

8155-6

5/27/2010

1024



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

MAY 27 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: High Detergent Crème Husky H/D/C Bowl Cleaner
EPA Registration No.: 8155-6
Amendment Date: February 18, 2010
EPA Receipt Date: February 26, 2010

Dear Mr. Wiegand,

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

Proposed Amendment

- Add Alternate formula #2 with wider certified limits for the quats and inert ingredients
- Update Precautionary Statements on label

Conditions

Revise the label as follows:

- 1.) Revise the claim, "Safe for septic tanks," to read "*Will not harm* septic tanks."
- 2.) Your product does not meet the criteria to support an "unqualified" germs claim as defined in the January 5, 2005 letter to Consumer Specialty Products Association (<http://www.epa.gov/oppad001/germs.htm>). The letter indicates that a product must have acceptable data against the three major classes of organisms (i.e. gram positive and gram negative bacteria [bacteria], trichopyton mentagrophytes [fungi], and one envelope and non-envelope virus [virus]) before an unqualified germs claim may be made on the label. However, your product does meet the criteria to make a "qualified" germs claim because acceptable data is on file against two of the three major classes of organisms. Therefore, you must qualify the "germs" claim on your label by adding an asterisk after the term, "germs*", and adding the reference asterisk next to the list of organisms the product mitigates. You will need to revise the claim, "When used as directed this product is effective" To read "*When used as directed,*

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

product demonstrates effective disinfection against *S. aureus, MRSA, E. faecalis (VRE), S. enterica, and HIV-1.”

3.) The nomenclature for Salmonella choleraesuis has been updated to “S. enterica.” You must revise your label accordingly.

4.) Revise the third statement under the “Precautionary Statements” to read “May be fatal if swallowed” such that it is in agreement with the acute oral toxicity classification of category II from the Mineral Acid Reregistration Eligibility Document.

5.) Revise the Storage and Disposal Statements for commercial/institutional/industrial use by adding “Pesticide Storage” statements and heading that read:

Pesticide Storage: Store in an area inaccessible to children and persons unfamiliar with its use.

6.) Add the statement, “This product is toxic to fish and aquatic invertebrates”, as the first statement under “Environmental Hazards”.

General Comments

The Confidential Statement of Formula for alternate formulation #2 dated February 18, 2010 is not acceptable. The diluent’s certified limits are not calculated correctly. You must revised in accordance to 158.350(b)(2), Table of Certified Limits.

A stamped label 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 concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 or by e-mail at swift.killian@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane
Jacqueline McFarlane
Product Manager (34)

Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped accepted labeling

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

3044

HIGH DETERGENT CREME
HUSKY *H/D/C BOWL CLEANER
(ANTIBACTERIAL ANTI-MICROBIAL THICK LIQUID, FRESH SCENT
CLEANS, DISINFECTS, DEODORIZES, REMOVES RUST)
(READY TO USE)

(KILLS THE FOLLOWING GERMS - Staphylococcus aureus(Staph), Staphylococcus aureus-Methicillin Resistant(MRSA), Enterococcus faecalis-Vancomycin Resistant and Salmonella choleraesuis(Salmonella) Safe for septic tanks)
(Microscopically Clean)
(PICTOGRAM)

ACTIVE INGREDIENTS:

Hydrogen chloride	9.50%
n-Alkyl(C ₁₄ 60%, C ₁₆ 30%, C ₁₂ 5%, C ₁₈ 5%) dimethyl benzyl ammonium chlorides	0.05%
n-Alkyl(C ₁₂ 68%, C ₁₄ 32%) dimethyl ethylbenzyl ammonium chlorides	0.05%
OTHER INGREDIENTS:	90.40%

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See First Aid statement and additional precautions on the reverse side.
(See back (side) (reverse) panel for (First Aid and) additional precautionary statements.)
Net Contents: One Quart (32 FL. OZ.) 946 ml

EPA Reg. No. 8155-6 EPA Est. No. 8155-OH-1
Manufactured by: Canberra Corporation
3610 Holland-Sylvania Rd.
Toledo, Ohio 43615

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 27 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **8155-6**

Back panel

Thick formula coats toilet bowl surface. Cleans and disinfects.
Cleans, disinfects and deodorizes for a microscopic clean.

