

PM 34 303-223 8-14-97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEST COPY AVAILABLE

AUG 14 1997

Ecolab Inc.
370 N. Wabasha Street
St. Paul, Minnesota 55102

Attention: Ms. Ann M. Oxford
Manager, Regulatory Services/North America

Subject: Boucop II
EPA Registration Number 303-223
Your Letter Dated May 16, 1997

This is in response to your letter dated May 16, 1997, regarding the efficacy evaluation of Boucoup II vs. Vancomycin resistant Staphylococcus aureus and MRID 44127101 data for efficacy of the Matar/Matar II/MTR Phenolic against S. Aureus (VRSA), in the presence of AOAC synthetic hard water and a 5% soil land containing information on the neutralization and subculturing procedures.

Michelle Wingfield, Section Head, EETMS/RASSB, has review the data and it supports the neutralization and subculturing procedures, therefore, we will not request any further information pertaining to this product EPA Registration Number 303-223 per your letter dated May 16, 1997.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. A stamped copy is enclosed for your records. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,

Portia M. Jenkins
Acting Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:		CONCURRENCES					
SYMBOL	7510W						
SURNAME	Jenkins						
DATE	8/14/97						

BEAUCOUP II

Product Number 102614

- Cleans, Disinfects, Deodorizes
- Pleasant Fragrance

ACTIVE INGREDIENTS:

o-phenylphenol	2.94%
o-benzyl-p-chlorophenol	4.56%
p-tert-amylphenol	1.49%
INERT INGREDIENTS:	91.01%
Total	100.00%

DILUTION: 1 TO 128 ONE OUNCE PER GALLON

KEEP OUT OF REACH OF CHILDREN DANGER

(See side panel for additional precautionary statements and practical treatment statements.)

CONTENTS ONE GALLON (3.785 Liters)

DILUTION: 1 TO 128 ONE OUNCE PER GALLON

DIRECTIONS FOR USE

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

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.

FOR DISINFECTING:

USES: For use on hard, non-porous surfaces such as floors, walls, metal surfaces, polished surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring, and lavatory fixtures. For use in hospitals and nursing homes, schools and colleges, medical and dental offices, farm premises, and veterinary clinics.

APPLICATIONS: Use 1 ounce of BEAUCOUP II 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 II 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. Tuberculocidal effectiveness is in 10 minutes at 20°C when used at a dilution of 1 ounce per gallon of water.

KILLS HIV ON PRECLEANED 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 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: Intact latex or intact vinyl gloves must be worn during all cleaning of body fluids and decontamination procedures.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of BEAUCOUP II. This cleaning may be accomplished with any cleaning solution including this product.

CONTACT TIME: HIV-1 (AIDS Virus) is inactivated after five (5) minutes of contact at 25°C. Use a 10 minute contact time at 20°C for other viruses and bacteria claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 14 1997

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

PSEUDOMONACIDAL STAPHYLOCIDAL TUBERCULOCIDAL *VIRUCIDAL FUNGICIDAL

BEAUCOUP II is a multi-purpose germicidal detergent tested by the AOAC Use Dilution Method in 400 ppm hard water (calculated as CaCO₃) in the presence of 5% organic bioload (Fetal Bovine Serum).

BEAUCOUP II's formula disinfects, cleans, and deodorizes in one labor-saving step.

BEAUCOUP II is effective against the following pathogenic organisms:

Pseudomonas aeruginosa	Trichophyton meningophyces
Enterobacter aerogenes	Candida albicans
Escherichia coli	†Staphylococcus aureus
†Proteus mirabilis	**Enterococcus faecalis (VRE)
Shigella flexneri	Enterococcus faecalis
Serratia marcescens	**Pseudomonas maltophilia
Salmonella choleraesuis	*Rubella (German measles)
†Enterobacter cloacae	*Hepatitis B virus (HBV)
Klebsiella pneumoniae	*HIV-1 (AIDS virus)
Proteus vulgaris	*Adenovirus Type 2
Salmonella typhimurium	*Herpes Simplex Type 1
Salmonella typhi	*Influenza Type A/Mich
Pseudomonas cepacia	*Vaccinia
*Pseudomonas aeruginosa	*Newcastle Disease virus
Providencia rettgeri	*Canine parvovirus
Mycobacterium bovis	*Human rhinovirus Type 38
Streptococcus pyogenes	*Polio I virus
**Staphylococcus aureus (VISA)	

**Tested against antibiotic resistant strain only.

†Tested against standard ATCC strains and antibiotic resistant strains.

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

EPA Reg. No. 303-223 EPA Est. No. 303-IN-1

For product information call 1 800-537-5724
In Canada call 1 800-465-LABS

Huntington Laboratories, Inc. Huntington, IN 46750
Lansdale, PA 19446 • Dallas, TX 75227
Oakland, CA 94621 • Bramalea, Ontario, Canada L6T 1E3

STATEMENT OF PRACTICAL TREATMENT

In case of skin contact, wash thoroughly with soap and water. In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. If swallowed, drink promptly large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Concentrate causes eye and skin damage. May be absorbed through the skin. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Avoid contamination of food, water, or feed.

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 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.

STORAGE AND DISPOSAL

PROHIBITIONS

Do not contaminate water, food, or food by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinseate 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

Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

091896

BEAUCOUP II

DILUTION: 1:128 I OUNCE PER GALLON

DIRECTIONS FOR USE ON FARM PREMISIS

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 fixture 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 treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(Refer to label for precautionary and practical treatment statements.)

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