

1677-100

1-8-2003

4/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

January 8, 2003

Brian C. Brosdahl
Manager, North American Registrations
Ecolab, Inc.
370 Wabasha Street North
St. Paul, MN 55102

Subject: Institutional Scrub Free®
EPA Registration No. 1677-100
Application Date: October 15, 2002
EPA Received Date: October 18, 2002

Dear Mr. Brosdahl:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

Proposed Amendment

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Revise the statement "Wear protective clothing and rubber gloves." to read "Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves." in the Precautionary Statements section.
2. Since this product has a Toxicity Category I for eye and skin irritants, you must include the "Note to Physician" which should be located in close proximity to, and preferably below, the "First Aid Statements" but clearly distinguished from it. The statement should read as follows:

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

		CONCURRENCES				
SYMBOL	7510C					
SURNAME	Gray					
DATE	1-8-03					

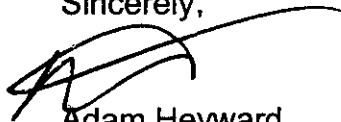
3. Since this product label includes claims as a virucidal, fungicidal, and deodorizer, you must include corresponding directions on the product label. Revise the heading "**For Disinfection**" to read "**For Disinfection/*Virucidal/Fungicidal/Deodorizer**"
4. The statement beginning "This product kill HIV..." should be revised to begin as follows: "***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS...**" This statement should be capitalized and in bold print to set it apart from the other parts of its text.
5. Revise the first sentence of the "Pesticide Disposal" section to read "*Pesticide wastes are acutely hazardous.*"

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit one(1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,



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

3/4

INSTITUTIONAL SCRUB FREE

HEAVY DUTY BATHROOM CLEANER/DISINFECTANT

ONE-STEP CLEANER•DISINFECTANT•SANITIZER•VIRUCIDAL*•FUNGICIDAL•DEODORIZER

Cleans Like Cleanser WITHOUT Scrubbing!

CLEANS AND DISINFECTS ENTIRE BATHROOM INCLUDING:

SHOWERS, SINKS, COUNTERS, FIXTURES, TUBS, FLOORS, WALLS, EXTERIOR SURFACES OF TOILETS, TILE, CHROME, PORCELAIN, FIBERGLASS

For Hospital, Institutional and Industrial Use

Active Ingredients:

Phosphoric Acid 17.4%

Citric Acid..... 4.9%

Inert Ingredients** 77.7%

Total.....100.0%

Formula does not contain more than 5.6% Phosphorous

**Active as cleaning and buffering agents.

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

JAN - 8 2003

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-100*

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not anything by mouth to an unconscious person.

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 further treatment advice.

Have the product container of label with you when calling a Poison Control Center or doctor or going for treatment.

**FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-612-292-4064**

ENVIRONMENTAL HAZARDS (only for 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.

4/6

For Hospital, Institutional and Industrial Use. Cleans, deodorizes and disinfects in one operation. Kills odor causing bacteria, mildew and pathogenic fungi (*T. mentagrophytes*, athlete's foot fungus) and *Staphylococcus aureus*. Disinfects Human Immunodeficiency Virus, Type 1 (commonly known as the AIDS virus), Adenovirus Type 2, Herpes Simplex Type 1 and Influenza A2/Hong Kong on inanimate, hard nonporous surfaces. Removes the toughest soap scum, dirt and even hard water deposits WITHOUT SCRUBBING. Use on nonporous surfaces such as bathroom chrome, fixtures, tile sinks, shower doors and tubs, including porcelain and fiberglass. **Do not use on PVD finish surfaces.** Non-abrasive; won't scratch. Leaves surfaces shiny clean. *Institutional Scrub Free* has been found effective against Human Immunodeficiency Virus, Type 1, (commonly known as the AIDS virus) on inanimate surfaces when tested according to the EPA Virucidal testing requirements.

*Effective against Human Immunodeficiency Virus, Type 1, (commonly known as the AIDS virus), Adenovirus Type 2, Herpes Simplex Type 1 and Influenza A2/Hong Kong.

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 except water. Use *Scrub Free* Spray Bottle and Foamer only for mixing and dispensing product.

For Daily Cleaning and Sanitizing: Add 4 oz. of *Institutional Scrub Free* to 16 oz. *Scrub Free* bottle and fill with water (1:4 dilution). Completely foam the surface to be cleaned. Allow 2 minute contact with surface, then wipe with damp sponge or cloth. Rinse surface promptly with water.

For Cleaning Heavy Build-Ups: Add 8 oz. *Institutional Scrub Free* to 16 oz. *Scrub Free* bottle and fill with water. Completely foam surface to be cleaned. Allow a few minutes for *Institutional Scrub Free* to work and wipe with damp sponge or cloth. Rinse promptly with water. (For excessively heavy build-ups, a second application may be necessary.)

