella pneumoniae
- Enterococcus faecalis
- Streptococcus pyogenes
- Candida albicans
- *Rubella
- *Vaccinia
- *Influenza A/PR

This product is a sanitizer for hard non-porous non-food contact surfaces at 2-3 ounces per gallon against: Enterobacter aerogenes
Staphylococcus aureus

DIRECTION FOR USE

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

Preparation of use solution:

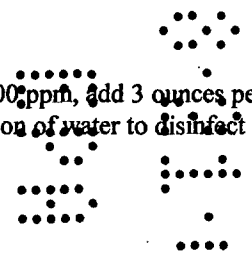
For water hardness up to 250 ppm, add 2 ounces per gallon of water; for water hardness up to 400 ppm, add 3 ounces per gallon of water, to disinfect hard non-porous surfaces. For heavy duty use, add 8 ounces per gallon of water to disinfect hard non-porous surfaces.

Disinfection/Virucidal* Directions:

For heavily soiled areas, a preliminary cleaning is required.

Apply use-solution to hard(inanimate), non-porous surfaces, thoroughly wetting surfaces as recommended and required, with a cloth, mop, sponge or sprayer. Treated surfaces must remain wet for 10 minutes (2 minutes for disinfection against all viruses claimed except HBV). Wipe dry with clean cloth or sponge or allow surface to air dry. For sprayer applications, use a coarse spray device. Spray 6-8 inches from surface. Rub with brush, sponge or cloth. Wipe dry with clean cloth or sponge or allow surface to air dry. Do not breathe spray mist.

Note to Reveiwer - Copy in brackets [] is optional marketing information. Italicized is new copy.
August 12, 2008 Amendment 8155-24 Compliance with PR Notice 2007-4



Prepare a fresh solution daily or when use solution becomes diluted or soiled.

For food contact surfaces such as counters, tables and appliances, thoroughly rinse surfaces with potable water. Do not use on dishes, glasses and utensils.

(One of the following statements must be used for labels listing medical site uses and stainless steel or metal surfaces.)

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.

(or) This product is not for use on *critical or semi-critical* medical device surfaces.

Cleaning: (Add) Dilute 1-4 ounces of product per gallon of water. Thoroughly wet surfaces with a cloth, mop, sponge or sprayer. Remove excess solution with a cloth or allow to air dry.

Mold and Mildew Directions: Add 2 ounces per gallon of water to control the growth of mold and mildew and their odors on hard, non-porous surfaces. Thoroughly wet all surfaces completely. Let air dry. Repeat application weekly or when growth or odor reappear.

Sanitizing Non-Food Contact Surface Directions: Add 2 ounces per gallon of water to sanitize hard, non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

***KILLS HIV AND HBV 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) or Hepatitis B Virus (HBV).

“SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV 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 or HBV must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** For HIV: Use 2 oz. of concentrate per gallon of water. Leave surface wet for 2 minutes. For HBV: Use 3 oz. of concentrate per gallon of water. Leave surface wet for 10 minutes.

For disinfection against all other bacteria and fungi claimed: Use a 10 minute contact time. **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.

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER Keep out of reach of children. Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination with food. Wash thoroughly with soap after handling.

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.

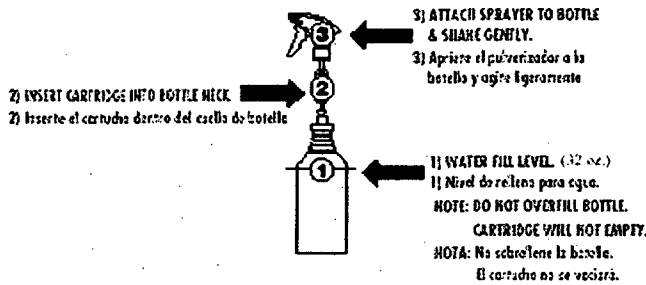
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the 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 if available. 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.

(Note to reviewer: The following is to be used with the closed spray bottle system, which consists of a small cartridge containing the concentrate. This information will appear on the outside of the package containing the cartridge)



SMALL PACKAGE LABEL TO BE USED WITH MASTER CONTAINER LABEL

HUSKY 800 N/D

ACTIVE INGREDIENT:

Didecyl dimethyl ammonium chloride..... 003.85%

OTHER INGREDIENTS..... 096.15%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See Precautionary and First Aid Statements on Master Label

DIRECTION FOR USE

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

For water hardness up to 250 ppm CaCO₃

Completely empty package contents (Y) Fl. Oz. in (Y x 64) Fl. Oz. of water for a 1:64 dilution (2 fl. oz. per gallon of water).

For water hardness up to 400 ppm CaCO₃

Completely empty package contents (Z) Fl. Oz. in (Z x 42) Fl. Oz. of water for a 1:42 dilution (3 fl. oz. per gallon of water).

SEE MASTER LABEL FOR PROPER USE DIRECTIONS.

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.

EPA REG. NO. 8155-24

EPA EST. NO. 8155-OH-1

NET CONTENTS: (Y) Fl. Oz. (mL)

Manufactured by:

Canberra Corporation

3610 Holland-Sylvania Rd.

Toledo, Ohio 43615

