

1677-202

9/16/2008

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

OFFICE OF
 PREVENTION, PESTICIDES
 AND TOXIC SUBSTANCES

SEP 16 2008

Rhonda K. Schulz
 Associate Director, Regulatory Affairs
 Ecolab Inc.
 370 N. Wabasha Street
 St. Paul, MN 55102

Subject: Oasis Pro 66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant
 EPA Registration No. 1677-202
 Amendment Dated: May 05, 2008
 EPA Received Date: May 07, 2008

Dear Rhonda K. Schulz

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

Proposed Amendment

- Add Norovirus
- Revise Container Disposal

Efficacy Data

| Data Requirement | Means of Support | Status |
|-------------------------------|---------------------------------------|--|
| AOAC Use Dilution - Norovirus | Submitted study, MRID 47421902 and 03 | Acceptable, 5% organic soil load, 10 minute contact time |

Chemistry Data

- The Confidential Statement of Formula contained a fragrance that had not previously been approved for use in pesticides. The fragrance supplier submitted the composition of the ingredient to the Agency, and the fragrance has now been included in the Agency's electronic database of approval ingredients. For more information about this ingredient. (See Attached Review)
- All other ingredients in the formulation have previously been approved for use in pesticides.

| | | | | | | | |
|--------|-------|--|--|--|--|--|--|
| SYMBOL | 75716 | 3. The Storage and Stability/Corrosion/Compatibility tests were conducted using good Laboratory Practices as required. (See Attached Review) | | | | | |
| URNAME | | | | | | | |
| DATE | | | | | | | |

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4. The Certified Limits of the fragrance and the dye do not conform to the current Agency standards. To retain these standards a rationale which supports in the need for the wider limits must be submitted to the Agency for review and approval.

Label Comments

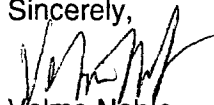
1. Change Norwalk virus to read Norovirus.
2. Change the nomenclature of Salmonella choleraesuis to Salmonella enterica.
3. Change ATCC number from 0157 to O157.

General Comments

A stamped copy of the accepted labels are enclosed for your records. Submit (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit revised labeling for review by the agency. Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Division (7510c)

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OASIS PRO 66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT

*Detergent-Disinfectant / Bactericidal / Virucidal / Mildewstatic / Fungistatic /
Deodorizer*

*Hospitals - Nursing Homes - Institutions - Schools
Restaurants - Food Service - Beverage and Food Processing Plants
Veterinary and Industrial Use*

ACCEPTED
in EPA Letter Dated:
SEP 16 2008

Active Ingredients:

n-Alkyl (50% C14, 40% C12, 10% C16)

Dimethyl Benzyl Ammonium Chloride.....

Didecyl Dimethyl Ammonium Chloride.....

Other Ingredients:

Total:

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

1677-202

0.52%

97.00%

100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist or vapors. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

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

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS: 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 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.

OASIS PRO 66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT is a "one-step" Disinfectant, Cleaner, Bactericide, Mildewstat and Virucide.

OASIS PRO 66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT is formulated to clean, disinfect and sanitize in one step. It is, phosphate free, and effective in hard water. It is recommended for cleaning and disinfecting walls, floors and other hard non-porous environmental surfaces such as bathroom fixtures, sinks, tables, chairs, countertops, shelves, racks, carts, refrigerator exteriors, non-food contact surfaces of coolers, drains, glazed tile, linoleum, vinyl, plastic (such as polyethylene, polypropylene, polyvinylchloride, and polycarbonate), metal, glazed porcelain, glass, and painted surfaces. Will not damage PVD coated fixtures and finishes.

Areas of Use: hospitals, nursing homes, other health care-facilities, hospitality, educational, institutional, recreational, industrial, scientific and commercial, food service, food processing, manufacturing, retail, wholesale as well as animal care and rearing facilities.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not mix with anything but water.

| Claim | Use Dilution |
|--------------------------------------|---------------------|
| Daily Cleaning & Disinfection | 4 - 8 oz. / gallon |
| Heavy Duty Cleaning & Disinfection | 8 - 12 oz. / gallon |
| Toilet Bowl Cleaning & Disinfection | 8 - 12 oz. / gallon |
| Mildewstatic/Fungistatic | 4 - 8 oz. / gallon |
| Sanitizing Non-Food Contact Surfaces | 0.5 oz. / gallon |

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 devices prior to sterilization or high-level disinfection.

