

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 30, 2004

Brian C. Brosdahl
Senior Manager, Regulatory Affairs
Airkem Professional Products
Division of Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: Matar Germicidal Detergent
EPA Registration No. 303-225
Application Dates: January 13, 2004
EPA Received Dates: January 16, 2004

Dear Mr. Brosdahl:

The following amendments, submitted under connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with the conditions listed below:

Proposed Amendment

- Submission of Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus Study
- Revised labeling

Acceptable Data

The submitted efficacy data (MRID No. 461755-01) support the use of the product, MATAR Germicidal Detergent, as a disinfectant with virucidal activity against the Human coronavirus on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a 1:270 dilution. Complete inactivation (no growth) was indicated in the 10⁻¹ to 10⁻⁶ dilutions. Cytotoxicity was not observed. A recoverable virus titer of at least 10⁴ was achieved.

CONCURRENCES

SYMBOL	7510c						
SURNAME	Hay						
DATE	6-30-04						

Labeling

Revise the label as follows:

1. The proposed label claims are acceptable regarding the use of the product, as a disinfectant against the Human coronavirus on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 10 minutes at the label-specified 1:256 dilution.
2. Revise the Precautionary Statements by changing the statement "Causes irreversible eye damage or skin burns." to read "Causes irreversible eye damage and skin burns."
3. Revise the "Personal Protection Equipment" to read "Personal Protective Equipment".
4. Revise the If Swallowed section by changing the statement "Have a person sip..." to read "Have person sip..."
5. Change the statement "Have the product container or label with when..." to read "Have the product container or label with you when..."
6. Change the statement "It is a violation of Federal law to use this product in manner..." to read "It is a violation of Federal law to use this product in a manner..."
7. Revise the HIV-1 instructions by changing the statement "**PERSONAL PROTECTION:** Disposable latex or vinyl gloves, gowns faces masks..." to read "**PERSONAL PROTECTION:** Disposable latex or vinyl gloves, gowns, face masks..."

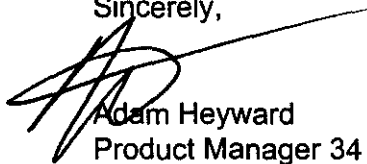
General Comments

For detailed information, refer to the enclosed Antimicrobials Division Science Support Branch Efficacy review, dated June 14, 2004.

A stamped copy of the labeling accepted with comments is enclosed. Submit three(3) copies 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)

JUN 30 2004

MATAR

Germicidal Detergent

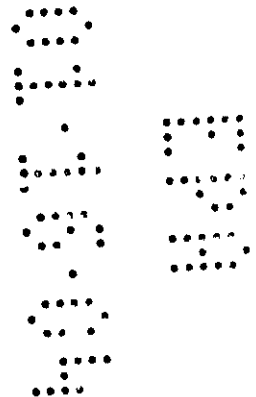
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, under EPA Reg. No. 303-225

Cleans, Disinfects & Deodorizes, Pleasant Fragrance

PSEUDOMONACIDAL-STAPHYLOCIDAL-TUBERCULOCIDAL-*VIRUCIDAL-FUNGICIDAL

ACTIVE INGREDIENTS:

o-phenylphenol	7.06%
o-benzyl-p-chlorophenol.....	10.60%
p-tert-amylphenol	3.62%
OTHER INGREDIENTS:	<u>78.72%</u>
TOTAL:	100.00%



KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: 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 (safety glasses). Wear protective clothing (long-sleeve shirt and long pants, socks plus shoes and chemical resistant gloves, such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse. Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application.

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 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 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.

ENVIRONMENTAL HAZARDS: (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.

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

Matar is effective against the following pathogenic organisms:

- | | |
|---|--|
| <i>Pseudomonas aeruginosa</i> (ATCC 15442) | <i>Salmonella typhi</i> (ATCC 6539) |
| <i>Salmonella choleraesuis</i> ATCC 10708) | <i>Salmonella typhimurium</i> (ATCC 14028) |
| <i>Staphylococcus aureus</i> (ATCC 6538) | <i>Serratia marcescens</i> (ATCC 8100) |
| <i>Pseudomonas cepacia</i> (ATCC 25609) | <i>Clostridium difficile</i> (ATCC 9689) |
| <i>Proteus mirabilis</i> (ATCC 25933) | <i>Escherichia coli</i> (ATCC 11229) |
| <i>Enterobacter cloacae</i> (ATCC 13047) | <i>Mycobacterium bovis</i> |
| <i>Candida albicans</i> (ATCC 10231) | <i>Providencia rettgeri</i> HL-92 |
| <i>Shigella flexneri</i> (ATCC 12022) | <i>Klebsiella pneumoniae</i> (ATCC 4352) |
| <i>Streptococcus pyogenes</i> (ATCC 19615) | <i>Enterobacter aerogenes</i> (ATCC 13048) |
| <i>Enterococcus faecalis</i> (ATCC 19433) | <i>Trichophyton mentagrophytes</i> (ATCC 9533) |
| <i>Proteus vulgaris</i> (ATCC 13315) | |
| <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) (ATCC VR-810) | *Newcastle Disease Virus (ATCC VR-109) |
| *Rubella, German measles (ATCC VR-315) | *Vaccinia (ATCC VR-156) |
| *Herpes Simplex Type 1 (ATCC VR-735) | *Adenovirus Type 2 (ATCC VR-846) |
| *HIV-1 (AIDS Virus) | *Human Coronavirus (ATCC VR-740) |

DIRECTIONS FOR USE

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

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 ½ ounce of *Matar* per gallon of water (1/4 oz. of *Matar* per 64 oz. 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. *Matar* 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.

Matar 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 1 ounce per gallon of water (1/4 oz. per 32 oz. 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 *Matar*. 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 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.

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:

(1/4 ounce packet) - Do not reuse packet. Wrap packet and put in trash.

(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

6 8 6

MATAR label

January 13, 2004

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. *Matar* for use with listed electrically conductive flooring of the vinyl type." 378Y

EPA Reg. No. 303-225

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