

PM 34

63281-4

10-23-97

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 23 1997

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

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

Subject: MTR Phenolic Germicidal Cleaner  
EPA Registration Number 63281-4  
Your Letter Dated September 22, 1997

This letter is in response to include additional pathogenic organisms such as Enterococcus faecalis, Enterococcus faecalis (VRE) and Staphylococcus aureus (VRSA) per our letter dated August 14, 1997, and expanding the HIV-1 special cleaning instructions, Directions for Use on farm premise and the removal pathogenic organisms Enterococcus sp., Hepatitis B Virus (HBV) and deletion of Mycobacterium tuberculosis var. bovis per the stamped label dated June 5, 1995.

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

On your proposed label dated October 1, 1997, please remove the following pathogenic organisms Enterococcus sp. and Hepatitis B. Virus (HBV) and not cross out in black ink as indicated on the October 1, 1997 label.

If you have further 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	AM						
DATE	10/23/97						

# MTR PHENOLIC GERMICIDAL CLEANER

Cleans, Disinfects, Deodorizes

PSEUDOMONACIDAL STAPHYLOCIDAL

\*VIRUCIDAL FUNGICIDAL TUBERCULOCIDAL

DILUTION: 1 to 250 . . . . . ONE-HALF 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.

## GENERAL USE DIRECTIONS

**USES:** For use on hard, non-porous surfaces such as floors, walls, metal surfaces, painted surfaces, exterior bowl surfaces, empty basins, showers, conductive flooring and lavatory fixtures. For use in hospitals, nursing homes, schools, colleges, medical and dental offices, farms, hog farms, equine farms, poultry and turkey farms, tack shops, kennels, pet shops, veterinary clinics, and animal life science laboratories. This includes barns, calf pens, laying operations, hatcheries, breeder operations, agricultural buildings and premises, live haul equipment, trucks, foot baths, and meat and poultry processing plants.

**APPLICATION:** Use 1/2 ounce 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. This product can be applied with a cloth, mop, or sponge; 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 1/2 ounce per gallon of water.

**HATCHERY:** Can be used for cleaning, disinfecting and deodorizing floors, walls and equipment throughout the hatchery. This includes incubators, setters, and racks. Add 1/2 ounce per gallon of water. Hot or cold water may be used. Remove loose waste, gross filth, and heavy soil deposits prior to disinfecting. Repeat with fresh solution to disinfect.

**USDA:** For use in federally inspected meat and poultry plants as a floor and wall cleaner. Before use of this compound, food products and packaging materials must be removed from the room and carefully protected. After use of this compound, all surfaces in the area must be thoroughly rinsed with potable water. Use 1/2 ounce per gallon of water.

A multi-purpose germicidal detergent proven effective by the AOAC Use-Dilution Method in 400 ppm hard water (calculated as CaCO<sub>3</sub>) in the presence of 5% organic bioload (Fetal Bovine Serum). Disinfects, cleans, and deodorizes in one labor-saving step.

Effective against the following pathogenic organisms:

- |                                |                             |
|--------------------------------|-----------------------------|
| Pseudomonas aeruginosa         | †Staphylococcus aureus      |
| Enterobacter aerogenes         | Streptococcus pyogenes      |
| Escherichia coli               |                             |
| †Proteus mirabilis             | *Rubella Virus              |
| Shigella flexneri              | *Hepatitis B virus (HBV) ✓  |
| Serratia marcescens            | *HIV-1 (AIDS Virus)         |
| Salmonella choleraesuis        | *Adenovirus Type 2          |
| †Enterobacter cloacae          | *Herpes Simplex Type 1      |
| Klebsiella pneumoniae          | *Influenza Type A/Mich      |
| Proteus vulgaris               | *Vaccinia Virus             |
| Salmonella typhimurium         | *Newcastle Disease Virus    |
| Salmonella typhi               | *Canine parvovirus          |
| Pseudomonas cepacia            | *Human rhinovirus Type 38   |
| ✓ <del>Enterococcus sp.</del>  | *Polio 1 virus              |
| Providenceia rettgeri          |                             |
| **Pseudomonas maltophilia      | Candida albicans            |
| ✓ Enterococcus faecalis        | Trichophyton mentagrophytes |
| **Enterococcus faecalis (VRE)  |                             |
| ✓ Mycobacterium bovis          |                             |
| ✓ Staphylococcus aureus (VRSA) |                             |

†Tested against standard ATCC strains and antibiotic strains.  
\*\*Tested against antibiotic resistant strain only.

## ACTIVE INGREDIENTS:

o-phenylphenol . . . . .	5.88%
o-benzyl-p-chlorophenol . . . . .	9.12%
p-tert-amyphenol . . . . .	2.97%
INERT INGREDIENTS: . . . . .	82.03%
TOTAL . . . . .	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

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

EPA Reg. No. 63281-4  
EPA Est. No. 63281-IN-01

Net Contents \_\_\_\_\_

RSP PRIVATE LABEL PACKAGING  
969 East Tipton Street  
Huntington, IN 46750

## 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, promptly drink a large quantity 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 on 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 feed 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 rinse 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

#### PLASTIC CONTAINERS

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. (For 1 gallon or less)

Do not reuse empty container. Rinse thoroughly before discarding in trash. Securely wrap original container in several layers of newspaper and discard in trash.

#### FIBER DRUMS WITH LINERS

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

#### METAL CONTAINERS

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

091896

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
OCT 23 1997

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

63281-4

Handwritten signature/initials

3.44

Page 2 of 3  
(label directions for use continued)

## MTR PHENOLIC GERMICIDAL CLEANER

**\*KILLS HIV-1 (AIDS virus) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare 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:** Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, and blood and during decontamination procedures.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application. This cleaning may be accomplished with any cleaning solution, including this product.

**Contact Time:** HIV-1 (AIDS virus) is inactivated after (5) minutes of contact at 25°C. Use a 10 minute contact time at 20°C for other common types of 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.

[For use as package insert or hang tag or place on label.] -

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Page 3 of 3  
(label directions for use continued)

## MTR PHENOLIC GERMICIDAL CLEANER

Dilution: 1:256 . . . . . 1/2 ounce per gallon

### DIRECTIONS FOR USE

[Farm premise, Livestock, Turkey, Poultry, Hog Farm] Disinfectant

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, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, 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.)

EPA Reg. No. 63281-4

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