Quickly eliminates rust, lime and uric acid deposits. Will not harm bacteria action of septic tanks. When used as directed, product demonstrates effective disinfection against Staphylococcus aureus, Staphylococcus aureus - Methicillin Resistant(MRSA), Enterococcus faecalis - Vancomycin Resistant(VRE) and Salmonella choleraesuis. Efficacy tests have demonstrated it to be an effective one-step toilet bowl cleaner disinfectant in the presence of organic soil (5% blood serum).

For use in commercial and industrial buildings, (homes, households), schools, manufacturing plants, public restrooms, hotels and motels. For use inside toilet bowls and urinals. Use of this toilet bowl cleaner on other than vitreous ware is done at user's risk. (With all the news about germs and bacteria, just looking clean isn't good enough. This product does it all -- cleans, disinfects and deodorizes, even under the rim. Effective thick formula kills germs and quickly eliminates toilet rings, hard water stains, mineral deposits and rust stains, plus leaves a light fresh scent. Will not harm plumbing or septic tanks. Kills the following common (household) germs, Staphylococcus aureus(Staph) and Salmonella choleraesuis(Salmonella). This product is a combination of effective cleaners, plus antibacterial disinfectants, so you can be sure your bowl is completely clean.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its' labeling. (To open child resistant cap: Use fingernail or coin to pull back and push down rear-most ridge of spout. Push spout down after use.) (ALTERNATE CRC CLOSURE INSTRUCTIONS) To open child resistant cap: Hold bottle firmly with one hand on flat surface. With other hand, squeeze sides of cap where indicated and turn counterclockwise. Avoid squeezing bottle while opening. Close bottle by turning clockwise.)

General Cleaning: Open cap. Squeeze gently, directing bowl cleaner under rim and on sides of bowl, inside only. Brush clean and flush toilet. Close cap. Rinse brush with clean water. Do not use on any other surfaces including toilet seat, toilet lid, countertops, tubs and sinks. To clean other acid resistant surfaces, dilute product with 3 parts water. Do not allow solution to remain on surfaces without immediately rinsing thoroughly with water.

To Disinfect Toilet Bowls (or Urinals): Remove water from bowl (or urinal). Squeeze gently 1 ounce of bowl cleaner onto bowl brush. Clean entire unit, especially under rim at water outlets. Allow to remain 10 minutes. Flush and rinse out bowl brush with clean water. A preliminary cleaning is required for the removal of heavy soil prior to disinfection.

Note to Reveiwer - Copy in parentheses is optional marketing information. Highlighted is new copy.
Feb. 18, 2010 Amendment 8155-6 Alternate formula and label update

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 PRE-CLEANED 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 or 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 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. See disinfection directions above. **Contact Time:** Leave surface wet for 10 minutes. **Disposal of Infectious Material:** Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

Danger: Corrosive. Causes irreversible eye damage and skin burns. Harmful or fatal if swallowed. Do not breathe vapor or fumes. Do not get in eyes, on skin or on clothing. Wear protective eyewear (safety goggles or face shield), protective clothing and rubber gloves when handling. Use with adequate ventilation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

Chemical Hazards: Never use with chlorine products. Can react to give chlorine gas. If this occurs, flush toilet to remove chemicals and leave area. Do not return for half an hour. Ventilate if possible. Never use or mix with other cleaners or chemicals. Clean up any spills or drips immediately. Do not use on any surface that can be damaged by acidic materials. Many surfaces are not resistant to acid. **Do not use on PVD finished surfaces.**

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. 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 to an unconscious person. Call a poison control center or doctor for further treatment advice.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).

FOR HOUSEHOLD CONTAINER SIZES 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.