



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

August 29, 2016

Nicole Listner
Associate Regulatory Specialist II
EcoLab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: PRIA Label Amendment – Addition of Hospital Disinfection Claims
Product Name: 66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant
EPA Registration Number: 1677-202
Application Date: 04/04/2016
Decision Number: 516397

Dear Ms. Listner:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Jamil Mixon at (703) 308-8032, or via email at mixon.cletis@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs
Date: August 29, 2016

Enclosure

66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT

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

***Hospitals - Nursing Homes - Institutions - 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

08/29/2016

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**

(See [back], [side], [other] label for [complete] [additional] [directions for use] [precautionary
statements] [and] [first aid])

(Refer to the (MSDS) (SDS) for additional product hazard information)

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, 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 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.

(For 5 gallon containers or larger):

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.

66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT is a one-step (Hospital) Disinfectant, Cleaner, Bactericide, Mildewstat and Virucide*.

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

(These contact times will not control all organisms on the label. See label for other contact times for specific uses)

(Note to reviewer: language in parenthesis is optional. Any claim not approved by CDPR will include the statement "Use not approved in the state of California")

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.

This product is for use on non-food contact surfaces only

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:

[Note to reviewer: the following directions for use are for spray applications ONLY]

HOSPITAL DISINFECTION SPRAY APPLICATION:

For hospital disinfection and cleaning of hard non-porous, non-food contact surfaces in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum). Add 12 - 14 oz. of (**66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT**) (*This product*) per 1 gallon of solution. Spray (or use a foaming apparatus to produce foam) 6-8 inches from the surface. Allow for a 5-minute contact time and then remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare 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 gloves (vinyl or latex), gowns, eye covering (face masks or goggles) 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 (*66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant*) (*This Product*). This cleaning may be accomplished with any cleaning solution, including this product.

Contact Time: 2 minutes for spray application

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

BACTERICIDAL SPRAY APPLICATION:

Add 8 – 12 oz. of product per 1 gallon of solution. Apply to hard non-porous, non-food contact surfaces by spray (or foaming) application. Spray (or use a foaming apparatus to produce foam) 6-8 inches from the surface. Allow for a 5 minute contact time and then remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain. For heavily soiled areas, a pre-cleaning step is required.

Effective against the following pathogenic bacteria in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum) with a 5 minute contact time when using the spray application:

8 oz. / gallon use solution:

Enterobacter aerogenes (ATCC 13048)

Escherichia coli (ATCC 11229)

Escherichia coli O157:H7 (ATCC 43888)

Enterococcus faecalis (VRE) (ATCC 51299)

Klebsiella pneumoniae (ATCC 4352)

Salmonella enterica (ATCC 10708)

Serratia marcescens (ATCC 14756)

Staphylococcus aureus (ATCC 6538)

Staphylococcus aureus(CA-MRSA) (ATCC BAA-1683)

12 oz. / gallon use solution:

Pseudomonas aeruginosa – (ATCC 15442)

VIRUCIDAL SPRAY APPLICATION:

Add 8 - 12 oz. of product per 1 gallon of solution. Apply to hard non-porous, non-food contact surfaces by spray (or foam) application. Spray (or use a foaming apparatus to produce foam) 6-8 inches from the surface. Allow for a 2 minute contact time and then remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain. For heavily soiled areas, a pre-cleaning step is required.

Effective against the following viruses at 8 oz. of product per 1 gallon of solution in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum) with a 2 minute contact time when using the spray application:

- *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)

ONE-STEP DAILY CLEANING (AND) (OR) DISINFECTION SPRAY APPLICATION:

Add 8 -12 oz. of product per 1 gallon of solution. Apply to hard non-porous, non-food contact surfaces by spray (or foam) application. Spray (or use a foaming apparatus to produce foam) 6-8 inches from the surface. Allow for a 5-minute contact time and then remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

[Note to reviewer: the following directions for use are for coarse sprayer, foamer, cloth, mop, sponge, brush, scrubber, soaking applications]

HOSPITAL DISINFECTION:

For hospital disinfection and cleaning of hard non-porous, non-food contact surfaces in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum). Add 12 - 14 oz. of (**66 HEAVY DUTY ALKALINE BATHROOM CLEANER AND DISINFECTANT**) (*This Product*) per 1 gallon of solution with a coarse sprayer, foamer, wet cloth, mop, sponge, brush, scrubber, or by soaking. Allow for a 10-minute contact time. Remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare 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 gloves (vinyl or latex), gowns, eye covering (face masks or goggles) 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 (*66 Heavy Duty Alkaline Bathroom Cleaner and Disinfectant*) (*This Product*). 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 must be autoclaved and disposed of according to local regulations for infectious waste disposal.

