

1677-204

9/9/2008

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 9, 2008

OPP Decision Number: D-392906

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

Subject: Product Name: 65 Disinfectant Heavy Duty Acid Bathroom Cleaner
 EPA Registration Number: 1677-204
 Application Date: April 18, 2008
 Receipt Date: April 23, 2008

Dear Ms. Schulz:

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

Proposed amendment:

- Add Norovirus claims.

Acceptable data:

- The submitted data (MRIDs 474141-01 and 474141-02) supports the use of the product, 65 Disinfecting Heavy Duty Acid Bathroom Cleaner, as a hard surface disinfectant with virucidal activity against Norovirus (using Feline Calicivirus, ATCC VR-782, as a surrogate) at a 1:19 dilution (minimum 5.11g product to 94.89 g solution) in the presence of light organic soil and 0.005% sodium stearate (representative of soap residue) at room temperature with a contact time of 3 minutes.

Labeling Comments:

1. The proposed label claims that the product, 65 Disinfecting Heavy Duty Acid Bathroom Cleaner, is an effective one-step disinfectant with virucidal activity against "Norwalk virus (Feline calicivirus surrogate – ATCC – VR-782)" in the presence of moderate organic soil (5% serum) and 0.005% soap residue at a 6.0 to 8.0 ounce product per gallon of water dilution (1:21 to 1:16) with a contact time of 10 minutes on hard, nonporous surfaces. These claims are partially acceptable, pending the following label changes to reflect product testing.

a). Change "Norwalk virus" to read "Norovirus." Feline calicivirus was chosen as a surrogate for the family of caliciviruses, also known as Noroviruses. Since the strain specific to the 1968 Norwalk outbreak in Ohio was not the one tested, it is not permissible to state this on the label. For further information see the CDC's technical fact sheet for Norovirus (<http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-factsheet.htm>).

b). One lot of the product was tested at a dilution of 5.11 grams of product to 94.89 grams of water. This represents a 1:18.6 dilution, which is more stringent (less dilute) than the label directed 6oz/Gallon dilution (a 1:21 dilution). Use directions must be modified to match, or be less dilute than the tested dilution (i.e. an 8oz/Gallon, 1:16 dilution, would be acceptable).

2. The ATCC has changed the nomenclature of "*Salmonella choleraesuis*" to "*Salmonella enterica*." Make this change on page 3 of the proposed label.

General comments:

Submit three copies (3) copies of your final printed labeling bearing the above revisions before distributing or selling the product. A Stamped copy of the label is enclosed for your record.

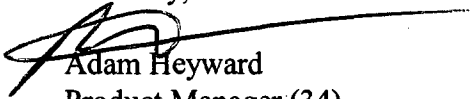
The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

Other comments:

For detailed information and considerations, please refer to the enclosed Antimicrobials Division Product science Branch efficacy review dated July 30, 2008.

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov or ShaRon Carlisle by telephone at (703) 308-6427 or by email at carlisle.sharon@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,


Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: {Stamped labeling & Efficacy review}

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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
in EPA Letter Dated:

**KEEP OUT OF REACH OF CHILDREN
DANGER**

SEP - 9 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide 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, 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: 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP - 9 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

1677-204

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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 recommended 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.

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.

For Disinfection and Heavy Duty Cleaning:

Apply 8.0 to 12 oz. (7.2 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.

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 CaCO_3).

Pseudomonas aeruginosa – ATCC 15442
Staphylococcus aureus – ATCC 6538
Salmonella choleraesuis – ATCC 10708
Enterobacter aerogenes – ATCC 13048
Enterococcus faecalis (VRE) – ATCC 51299

Klebsiella pneumoniae – ATCC 4352
Candida albicans – ATCC 10231
Escherichia coli – ATCC 11229
Escherichia coli O157:H7 – ATCC 43895
Norwalk virus (*Feline calicivirus surrogate* – ATCC – VR-782)

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 CaCO_3).

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

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.

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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-PR-1 (B), 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)