



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 29 2009

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 Date: November 20, 2009  
Receipt Date: November 30, 2009

Dear Mr. Head:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3(c) 9.

**Proposed Notification:**

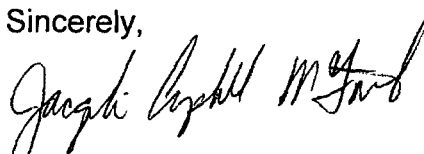
Optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1.

**General Comments:**

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me by telephone at 703-308-6416 or by email at [mcfarlane.jacqueline@epa.gov](mailto:mcfarlane.jacqueline@epa.gov) or Killian Swift by telephone at 703-308-6346 or by email at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). 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  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number <b>1677-204</b>	2. EPA Product Manager <b>Sharon Carisle</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) <b>65 Disinfecting Heavy Duty Acid Bathroom Cleaner</b>	PM# <b>34</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102</b>  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to 8-5-09
<input type="checkbox"/> Resubmission in response to Agency letter dated September 21, 2005	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional Page(s) if necessary. (For section I and Section II)

Optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-204 (65 Disinfecting Heavy Duty Acid Bathroom Cleaner).

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No  * <b>Certification must be submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 qt., 1 gal, 2 L, 2.5 gal, 5 gal, 55 gal	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)			
Name <b>Theodore D. Head</b>	Title <b>Product Registration Manager</b>	Telephone No. (Include Area Code) <b>(651) 293-2848</b>	
<b>Certification</b> I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title <b>Product Registration Manager</b>		
4. Typed Name <b>Theodore D. Head</b>	5. Date <b>November 20, 2009</b>		



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**THEODORE HEAD**  
Manager, Product Registration  
Regulatory Affairs  
T 651.293.2848  
F 651.225.3122  
ted.head@ecolab.com

November 20, 2009

Document Processing Desk (E-SUB)  
Office of Pesticide Programs (7502P)  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive  
Arlington, VA 22202

**ATTN: Sharon Carisle, PM-34**

**Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-204 (65 Disinfecting Heavy Duty Acid Bathroom Cleaner)**

Dear Sharon:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1.

Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8750-1.
- Certification with Respect to Label Integrity.
- Proposed Labeling (5 copies)
- Label CD

If you have any questions please contact me at the above phone, fax or email address.

Sincerely,



Theodore D. Head  
Product Registration Manager  
Regulatory Affairs  
Ecolab Inc.

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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%

**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, 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.

**NOTIFICATION**

Date Reviewed: 12/29/07  
Reviewed By: A. Smith

11/20/09

**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.

<b>Claim</b>	<b>Use Dilution</b>
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.

**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<sub>3</sub>).

*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 CaCO<sub>3</sub>).

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. 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-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)

### **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).

- 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.

11/20/09

- 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.