ONE-STEP DAILY CLEANING (AND) (OR) DISINFECTION:

Add 8 –14 oz. of product per 1 gallon of solution. Apply to hard non-porous, non-food contact surfaces with a coarse sprayer, foamer, wet cloth, mop, sponge, brush, scrubber, or by soaking. 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.

TOILET BOWLS CLEANING AND DISINFECTION:

Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Flush toilet and allow the toilet bowl to refill. To clean and disinfect adding 8 - 12 oz. of product directly into the bowl (resulting in a use-solution for disinfection). Use a brush to clean around the bowl and up under the rim. Stubborn stains may require brushing. The outside of the bowl can be cleaned by using the brush and solution to scrub. If preferred the outside of the bowl can be cleaned using a bucket with 8 – 12 oz. of product per 1 gallon solution.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNs, KENNELS, CAGES, HUTCHES):

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 **One-Step Daily Cleaning**. 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.

BACTERICIDAL:

Effective against the following pathogenic bacteria in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum) with a 10 minute contact time when applied to hard non-porous surfaces with a coarse sprayer, foamer, wet cloth, mop, sponge, brush, scrubber, or by soaking.

8 oz. / gallon use solution:

Enterobacter aerogenes (ATCC 15038)

Escherichia coli (ATCC 11229)

Escherichia coli O157:H7 (ATCC 43888)

Enterococcus faecalis (VRE) (ATCC 51575)

Klebsiella pneumoniae (ATCC 4352)

Salmonella enterica (ATCC 10708)

Serratia marcescens (ATCC 14756)

Staphylococcus aureus (ATCC 6538)

Methicillin Resistant *Staphylococcus aureus* (ATCC 33592)

12 oz. / gallon use solution:

Pseudomonas aeruginosa (ATCC 15442)

VIRUCIDAL:

Effective against the following viruses at 8 oz. / gallon use solution in 400 ppm hard water (as CaCO_3) and in the presence of 5% blood serum (and soap scum) with a 10 minute contact time when applied to hard non-porous surfaces with a coarse sprayer, foamer, wet cloth, mop, sponge, brush, scrubber, or by soaking.

*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)

MILDEWSTATIC / FUNGISTATIC:

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

SANITIZATION:

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, non-food contact environmental surfaces. Treated surfaces must remain wet for 5 minutes.

CLEANING:**DAILY CLEANING SPRAY APPLICATION:**

Removes common soils and heavy soap scum on tubs, showers, counter tops, toilet and sinks. Add 8 - 10 oz of product per 1 gallon of solution. Apply to hard non-porous, non-food contact surfaces by spray (or foam) application. Spray (or use a foaming apparatus to produce foam) 6-8 inches from the surface. Allow for a 5-minute contact time and then remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

DAILY CLEANING:

Removes common soils and heavy soap scum on tubs, showers, counter tops, toilet and sinks. Add 8 -10 oz. of product per 1 gallon of solution. Apply to hard, non-porous, non-food contact surfaces and allow solution to saturate soil. Remove solution and entrapped soil with a clean wet mop, cloth, sponge, vacuum pickup or rinse to drain.

(\leq 1 gallon):

STORAGE & DISPOSAL

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use.

(> 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 Handling and 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 in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(\leq 5 gallons rigid) Nonrefillable container. Do not refill or reuse this container. 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 $\frac{1}{4}$ 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. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(>5-55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank.

Fill the container $\frac{1}{4}$ 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

procedure two more times. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Reg. No. 1677-202
EPA Est.: 303-IN-1 (L), 1677-MN-1 (P),
1677-CA-2 (R), 1677-TX-1 (D),
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
(Made in United States of America) (Made in USA)

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)

SECONDARY/USE DILUTION CONTAINER LABEL

(Note to reviewer: This secondary/use dilution container label will be used when the product is diluted up to 12 oz per gallon solution, 9.4%. Use dilution is to be prepared by end user. This secondary/use dilution label will only be used by the end user and will not be sold or distributed. When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements)

**66 HEAVY DUTY ALKALINE BATHROOM
CLEANER AND DISINFECTANT**

(Concentrate Ingredient Statement)

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%

The product in this container must be diluted at the use rate as directed on the concentrate product label.

Diluted product in this container is _____ oz per gallon solution

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

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.

(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.)

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.

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

Use solution prepared by end user.

Not for sale or distribution

(Do Not Drink)

EPA Reg. No. 1677-202