



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 2, 2004

Brian C. Brosdahl
Senior Manager, Regulatory Affairs
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: **Beaucoup Germicidal Detergent**
EPA Registration No.303-223
Application Dated January 13, 2004

Dear Mr. Brosdahl:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable providing the following label revisions are made.

Proposed Amendment

- Revised labeling (additional claims)
- Revised basic formula (see CSF dated 3/13/03)

Product Chemistry Comments

- The certified limits for both the active and inert ingredients must be based on the nominal concentrations of each ingredient. It was noted in the Basic Confidential Statement of Formula (CSF) dated March 13, 2002, that the certified limits for only the active ingredients were based on the nominal concentration. Therefore the inert ingredients shown in the Basic CSF must be updated.

Efficacy Data Review

The submitted efficacy data (MRID No. 461754-01) support the use of the product, Beaucoup Germicidal Detergent, as a disinfectant with virucidal activity against Human Coronavirus on hard, non-porous surfaces at a 1:270 dilution in the presence of 400 ppm hard water in the and 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes. Complete inactivation (no growth) was indicated dilutions 10^{-1} through 10^{-6} . Cytotoxicity was not observed. A recoverable virus titer of at least 10^4 was achieved.

Labeling Comments

1. In the Precautionary Statement, change the statement from "Causes irreversible eye damage or skin burns" to "Causes irreversible eye damage and skin burns."
2. Change the statement in the First Aid section to read, "Have the product container or label with when calling....." to " Have the product container or label with you when calling....."
3. On page 1, change "Personal Protection Equipment" to read "Personal Protective Equipment."

Other Comments

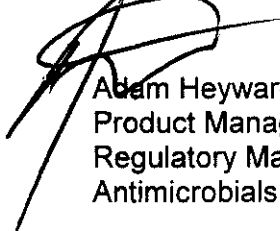
Submit an updated Basic CSF bearing the correction as stated above.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

For detailed information and consideration refer to the EPA/PSB efficacy review dated March 24, 2004.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,



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

Enclosure

316

BEAUCOUP

Germicidal Detergent

Cleans, Disinfects, Deodorizes.....Pleasant Fragrance

ACTIVE INGREDIENTS:

o-phenylphenol	3.55%
o-benzyl-p-chlorophenol.....	5.32%
p-tert-amylphenol.....	1.81%
OTHER INGREDIENTS:	<u>89.32%</u>
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive: Causes irreversible eye damage or skin burns. Harmful if swallowed absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles, safety glasses or face shield when handling. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Handlers must wear long-sleeved shirt and long pants, shoes plus socks, goggles or face shields, and chemical resistant gloves (such as barrier laminate or butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton at ≥ 14 mils).

Users should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and put on clean clothing.

Follow manufacturers' instructions for cleaning/maintaining Personal Protection Equipment (PPE). If no such instructions for washables use detergent and hot water. Keep and wash PPE separately from other laundry.

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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If the person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further 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. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

ACCEPTED
With COMMENTS
EPA Letter Dated:

JUN - 2 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 303-223

4/6

ENVIRONMENTAL HAZARDS: (for 5 gallon 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 the 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.

PSEUDOMONACIDAL STAPHYLOCIDAL TUBERCULOCIDAL VIRUCIDAL* FUNGICIDAL

BEAUCOUP is a multi-purpose germicidal detergent tested by the AOAC Use-Dilution Method in the presence of 5% organic bioload (Fetal Bovine Serum). **BEAUCOUP**'s formula disinfects, cleans and deodorizes in one labor-saving step.