For Disinfection: Add 8 oz. *Institutional Scrub Free* to 16 oz. *Scrub Free* bottle and fill with water (1:2 dilution). First remove any heavy soil deposits, then completely foam the surface with *Institutional Scrub Free*. Allow 2 minutes contact with surface then wipe with damp cloth or sponge. Rinse promptly with water.

This product kill HIV 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 are likely to be soiled with blood or body fluids that 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 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: When handling items soiled with blood or body fluids, wear personal protection such as disposable latex gloves, gowns, masks, or eye coverings.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time: 2 minutes

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

For precise, automatic mixing, dispense through Control Tower Specialty Product Dispenser.

Note: Do not use on natural marble, polished aluminum or special colored grout. May etch some older sinks and tubs. If in doubt, spot test hidden area first. Use only with foamer provided. Do not use any other sprayer.

This product is an effective disinfectant diluted at 1:2 (8 oz. product in 16 oz. bottle) in the presence of 5% blood serum and soap residue with a 2 minute contact time against the organisms listed below. Follow directions for disinfection. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *clostridium difficile* (vegetative form), *Enterococcus faecalis* (vancomycin resistant strain), and *Trichophyton mentagrophytes*.

For service or additional information, call 1-800-35-CLEAN (352-5326)
Authorized by USDA for use in Federally inspected Meat and Poultry Plants.

STORAGE & DISPOSAL**DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL**

Storage: Store in a cool, dry area secured from general admission. Keep upright with cap tightly closed. Do not stack containers more than 2 high or under heavy objects. If container is damaged or leaking, isolate and place in secure area or receptacle. For spills, dike or plug drain. Flood with plenty of water. Broadcast SODIUM BICARBONATE or SODIUM CARBONATE over area. Rinse to drain.

Pesticide Disposal: Untreated wastes are hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. Dilute 50:50 with water and neutralize with SODIUM BICARBONATE or SODIUM CARBONATE. Residue may be flushed to drain with plenty of water. If 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: Do not reuse empty container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Scrub Free* is a registered trademark of Benckiser, and licensed to Ecolab Inc.

Net Contents:

1 U.S. Gal. (3.78 L)

2.5 U.S. Gals. (9.46 L)

15 U.S. Gals. (56.7 L)

Manufactured by:
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-100
EPA Est.: 1677-MN-1(P), 1677-CA-2(R), 1677-TX-1(D)
1677-OH-1(H), 1677-IL-2(J), 1677-MO-1(K), 1677-PR-1(B)
1677-CA-1(S), 1677-NJ-1(W), 1677-GA-1(M), 1677-WV-1(V)
Superscript refers to first letter of date code.

6/6

Alternate Directions for Use

(Alternate dilution numbers for the same ratios)

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 except water. Use *Scrub Free* Spray Bottle and Foamer only for mixing and dispensing product.

For Daily Cleaning and Sanitizing: Add 6 oz. of *Institutional Scrub Free* to 24 oz. *Scrub Free* bottle and fill with water (1:4 dilution). Completely foam the surface to be cleaned. Allow 2 minute contact with surface, then wipe with damp sponge or cloth. Rinse surface promptly with water.

For Cleaning Heavy Build-Ups: Add 12 oz. *Institutional Scrub Free* to 24 oz. *Scrub Free* bottle and fill with water. Completely foam surface to be cleaned. Allow a few minutes for *Institutional Scrub Free* to work and wipe with damp sponge or cloth. Rinse promptly with water. (For excessively heavy build-ups, a second application may be necessary.)

For Disinfection: Add 12 oz. *Institutional Scrub Free* to 24 oz. *Scrub Free* bottle and fill with water (1:2 dilution). First remove any heavy soil deposits, then completely foam the surface with *Institutional Scrub Free*. Allow 2 minutes contact with surface then wipe with damp cloth or sponge. Rinse promptly with water.

This product kill HIV 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 are likely to be soiled with blood or body fluids that 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 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: When handling items soiled with blood or body fluids, wear personal protection such as disposable latex gloves, gowns, masks, or eye coverings.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time: 2 minutes

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

For precise, automatic mixing, dispense through Control Tower Specialty Product Dispenser.

Note: Do not use on natural marble, polished aluminum or special colored grout. May etch some older sinks and tubs. If in doubt, spot test hidden area first. Use only with foamer provided. Do not use any other sprayer.

This product is an effective disinfectant diluted at 1:2 (12 oz. product in 24 oz. bottle) in the presence of 5% blood serum and soap residue with a 2 minute contact time against the organisms listed below.

Follow directions for disinfection. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *clostridium difficile* (vegetative form), *Enterococcus faecalis* (vancomycin resistant strain), and *Trichophyton mentagrophytes*.

