

3862-53

12/18/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 18 2009

Ms. Kim Inman
ABC Compounding Co., Inc
PO Box 16247
Atlanta, GA 30321

SUBJECT: Lem-O-Dis 19-30
EPA Registration No.: 3862-53
Amendment Date: September 29, 2008
EPA Receipt Date: September 15, 2009

Dear Ms. Inman,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions listed below.

Proposed Amendment

Update Storage and Disposal per PR Notice 2007-4

Conditions

Revise the label as follows:

- 1) The graphic of the man surrounded by microbes is unacceptable and must be deleted from the label.
- 2) AOAC has updated the species nomenclature for *Salmonella choleraesuis* to *Salmonella enterica*. Revise your label accordingly.
- 3) The "Personal Protection" statement under the HIV directions must be revised to delete the term, "or" and state "and." The personal protection items are not optional when cleaning blood and body fluids from a soiled surface.
- 4) The "Disposal of Infectious Material" statement under the HIV directions must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, should, and stating "must."

CONCURRENCES

CONCURRENCES							
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4) The last statement under "Precautionary Statements" must be revised to comply with Label Manual by stating "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."

General Comments

A stamped copy of the acceptable labeling 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 Jacqueline McFarlane at (703) 308-6416.

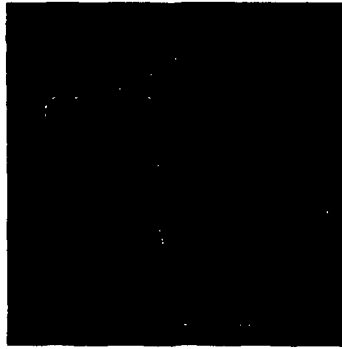
Sincerely,

Handwritten signature of Velma Noble

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



Manufactured by:
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321-0247
Toll Free 800-795-9222

EPA REG NO. 3862-53
EPA EST NO. 3862-GA-1

ACTIVE INGREDIENTS:
n-alkyl (60% C₁₂, 30% C₁₁, 5% C₁₃,
5% C₁₄) dimethyl benzyl ammonium
chlorides:.....1.6%
n-alkyl (68% C₁₂, 32% C₁₁) dimethyl
ethylbenzyl ammonium
chlorides:..... 1.6%
OTHER INGREDIENTS:.....96.8%
TOTAL:.....100.0%

Lem-O-Dis 19-30
● **CLEANER** ● **DISINFECTANT** ● **DEODORIZER**
● **FUNGICIDE** ● ***VIRUCIDE**
Desinfectante y desodorante pino

Desinfectante y desodorante limon Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.



Net Contents:

Batch No.:

ACCEPTED
with COMMENTS
in EPA Letter Dated:
DEC 18 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the FIFRA Act,
EPA Reg. No.
3862-53

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product is a phosphate free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools, and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to disinfect inanimate hard nonporous surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, telephones, and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting. This product may not be used in heating, ventilation, and air conditioning (HVAC) systems.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls and other areas which are prone to odors caused by microorganisms.

CLEAN/DEODORIZE- Mix 2 oz. per gallon water. Apply use solution to hard nonporous surfaces with cloth, sponge, or mop.

DISINFECTION- To disinfect inanimate, hard surfaces apply solution with a mop, cloth, or sponge so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry.

GENERAL DISINFECTION- Add 2 ounces of this product per gallon of water.

HOSPITAL DISINFECTION- Add 3 ounces of this product per gallon of water.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls, flush toilet, add 2 ounces of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

BACTERICIDAL ACTIVITY- When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against *Salmonella* and *Staphylococcus aureus*. When diluted at the rate of 3 ounces per gallon of water, this product exhibits effective disinfectant activity against *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, Methicillin resistant *Staphylococcus aureus* (MRSA), and Vancomycin intermediate resistant *Staphylococcus aureus* (VISA), and meets all requirements for hospital use.

***VIRUCIDAL ACTIVITY-** This product, when used on environmental, inanimate, hard, non-porous surfaces at 3 ounces per gallon of water, exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 2 (causative agent of upper respiratory infections), Vaccinia virus (representative of the Pox virus group), Human Immunodeficiency Virus Type 1 (HIV-1), and Hepatitis B Virus (HBV).

FUNGICIDAL ACTIVITY- At the 2 ounces per gallon dilution, this product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

***KILLS HIV-1 AND HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) 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) and Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

FOR INDUSTRIAL USE ONLY Seller warrants that this product corresponds to all claims and descriptions on the label thereof and is reasonably fit for use for any purpose stated on such label only when used in accordance with directions under normal use conditions. Seller makes no warranties of merchantability or fitness for a particular purpose nor any other express or implied warranty except as stated above.

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 medical devices prior to sterilization or high level disinfection.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

FIRST AID:

If in eyes	<ul style="list-style-type: none"> 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 further treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> Call a poison control center or doctor for further treatment advice. Have 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 give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you 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- This product is toxic to fish and aquatic invertebrates. 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

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

PESTICIDE STORAGE: Open dumping is prohibited. If container is damaged, stop any leaks by repositioning the container or by patching or otherwise repairing the leaks. Take care to avoid contact with pesticide and wear protective gear. On cleanup of spilled liquids, wear protective equipment as required to prevent exposure. Clean up spilled areas with generous amounts of absorbent material, such as clay, diatomaceous earth, sand or sawdust. Sweep the contaminated absorbent on to a shovel and put the sweepings into a salvage drum. Dispose of the wastes as below. Place any leaking container into a similar drum or glass as below. Mark the container with name of product, ingredient statement, precautionary statements and signal word.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of rinsate 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 - (For containers greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(For containers equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.