BEAUCOUP is effective against the following pathogenic organisms:

<i>Pseudomonas aeruginosa</i>	<i>Shigella flexneri</i>	<i>Salmonella typhi</i>
<i>Salmonella choleraesuis</i>	<i>Streptococcus pyogenes</i>	<i>Salmonella typhimurium</i>
<i>Staphylococcus aureus</i>	<i>Enterococcus faecalis</i>	<i>Serratia marcescens</i>
<i>Pseudomonas cepacia</i>	<i>Proteus vulgaris</i>	<i>Clostridium difficile</i>
<i>Proteus mirabilis</i>	<i>Klebsiella pneumoniae</i>	<i>Escherichia coli</i>
<i>Enterobacter cloacae</i>	<i>Enterobacter aerogenes</i>	<i>Mycobacterium bovis</i>
<i>Candida albicans</i>	<i>Trichophyton mentagrophytes</i>	<i>Providencia rettgeri</i> HL-92
<i>Pseudomonas maltophilia</i> (antibiotic resistant) HL-131		
<i>Enterococcus faecalis</i> (vancomycin resistant) ATCC 51299		
<i>Staphylococcus aureus</i> (methicillin resistant) ATCC 29213		
<i>Staphylococcus aureus</i> (vancomycin resistant) 523K		
<i>Staphylococcus epidermidis</i> (antibiotic resistant) HL-123		
*Influenza Type A (H3N2)	*HIV-1 (AIDS Virus)	*Newcastle Disease Virus
*Rubella (German measles)	*Vaccinia	*Adenovirus Type 2
*Herpes Simplex Type 1	*Human Coronavirus	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in manner inconsistent with its labeling.

GENERAL PRECAUTIONS

Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application. Following application as a low-pressure or high-pressure spray, do not enter or allow others to enter until sprays have dried.

FOR DISINFECTING

USES: For use on hard, non-porous surfaces. For use in hospitals and nursing homes, schools and colleges, medical and dental offices, farm premises and veterinary clinics.

APPLICATION: Use 1 ounce of **BEAUCOUP** per gallon of water for a minimum contact time of 10 minutes in a single application. For disinfecting, remove gross filth and heavy soil deposits, then thoroughly wet surfaces. **BEAUCOUP** is a multi-purpose germicidal detergent and can be applied with a mop, sponge or cloth; or by soaking. The recommended use solution is used once and discarded. Rinsing is not necessary on floor surfaces unless floors are to be waxed or polished.

BEAUCOUP 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.

TUBERCULOCIDAL: This product is tuberculocidal diluted 2 ounces per gallon of water with a 10 minutes contact time at 20°C. Apply as directed above.

***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 faces 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 *BEAUCOUP*. 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.

DISINFECTION OF BARBER AND BEAUTYSHOP INSTRUMENTS AND TOOLS

Thoroughly pre-clean instruments/tools. Use dilution rate is 1:128 (1/4 oz. per 32 oz. of water or 8 ml. per liter of water). Completely immerse brushes, combs, shears, clipper blades, razors, tweezers, manicure and other shop tools for 10 minutes at room temperature (or as required by local authorities). After disinfection, remove instruments and rinse thoroughly and let dry. Fresh solution should be prepared daily, or more often if solution becomes diluted or soiled. Prolonged soaking may cause damage to metal instruments.

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

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. 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.
8. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house poultry, livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

6/6

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in securely closed original container. Avoid storage at temperature extremes or in direct sunlight.

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 directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(1 gallon or less): Do not reuse empty containers. Wrap container and put in trash.

(1 gallon or greater): 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.

(Reusable container statement): Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser [specific equipment such as "Simplex dispenser" can be named to replace "dilution dispenser".] Dispenser will automatically dilute a sanitizer [or disinfectant] solution. Remove concentrate label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

"Classified by Underwriters Laboratories Inc.®, as to electrical conductivity when used on conductive floors and spontaneous heating. *BEAUCOUP* for use with listed electrically conductive flooring of the vinyl type." 378Y

EPA Reg. No. 303-223

EPA Est. 303-IN-1(L), 1677-IL-2(J), 1677-NJ-1(W), 1677-TX-1(D), 1677-GA-1(M), 1677-MN-1(P), 1677-CA-1(S), 1677-PR-1(B), 1677-OH-1(H), 1677-CA-2(R), 1677-WV-1(V)

The superscript refers to the first letter of the date code.

Net Contents: 1 U. S. Gal. (3.78 L)
 5 U.S Gal. (18.9 L)

Huntington Professional Products
A Service of Ecolab Inc.
370 North Wabasha Street
St. Paul, MN 55102