

1677-202

UN D STATES ENVIRONMENTAL PROTEC N AGENCY

04/30/2010

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Rhonda Schulz
Associate Director, Product Registration
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

APR 30 2010

Subject: 66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant
EPA Registration No. 1677-202
Amendment Date: December 12, 2009
EPA Receipt Date: December 11, 2009

Dear Ms. Schulz,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

Proposed Amendment

- Change of Name of Record
- Deletion of Hospital and related uses due to ATP testing failure
- Change in application rate
- Revise Confidential Statement of Formula (CSF) and Chemistry Data

Conditions

Revise the label as follows:

1) Add the following phrase to the Precautionary Statements: "...Wash thoroughly...chewing gum, *using tobacco or using the toilet.*"

2) Delete the reference to the use of this product in health care settings from the HIV directions as follows: "KILLS HIV-1...SOILED WITH BLOOD/BODY FLUIDS *in settings* in which there is an expected likelihood..." In this same section, revise to state: "...vinyl gloves, gowns, face masks and eye coverings must be worn..." such that it is clear to the user that all of this protective equipment is necessary.

CONCURRENCES							
SYMBOL	7510P						
SURNAME	J. Feltus						
DATE	4/30/10						

3) Delete "etc." from the heading of the Disinfections and Deodorizing or Animal Housing section. Your label should indicate the specific uses of the product.

4) Add the following text to the Container Disposal section:

For containers 5 gallons or less: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as pesticide waste. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times." As per [40 CFR 156.146(b)(1)]

For containers larger than 5 gallons: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as pesticide waste. Repeat this procedure two more times." As per [40 CFR 156.146(b)(3)]

Add the following language for containers of 5 gallons or less and greater than 5 gallons:
"...Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."

Add the following language to the bladder in box section: "...Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke." As per 40 CFR 156.140 (a)(3), PR Notice 2007-4, and PR Notice 83-3.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

Efficacy Data

The following efficacy study was submitted in support of this product. The review of this data is attached.

Study	MRID Number	Study Status
<i>P. aeruginosa</i> and <i>S. aureus</i>	47931802	Efficacy was not demonstrated against <i>P. aeruginosa</i> and efficacy was demonstrated against <i>S. aureus</i> at 8 oz per gallon in 5 % soil, 10 minute contact time.

Chemistry Data

The revised CSF dated 3/5/10 for the basic formula is acceptable. The submitted MRID 479318-01 is acceptable in support of guidelines 830.6317 and 830.6320 Storage Stability and Corrosion Characteristics. The review of this data is attached.

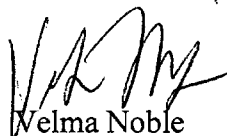
General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label, DERs DP 372973, 372974							
CONCURRENCES							
SYMBOL	7510P: T. Lantz: 4/30/2010: 1677-202 PRIA acceptable WC						
SURNAME							
DATE							

~~CASIO PRO~~ 66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT

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

***~~Hospitals - Nursing Homes - Laboratories~~ - Hospitality - Hotels - Schools -
Restaurants - Food Service - Beverage and Food Processing Plants
Veterinary and Industrial Use***

Active Ingredients:

n-Alkyl (50% C14, 40% C12, 10% C16)
Dimethyl Benzyl Ammonium Chloride..... 2.48%
Didecyl Dimethyl Ammonium Chloride..... 0.52%

Other Ingredients: 97.00%

Total:..... 100.00%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 30 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-202

**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.

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

~~CACIO 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	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 ~~CACIO 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.

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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.

Product	<i>Enterobacter aerogenes</i> (ATCC 15038)
<i>Staphylococcus aureus</i> (ATCC 6538)	<i>Serratia marcescens</i> (ATCC 14756)
<i>Salmonella enterica</i> (ATCC 10708)	<i>Escherichia coli</i> (ATCC 11229)
<i>Enterococcus faecalis</i> (VRE) (ATCC 51575)	<i>Escherichia coli</i> O157:H7 (ATCC 43888)
<i>Klebsiella pneumoniae</i> (ATCC 4352)	

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)
 Norovirus (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 ~~Quat 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

66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant 12/4/09
 waterers with soap or detergent, and rinse with potable water before reuse. Allow to air dry before reintroducing animals.

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-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)