

1677-204

12/13/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 13 2010

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Rhonda K. Schulz  
Ecolab Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102

Subject: 65 Disinfecting Heavy Duty Acid Bathroom Cleaner  
EPA Registration No.: 1677-204  
Application Date: July 21, 2010  
Receipt Date: July 23, 2010

Dear Ms. Schulz:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is accepted with conditions.

**Proposed Amendment:**

- Add additional virucidal and bacterial claims to label

**Data Summary**

| Data Requirement            | Means of Support                 | Status   |
|-----------------------------|----------------------------------|--|
| Human Coronavirus           | Submitted study, MRID, 481652-02 | Acceptable, 6/gallon of water in 5% soil for 5 minutes |
| Influenza A Hong Kong virus | Submitted study, MRID 481652-03  | Acceptable, 6/gallon of water in 5% soil for 1 minute  |

**Conditions**

Revise label as follows:

1.) A close parenthetic statement must be added the phrase, "(such as polyethylene, polypropylene....glass," on page 3.

2.) Revise the "Personal Protection" statement under the HIV-1 directions on page 3 by deleting the term, "or" and stating "and." The personal protection items are not optional when cleaning blood and body fluids.

**CONCURRENCES**

| SYMBOL  |  |  |  |  |  |  |  |
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| DATE    |  |  |  |  |  |  |  |



3.) Since this product may be used in veterinary clinics and animal life science laboratories, the following directions on how to clean in these areas must be added:

#### Veterinary Clinics and Animal Life Science Laboratories

Remove all animals and feed from premises and enclosures. Remove all litter and manure from floors, walls, and surfaces of kennels, cages, and other facilities/fixtures occupied or traversed by animals. Empty all feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with 6-8oz of product per gallon of water for a period of 10 minutes. Immerse all equipment used in handling or restraining animals as well as shovels and scrapers used for removing litter or manure. Ventilate buildings, kennels, cages, or other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feeding and watering equipment with soap or detergent, and rinse with potable water before reuse.

4.) The passage of the Container Rule resulted in certain portions of PR Notice 83-3 and 84-1 being rescinded; specifically, the storage and disposal statements will no longer be separated by container size but by use pattern (i.e. residential, institutional, industrial). Since your product appears to be sold in institutional, commercial, and industrial markets, you must revise the Storage and Disposal statements to provide appropriate container rinsate instructions as follows:

#### Storage and Disposal

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

**Pesticide Storage:** Acceptable statements

**Pesticide Disposal:** Acceptable statements

**Container Disposal:** Nonrefillable containers. Do not reuse or refill this container. Triple rinse container promptly after emptying. Offer for recycling if available. If not, puncture and dispose in a sanitary landfill or by procedures allowed by state and local authorities.

(5 gallons or less)

Triple rinse as follows: Empty the remaining contents into application equipment or 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 per Pesticide Disposal instructions. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(5 gallons or more)

Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container onto its other end and tip it back and forth several times. Dispose of rinsate per Pesticide Disposal instructions. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### CONCURRENCES

| SYMBOL  |  |  |  |  |  |  |  |  |
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**General Comments**

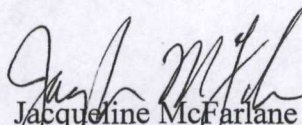
The Confidential Statements of Formulas for alternate formulations 3-7 are acceptable. They are in compliance with PR Notice 91-2 and in agreement with the label.

A stamped label with conditions is enclosed. Submit a copy of your final printed label before distributing or selling the product.

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.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at [campbell-mcfarlane.jacqueline@epa.gov](mailto:campbell-mcfarlane.jacqueline@epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or by email at [grigsby.stacey@epa.gov](mailto:grigsby.stacey@epa.gov) during the hours of 8:00 am to 4:00 pm 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  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure:    Stamped Label  
                  Efficacy Data Evaluation  
                  Product Chemistry Data Evaluation

**CONCURRENCES**

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# 65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER

*Detergent-Disinfectant / Bactericide / Virucide / Deodorizer*

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

**Active Ingredients:**

Octanoic Acid ..... 3.05%

**Other Ingredients:** ..... 96.95%

**Total:** ..... 100.00%

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

DEC 13 2010

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

1677-204

**PRECAUTIONARY STATEMENTS:**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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:** 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 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 a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

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

Have the product container or label with you 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 (5 gallons or greater):** 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.



7/21/2010

**65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER** is a "one-step" Disinfectant, Cleaner, Bactericide and Virucide. It is effective for the removal of soap scum and water hardness deposits.

