



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 13, 2017

Bridget Middleton
Regulatory Specialist
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

Subject: Notification per PRN 98-10 –Updating the master label, changing
The word, should to “must” throughout the label, adding optional marketing
Language. Plus, adding the 3-minute contact time clarified for Norovirus, data
previously reviewed and approved.
Product Name: 65 Disinfecting Heavy Duty Acid Bathroom Cleaner
EPA Registration Number: 1677-204
Application Date: October 13, 2017
Decision Number: 535449

Dear Ms. Middleton,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in blue ink, consisting of several overlapping, fluid strokes that form an illegible name.

Registration Risk Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Notification Label

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%

NOTIFICATION

1677-204

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/13/2017

**KEEP OUT OF REACH OF CHILDREN
DANGER**

(See [back], [side], [inside], [other] [fold-out] [booklet] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [precautionary statements] [and] [first aid] [and] [storage and disposal])

(Please [refer to] [see] reference sheet for [additional] [directions for use] [information])

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

OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

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.

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 fl. oz. per gallon
Disinfection & Heavy Duty Cleaning	8 - 12 fl. oz. per gallon
Sanitizing Non-Food Contact Surfaces	3 fl. oz. per gallon

DISINFECTION:

For hospital disinfection and cleaning of hard, non-porous surfaces only 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 fl. oz. (5.4 wt% to 7.2 wt%) per gallon of use-solution to hard, non-porous surfaces only. 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 fl. oz. (7.2 wt% to 10.7 wt%) per gallon of use-solution to hard, non-porous surfaces only, 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.

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 6-8 fl. oz. 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.

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 CaCO₃).

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 CaCO₃).

(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

(3 minute contact time)

*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, and 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 Disinfecting 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~~ must be autoclaved and disposed of according to local regulations for infectious waste disposal.

NON-FOOD CONTACT SURFACE SANITIZING:

Apply 3.0 fl. oz. per 1 gallon of water. This product is an effective sanitizer against *Staphylococcus aureus* and *Enterobacter aerogenes* on hard, non-porous environmental surfaces only. 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.

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:

(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, or puncture and dispose of in a sanitary landfill or by procedures allowed by state and local authorities.

(≤ 5-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate per pesticide disposal instructions. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill or by procedures allowed by state and local authorities.

(>5-55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ 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. Drain for 10 seconds after the flow begins to drip. Dispose of rinsate per pesticide disposal instructions. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill or by procedures allowed by state and local authorities.

EPA Reg. No. 1677-204

EPA Est.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R),
1677-TX-1 (D), 1677-IL-2 (J), 1677-GA-1 (M),
1677-WV-1 (V), 303-IN-1 (L), 58046-TX-2 (X),
5389-NC-1 (G)

Superscript refers to first letter of date code

(Manufactured for:)(Distributed by:)

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102 (USA)

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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:

FOR COMMERCIAL USE

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).

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.

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado: www.ecolab.com/patents

Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.

(Made in USA) (Made in United States of America)

SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary container label will be used only when the product is diluted at 12 fl. oz. or less per gallon of water. Other dilutions must use concentrate signal word and precautionary statements from page 1.)

65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER

Active Ingredients:

Octanoic Acid..... 3.05%

Other Ingredients: 96.95%

Total: 100.00%

The product in this container must be diluted at the use rate of 12 fl. oz. or less per gallon of water as directed on the concentrate product label.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

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

Follow the directions for use on the concentrate label when applying this product.

(Do not drink)
(Use solution prepared by end user)
(Not for sale or distribution)

EPA Reg. No. 1677-204