

1677-204

08/05/2009

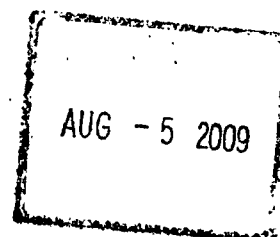
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Theodore D. Head
Product Registration Manager
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102



Subject: **65 Disinfecting Heavy Duty Acid Bathroom Cleaner**
EPA Registration Number: 1677-204
Application: March 13, 2009
Receipt Date: March 17, 2009

Dear Mr. Head:

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 comments.

Proposed Amendment

Update Basic Confidential Statement of Formula (CSF) (see CSF dated 3/20/09) and provide efficacy data to support public health pest.

Product Chemistry Comments

Please see confidential attachment for additional information regarding your formula.

The revised basic CSF 3/20/09 supersede all previously accepted basic CSFs.

Accepted Data

Efficacy

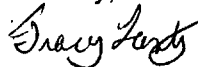
Data Requirement	Means of Support	Status
Methicillin Resistant Staphylococcus aureus (MRSA) ATCC 33592	Submitted study, MRID 477166-01	Acceptable, contact time 10 minutes, with soil

Labeling Comments

1. Revise the "for disinfection and heavy Duty Cleaning" to include a pre cleaning step since this product was only tested in the presence of light soil. Revise to include the following language: "Pre clean to remove gross soil prior to disinfection."
2. Revise "chewing gum, or using tobacco" in the Precautionary Statement to read "chewing gum, or using tobacco or using the toilet."
3. Page 2 of the label, revise as follows:
 - Delete "recommended" from the second paragraph per PR Notice 2000-5, Mandatory and Advisory Language labeling and replace with " *is for use in.*"
 - Add " *Do not use on food contact surfaces such as glassware, dishes and utensils*" to the second paragraph after "finishes or soft metals" on page 2.
 - The "For disinfection and daily cleaning" section, add "*with potable water*" after "Rinse surface." Also, add "*Prepare a fresh solution at least daily or sooner of solution becomes diluted or soiled*" as per DIS/TSS 15.
 - The "For disinfection and heavy duty cleaning" section, add "*with potable water*" after "Rinse surface." Also, add "*Prepare a fresh solution at least daily or sooner of solution becomes diluted or soiled*" as per DIS/TSS 15.
4. On page 3, add add "*Prepare a fresh solution at least daily or sooner of solution becomes diluted or soiled*" as per DIS/TSS 15 after last paragraph ending "or cloth or allow to air dry."

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: lantz.tracy@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email address at: mckelvin.Lisa@epa.gov.

Sincerely,



Tracy Lantz
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosed: Efficacy review dated 6/4/09
Product Chemistry review dated 7/20/09
Confidential Attachment

Confidential Attachment

The trade name of the third detergent is not cleared for use in pesticidal products. You must have your supplier send the complete compositional information of this ingredient to the Agency. This information must include the product name (must exactly match the name on the CSF), manufacturer name/address, and complete chemical composition including the chemical name, CAS Reg. No. and percentage by weight for each component of the mixture. This information must also be typed on the manufacturer's letterhead and accompanied by a signature.

65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER

Detergent-Disinfectant / Bactericide / Virucide / Deodorizer

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

AUG - 5 2009

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

Active Ingredients:

Octanoic Acid 3.05%

Other Ingredients: 96.95%

Total: 100.00%

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**KEEP OUT OF REACH OF CHILDREN
DANGER**

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.

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:

6:128 → 1:21.3

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. (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.

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).

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)

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)