**65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER** is for use in bathrooms, shower rooms and spas for disinfecting and cleaning walls, floors, tubs, showers, and other hard non-porous environmental surfaces such as bathroom fixtures, sinks, exterior surfaces of toilets, non-food contact surfaces of coolers, glazed tile, linoleum, plastic (such as polyethylene, polypropylene, polyvinylchloride, chrome, glazed porcelain, stainless steel and glass) Non-abrasive; won't scratch. Leaves surfaces shiny clean. Not for use on PVD coated fixtures and finishes or soft metals. Do not use on food contact surfaces such as glassware, dishes and utensils.

**Areas of Use:** hospitals, nursing homes, other health care-facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, dietary areas, beverage and food processing plants, restaurants, hotels, motels, office buildings, recreational facilities, retail and wholesale establishments.

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.

**DIRECTIONS FOR USE**

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

| Claim                                | Use Dilution          |
|--------------------------------------|-----------------------|
| Disinfection & Daily Cleaning        | 6 - 8 oz per gallon   |
| Disinfection & Heavy Duty Cleaning   | 8 - 12 oz. per gallon |
| Sanitizing Non-Food Contact Surfaces | 3 oz. per gallon      |

**DISINFECTION:**

For hospital disinfection and cleaning of hard non-porous surfaces according to the AOAC Use-Dilution Test method in 400 ppm hard water, in the presence of 5% blood serum and 0.005% soap residue . Apply **65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER** with a foamer, wet cloth, mop, scrubber, or by soaking.

**PREPARATION OF USE-SOLUTION:**

**For Disinfection and Daily Cleaning:**

Apply 6.0 to 8.0 oz. (5.4 wt% to 7.2 wt%) per gallon of use-solution to hard, nonporous surfaces. Allow a 10-minute contact with the surface. Wipe with damp cloth or sponge. Rinse surface with potable water. Prepare a fresh solution at least daily or sooner if solution becomes diluted or soiled.

**For Disinfection and Heavy Duty Cleaning:**

Pre clean to remove gross soil prior to disinfection. Apply 8.0 to 12 oz. (6.2 wt% to 10.7 wt%) per gallon of use-solution to hard, nonporous surfaces, thoroughly foaming surfaces with a sprayer. Allow a 10-minute contact with the surface. Wipe with damp cloth or sponge. Rinse surface with potable water. Prepare a fresh solution at least daily or sooner if solution becomes diluted or soiled.



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**BACTERICIDAL AGAINST:**

Effective against the following pathogenic bacteria according to the AOAC Use-Dilution Test method in the presence of 5% blood serum, 0.005% soap residue (sodium stearate) and 400 ppm water hardness (as  $\text{CaCO}_3$ ).

*Pseudomonas aeruginosa* – ATCC 15442  
*Staphylococcus aureus* (MRSA) – ATCC 33592  
*Staphylococcus aureus* – ATCC 6538  
*Salmonella enterica* – ATCC 10708  
*Enterobacter aerogenes* – ATCC 13048

*Klebsiella pneumoniae* – ATCC 4352  
*Enterococcus faecalis* (VRE) – ATCC 51299  
*Candida albicans* – ATCC 10231  
*Escherichia coli* – ATCC 11229  
*Escherichia coli* O157:H7 – ATCC 43895

**VIRUCIDAL AGAINST:**

Effective against the following viruses according to the Virucidal Qualification Test, modified in the presence of 5% blood serum, 0.005% soap residue (sodium stearate) and 400 ppm water hardness (as  $\text{CaCO}_3$ ).

(10 minute contact time)

HIV-1 (AIDS virus)  
 Herpes Simplex Virus Type 1 – ATCC VR-733  
 Herpes Simplex Virus Type 2 – ATCC VR-734

Rhinovirus Type 37 – ATCC VR-1147  
 Influenza A Virus – ATCC VR-544  
 Norovirus (*Feline calicivirus surrogate* – ATCC – VR-782)

(2 minute contact time)

Human Coronavirus – ATCC VR-740

(1 minute contact time)

Influenza A Hong Kong virus – ATCC VR-544

**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 *65 Heavy Duty Acid 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.

**NON-FOOD CONTACT SURFACE SANITIZING:**

Apply 3.0 oz. per 1 gallon of water. This product is an effective sanitizer against *Staphylococcus aureus* and *Enterobacter aerogenes* on hard, non-porous environmental surfaces. Apply product with a coarse trigger sprayer, wet cloth, mop, scrubber, or by soaking. Treated surfaces must remain wet for 5 minutes. Wipe dry with a sponge, mop, or cloth or allow to air dry. Prepare a fresh solution at least daily or sooner if solution becomes diluted or soiled.



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. 1677-204

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-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 (208.2 L)

**Optional Marketing Language:**

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).



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- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.