

875-189

1-8-2003

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN - 8 2003

Mr. Terry Sabatelli
Regulatory Specialist
DiverseyLever
3630 E. Kemper Rd.
Cincinnati, OH 45241

Subject: HLC-18
EPA Registration No. 875-189
Application Date: 10/03/02
Receipt Date: 10/10/02

Dear Mr. Sabatelli:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable:

- Update First Aid Statements
- Change the following words: Active ingredient(s) to Active ingredient and Inert to Other

GENERAL COMMENTS

The Toxicity Category should be accepted with the following categories:

- Primary Eye I
- Primary Skin I
- Acute Dermal III
- Acute Oral IV

Revise the current Precautionary Statements to read exactly as follows such that they are in agreement with the toxicity categories above and the Label Review Manual:

Corrosive. Cause irreversible eye damage and skin burns. Harmful if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, or face shield) protective clothing and rubber gloves, wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/5

Revise your labeling such that the Registration number 875-189 is included on the front panel (page 1) of the label. Revise your directions for "General Purpose Disinfection", to begin as follows: Remove heavy soil, preclean surfaces. To disinfect and deodorizes...

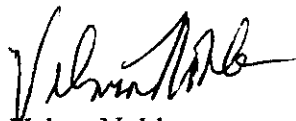
Clarify the directions "For restrooms and locker rooms". Since your label language includes the statement,and other hard non-porous surfaces... and you do not include directions for all surfaces in restrooms (ie. Toilets). Add the following phrase to the end of this sentence: ..."and other hard non-porous surfaces, excluding toilets in public restrooms."

General Comments

A stamped copy of the accepted labeling 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 Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)



HLC-18

®

Quaternary Germicidal Cleaner

For Industry Use

Active Ingredient:

Didecyl dimethyl ammonium chloride 4.175%

Other Ingredients: 95.825%

Total 100.000%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

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 the 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 immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call 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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 8 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No. 875-189

4/5

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. 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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal or cleaning of equipment.

PESTICIDE STORAGE: Store in original container in a dry place. Do not store on side. Avoid creasing of side walls. If frozen thaw and make usable.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of all excess pesticide, spray mixture, or 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: Plastic Containers – Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

This product contains no phosphorus.

DIRECTIONS FOR USE:

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

HLC-18 is a one-step disinfectant and fungicide designed for use in hospitals, nursing homes, schools, hotels and other institutions. At proper use dilutions, it will disinfect hard non-porous surfaces and deodorize areas where malodors may develop. It is effective in hard water up to 400 ppm hardness in the presence of organic soil.

GENERAL PURPOSE DISINFECTION: To disinfect and deodorize hard non-porous surfaces, mop or brush clean surface with a 1:64 (2 fluid ounces per gallon) solution of HLC-18 to wet all surfaces thoroughly. Allow a 10 minute contact time followed by a potable water rinse. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

FOR DISINFECTION IN HOSPITALS AND NURSING HOMES: Thoroughly preclean all surfaces to remove gross filth or heavy soil prior to disinfection. Apply HLC-18 at 1:64 (2 fluid ounces per gallon) for disinfecting hard non-porous surfaces such as floors, walls, storage areas, metal cabinets, and carts. Allow a 10 minute contact time and follow with a potable water rinse. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

FOR RESTROOMS AND LOCKER ROOMS: Use 1:64 (2 fluid ounces per gallon) solution for cleaning and disinfecting floors, walls, lockers, fixtures and other hard non-porous surfaces in public restrooms, locker rooms, and gymnasiums. Allow a 10 minute contact time followed by a potable water rinse. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

Accepted with COMMENTS in EPA Letter Dated:

JAN 8 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for use as a disinfectant, registered under EPA Reg. No. 875-189

5/5

FOR FUNGICIDAL CONTROL: To disinfect hard nonporous surfaces against pathogenic fungi, apply a 1:51 (2 ½ ounces per gallon of water) solution of HLC-18 to wet all surfaces thoroughly. Allow a 10 minute contact time followed by a potable water rinse. Prepare a fresh solution daily or when use solution becomes diluted or soiled.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

EPA Reg. No. 875-189

EPA Est. No. 875-OH-1[50]; 875-PA-1[80]; 875-CA-4[MD]; 875-WI-1[10]

Bracketed numbers/letters are the first numbers/letters of the batch number

Net Contents:

18.9 L (5gal)

4X3.78 L (1 US gal)

DiverseyLever

3630 E. Kemper Rd.

Cincinnati, OH 45241

800 626 5015

24 Hr EMERGENCY TELEPHONE:

Medical: (Call Collect) 303 592 1024

Transportation: (CHEMTREC) 800 424 9300

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