

3862-18

10/28/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

October 28, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

Subject: Germ-I-San
EPA Registration No. 3862-18
Application Date: September 29, 2008
Receipt Date: October 7, 2008

Dear Ms. Inman:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Update to Storage & Disposal Statement per PR Notice 2007-4

General Comments

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

The notification application is acceptable and a copy has been placed in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6345.

Sincerely,

Wanda Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	2810P	7510P					
URNAME	W. Henson	Inman					
DATE	10/28/08	10/28/08					

 United States Environmental Protection Agency Washington, DC 20460	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;"><input type="checkbox"/> Registration</td> <td rowspan="3" style="width: 70%; vertical-align: top;">OPP Identifier Number</td> </tr> <tr> <td><input type="checkbox"/> Amendment</td> </tr> <tr> <td><input checked="" type="checkbox"/> Other</td> </tr> </table>	<input type="checkbox"/> Registration	OPP Identifier Number	<input type="checkbox"/> Amendment	<input checked="" type="checkbox"/> Other
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<input type="checkbox"/> Amendment					
<input checked="" type="checkbox"/> Other					

Application for Pesticide - Section I

1. Company/Product Number 3862-18	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Germ-I-San	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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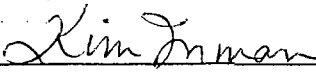
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

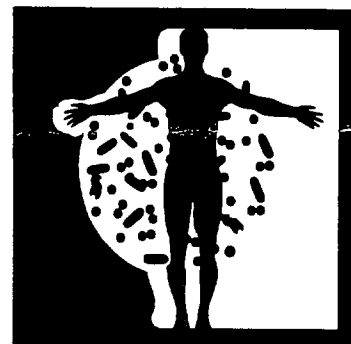
Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container			4. Size(s) Retail Container 55,35,20,5,1 gallon & quart		5. Location of Label Directions <input checked="" type="checkbox"/> On label		
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled <input type="checkbox"/> Other _____							

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Kim Inman	Title Regulatory Chemist	Telephone No. (Include Area Code) 770-968-9222
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Chemist	
4. Typed Name Kim Inman	5. Date 9-29-08	



Manufactured by:

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

EPA REG NO. 3862-18
EPA EST NO. 3862-GA-1

ACTIVE INGREDIENTS:

Iodine*	1.75%
Phosphoric Acid	9.00%
Inert Ingredients	89.25%
Total	100.00%

*From Nonylphenoxypolyethylene-oxyethanol-iodine complex

Germ-I-San
Iodine Sanitizer Detergent
 For use in restaurants and bars, food processing plants and federally inspected meat and poultry plants.
Detergente Sanitario Yodo

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.)

DANGER
KEEP OUT OF REACH OF CHILDREN
AVOID CONTAMINATION OF FOOD STUFFS
 See Back Panel for Additional Precautions

Net Contents: **Batch No.:**



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Does not leave any visible film on dishes or glassware. For glassware, dishes, etc. add 1 ounce of this product to 5 gallons of water in sink number one. Rinse in sink number two in clear water. Then sanitize in sink number three using 1 ounce of this product in 5 gallons of water. This will provide 25 ppm of titratable iodine. Dishes and glassware should air dry. UNLIKE MOST OTHER CLEANER-SANITIZERS, THIS PRODUCT PROVIDES ITS OWN INDICATOR OF GERMICIDAL ACTIVITY. While the brown or amber tint of iodine remains, the solution is active. When the color goes, the solution must be replaced. Public Health codes require a two-minute immersion in the sanitizing solution. Even though this product acts very rapidly Public Health regulations should be followed. this product can be used satisfactorily in 2 or 3 sink systems. Local regulations should be followed. For cleaning areas where food is prepared, scrub with a solution of 6 ounces of this product in 2 1/2 gallons of water.

DAIRY PLANTS: Flush remaining milk from all equipment and all surfaces with lukewarm water, after processing milk. Clean and sanitize with a solution of 1 ounce concentrate to 5 gallons of water. Apply solution with a sponge, mop, or spray so as to wet all surfaces thoroughly. Allow 1 minute contact time. Drain thoroughly and air dry before use. **MILKING MACHINE AND UTENSILS:** Flush remaining milk from all equipment with lukewarm water after each milking. Take equipment apart and immerse all parts, except pulsator, in solution of 1 ounce concentrate to each 5 gallons of water and brush thoroughly. Use the same method to clean and sanitize strainers, wash pails, etc., in the same solution. Rinse with warm water, reassemble and rack in clean, dust-proof place. Before using equipment previously cleaned as above, sanitize with a solution of 1 ounce concentrate to each five gallons of water.

STORAGE AND DISPOSAL

This product must be kept under locked storage sufficient to make inaccessible to children or persons unfamiliar with its proper use.

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 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.

FOR INDUSTRIAL USE ONLY No warranty, express or implied, of merchantability, fitness or otherwise is made.

**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. Wear protective clothing (coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant footwear) and rubber gloves (nitrile, butyl, neoprene and / or barrier laminate). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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 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 treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a Poison Control Center or doctor immediately for 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.
NOTE TO PHYSICIAN- Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

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 Board or Regional Office of the EPA.

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