NOV 23 2003

Ms. Kim Inman Regulatory Chemist ABC Compounding Co., Inc. P.O. Box 16247 Atlanta, GA 30321

Subject:

Lem-O-Dis 19-30

EPA Registration Number 3862-53

Notification Application Dated October 29 2009

EPA Received Date November 3, 2009

### Dear Ms. Inman:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

### **Proposed Amendment**:

 Add labeling claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09

### **General Comment:**

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions concerning this letter please contact me at Drusilla Copeland at (703) 308-6224.

Welma Noble
Product Manager (31)
Regulatory Management Branch

PONTURRENCES Division (7510P)

SURNAME

DATE

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Sincerely

Massa road instructions on much	o hafan namulasi	<u> </u>		E A		CARD No. 202		2/5	
United States Environmental Protecti Washington, DC 20			ion Agency			Registration Amendme Other	on	Approval expires 2-28-9: OPP Identifier Number	
	Į.	Application	on for Pestici	de - Sectio	on I				
1. Company/Product Number 3862-53			EPA Product Manager     Velma Noble					posed Classification  None Restricted	
4. Company/Product (Name) Lem-O-Dis 19-30			PM# 31						
5. Name and Address of Applicant (Include ZIP Code)			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling						
ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321			to: EPA Reg. No.						
Check if this is a i	new address		Produ	ct Name					
	·		Section -	1					
Amendment - Explain below.  Resubmission in response to Agency letter dated			· [_]	Final printed labels in repsonse to Agency letter dated "Me Too" Application.					
✓ Notification - Explain below.				Other - Explain below.					
Explanation: Use additional parameters and in the following in the following in the following in the confidential stateme EPA. I further understand that if this FIFRA and I may be subject to enforce in the following in the foll	wing text: "Kills Par the provisions of P ent of formula of this s notification is not	ndemic 2009 R Notice 95- s product. I un consistent w	H1N1 influenza A vir 2 and EPA regulation nderstand that it is a ith the terms of PR N	s at 40 CFR 15 violation of 18U lotice 95-2 and	2.46, a	and no other ch Sec. 1001 to wi	anges h	ave been made to the ake any false statement to	
Three and things be subject to enio	orcement action as	id perialiles d	Section - I						
1. Material This Product Will Be P	eckaged In:	<del></del>							
· · · · · · · · · · · · · · · · · · ·	Packaging		Water Soluble P	ackaging	T	2. Type of Co	ntainer		
Yes Yes ✓ No		Yes V			✓ P	Metal Plastic Glass			
* Certification must be submitted	Yes" Packaging wgt.	No. per container	if "Yes" Package wgt	No. per container		P	aper other (S)	pecify)	
3. Location of Net Contents Inform	nation	4. Size(s) Re	tail Container	5	. Loca	ation of Label	Direction	<b>ns</b>	
✓ Lebel Container 55,3		55,3	5,20,5,1 gallon & quart On label						
6. Manner in Which Label is Affixed to Product  Lithograph Paper glued Stenciled				Other			<del></del>		
	· · · · · · · · · · · · · · · · · · ·		Section - I	V				0 0 000000	
1. Contact Point (Complete items	directly below fo	r identificatio	on of individual to b	e contacted, if	neces	sary, to proce	ss this i	application.)	
Name Kim Inman			Title Regulatory Chemist				Telephone No. (Include Area Code) 77.0°-868-9222		
Certification    certify that the statements   have made on this form and all attachments thereto are true, accurate and complete.   acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment \( \frac{\partial \text{o}}{\partial \text{o}} \)   both under applicable law.					6. ଜଣତ Application Received				
2. Signature m mom			3. Title Regulatory Chemist				0000		
4. Typed Name			5. Date					<del></del>	

10-29-09

∝Kim Inman



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ATLANTA, GEORGIA

P.O. Box 16247 Atlanta, GA 30321 0247 Phone: 770.968.9222

Toll Free: 800.795.9222 Fax: 770.968.7281

DALLAS, TEXAS

Phone: 972.988.9200 Fax: 972.641.8170

Velma Noble, Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510C) U.S. Environmental Protection Agency Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

November 2, 2009

Ms. Noble,

Enclosed are the 8570-1 forms for PR Notice 95-2 for 3862-53 and 3862-112. Please send your decision via e-mail to <a href="mailto:kim.inman@abccompounding.com">kim.inman@abccompounding.com</a>.

Please note that I never received any acknowledgement of PR Notice 2007-4 (attached), sent to the agency 9-29-08 (3862-53) and 10-27-08 (3862-112). 3862-112 was sent to the wrong Project Manager, but on 9-18-09, Lisa McKelvin acknowledged that the 8570-1 had been forwarded to your department. I have been in e-mail contact with Jacqueline Campbell-McFarlane and Drusilla Copeland about this matter on 10-28-09, 10-20-09, 10-6-09 and 9-15-09. These labels reflect both PR Notices 2007-4 and 95-2.

Kim Inman

Regulatory Chemist

ABC Compounding Co., Inc.

PO Box 16247

Atlanta, GA 30321

phone 678-833-2107

fax 770-960-1059

kim.inman@abccompounding.com



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% C <sub>14</sub> , 30% C <sub>16</sub> ,	5% C₁₂,
5% C18) dimethyl benzyl ar	nmonium
chlorides:	1.6%
n-alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	dimethyl
ethylbenzyl ammonium	
chlorides:	1.6%
OTHER INGREDIENTS:	96.8%
TOTAL ·	100.0%



# **Lem-0-Dis 19-30**

- **CLEANER DISINFECTANT DEODORIZER**
- FUNGICIDE ●\*VIRUCIDE

### Desinfectante y desodorante pino

Desinfectante y desodorante limon Si usted no entiende la etiqueta, busque a algulen 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 **NANGER**

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

**Net Contents:** 

Batch No.:

NOTIFICATION

Date Reviewed: 4/23/1/

Reviewed By: 4/23/1/

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 phospitate 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,

y 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

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 tollet 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 choleraesuis and Staphylococcus aureus

Usinited 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 Vancornycin 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) (VIIIs Pandemie 2009 H1N1 Impuenza A virus (formerly called Swine Flu):

FUNGICIDAL ACTIVITY- At the 2 ounces per gallon dilution, this product is also fungicidal against the pathogenic fungi, Trichophyton mentagrophyes (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

\*KILLS HIV-1 AND HBY 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 solled with blood or body fluids use disposable latex gloves, gowns, masks, or 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 dispos

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 preclean 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 googles 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	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	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	Call a poison control center or doctor for further treatment advice. Have person sip a glass of water if able to swallow. On ort 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> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>			

Have the product container or label with you when calling a poison control center or doctor, or going for

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 takes, 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 FPA

### 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.

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