DISINFECTION:

For hospital disinfection and cleaning of hard non-porous surfaces in 400 ppm hard water (as CaCO_3), in the presence of 5% blood serum and soap scum. Apply **OASIS PRO 66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT** with a coarse sprayer, wet cloth, mop, sponge, brush, scrubber, or by soaking.

PREPARATION OF USE-SOLUTION:

Daily Cleaning and Disinfection:

Add 4 to 8 oz of product per 1 gallon of solution. Apply to hard, nonporous surfaces. Allow a 10-minute contact with the surface. Remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

For Heavy Duty Cleaning and Disinfection:

Add 8 to 12 oz. of product per 1 gallon of solution. Apply to hard, nonporous surfaces. Allow a 10-minute contact with the surface. Remove solution and entrapped soil with a clean, wet mop, cloth or rinse to drain.

Toilet Bowls Cleaning and Disinfection:

Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying 8 to 12 oz. of product per 1 gallon solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first remove or expel over the residual bowl water. Pour in three ounces of the use-solution. Swab the bowl completely using a scrub brush, making sure to get under the rim. Let stand for 10 minutes or overnight, then flush.

BACTERICIDAL:

Effective against the following pathogenic bacteria in 400 ppm hard water (as CaCO_3), in the presence of 5% blood serum and soap scum.

Pseudomonas aeruginosa – ATCC 15442
Staphylococcus aureus – ATCC 6538
Salmonella choleraesuis – ATCC 10708
Enterococcus faecalis (VRE) – ATCC 51575
Klebsiella pneumoniae – ATCC 4352

Enterobacter aerogenes – ATCC 15038
Serratia marcescens – ATCC 14756
Escherichia coli – ATCC 11229
Escherichia coli 0157:H7 – ATCC 43888

VIRUCIDAL:

Effective against the following viruses in 400 ppm hard water (as CaCO_3), in the presence of 5% blood serum and soap scum.

Herpes Simplex Virus Type 1 – ATCC VR-733
 Herpes Simplex Virus Type 2 – ATCC VR-734
 Influenza A (Hong Kong) (H3N3) Virus – ATCC VR-544
 HIV-1 (AIDS virus)
 Norwalk virus (Feline calicivirus surrogate) – ATCC – VR-782

KILLS HIV-1 (AIDS VIRUS) 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 the transmission of Human Immunodeficiency Virus Type 1 (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 must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedure: Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of *Oasis Pro 66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant*. This cleaning may be accomplished with any cleaning solution, including this product.

Contact Time: 10 minutes.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNs,

KENNELS, CAGES, HUTCHES, ETC): Remove animals and feed from facilities. Remove litter, waste matter, and gross soils. Empty all troughs, rack and other feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Disinfect surfaces as described under **Disinfection**. Ventilate buildings and other closed spaces. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. Allow to air dry before reintroducing animals.

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MILDEWSTATIC / FUNGISTATIC: Effectively inhibits the growth of mold and mildew and the odors caused by them at 4 to 8 oz. per 1 gallon of solution. Apply with spray bottle or sponge, allow to dry on surface. Repeat application after 7 days or when mold or mildew growth returns.

SANITIZING NON-FOOD CONTACT SURFACES: At 0.5 oz per 1 gallon of solution, this product is an effective sanitizer against *Staphylococcus aureus* and *Enterobacter aerogenes* on hard and non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes.

Containers 1 gallon or less:

STORAGE & DISPOSAL

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use. Do not reuse container. Wrap container and discard in the trash.

(1 gal. bladder in box) Remove empty bladder from outer corrugated box. Do not reuse bladder. Wrap bladder and box and put in trash.

Containers greater than 1 gallon:

STORAGE & DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal:

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

(2.5 gal bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling, if available.

EPA Reg. No. 1677-202

EPA Est.: 303-IN-1 (L), 1677-MN-1 (P), 1677-CA-2 (R), 1677-CA-1 (S), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 1677-IL-5 (N), 1677-PR-1 (B), 1677-NJ-1 (W), 1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code

Ecolab Inc.
370 North Wabasha Street
St. Paul, MN 55102-1390

Net Contents:

1 U.S. quart (946 ml)
1 U.S. gallon (3.78 L)
2 L
2.5 U.S. gallons (9.45 L)
5 U.S. gallons (18.9 L)
55 U.S. gallons (208.8 L)