Acres 3



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

June 4, 2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Julie Ownbey, Regulatory Affairs Manager Clearon Corporation 95 MacCorkie Avenue, S.W. South Charleston, WV 25303

Subject:

Notification per PR Notice 98-10

Product: Inovotabs

EPA Registration Number: **71847-3**Application Date: May 11, 2012
Application Receipt: May 14, 2012

Dear Ms. Ownbey:

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

Proposed Notification:

Medentech, Ltd. has submitted a Minor Label Change for the Invotabs Master Label, **EPA Reg. No. 71847-3.** The modifications to this label are consistent with the provisions of PR Notice 98-10.

These modifications include removing Pfizer's name from the label, additional words that add clarification to the directions for use and adding Medentec's email address to the label.

General Comments:

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

The Notification application is **acceptable.** A copy of the **accepted** Notification has been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact Killian Swift via email at swift.killian@epa.gov or by telephone at 703-308-6346 during the hours of 5:00 AM to 12:00 PM EDT.

Sincerely,

Monisha Hards, Product Manager 32

Regulatory Management Branch II Antimicrobials Division (7510P)

	 	•
\$EPA		
17 LI / 1		

United States

Registration Amendment Other
Amendment
Other

OPP Identifier Number

Environmental Prote Washington, DO		X Other	iment
Applic	ation for Pesticide -	Section I	
1. Company/Product Number 71847-3	2. EPA Produc M. Harris	t Manager	3. Proposed Classification
Company/Product (Name) Inovtabs	PM# 32		
5. Name and Address of Applicant (Include ZIP Code) Medentech Ltd./Clearon Coporation 95 MacCorkle Ave, SW South Charleston, WV 25303	(b)(i), my proi to: EPA Reg. N	duct is similar or ider	dance with FIFRA Section 3(c)(3) ntical in composition and labeling
Check if this is a new address		me	
	Section - II		
Amendment - Explain below. Resubmission in response to Agency letter dated X Notification - Explain below.	Agend	printed labels in repsor cy letter dated Foo" Application. - Explain below.	nse to
Explanation: Use additional page(s) if necessary. (For see Notification for (EPA Reg. No. 71847-3) to label and adding clarifying words to the label.	o reomve "Pifizer" fro abel. Certification for l	,	
	Section - III		
1. Material This Product Will Be Packaged In: Child-Resistant Packaging X Yes No Vertification must be submitted Unit Packaging If "Yes" Unit Packaging wgt.		ng 2. Type o	of Container Metal Plastic Glass Paper Other (Specify)
3. Location of Net Contents Information 4. Size(s) Retail Container	5. Location of L	abel Directions
, · · · · · · · · · · · · · · · · · · ·	lbs, supersacks, drum		
6. Manner in Which Label is Affixed to Product x P S	thograph aper glued tenciled	Other	
	Section - IV		
1. Contact Point (Complete items directly below for identifi	cation of individual to be conte	ected, if necessary, to	process this application.)
Name Julie Ownbey	Title Regulatory Manager	-	Telephone No. (Include Area Code) 304-720-3924
Cert I certify that the statements I have made on this form I acknowledge that any knowlingly false or misleadin both under applicable law.			
2. Signature	3. Title Regulatory Ma	ınager	
4. Typed Neme Julie Ownbey	5. Date 05/06/2012	<u>.</u>	

4/8

Julie Ownbey
Regulatory Affairs Manager
95 MacCorkle Avenue S.W
South Charleston WV 25303
julia.ownbey@icl-ipa.com
Phone: 304-720-3924
Fax: 304-746-4123



May 11, 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potamac Yard, Rm S-4900
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Monisha Harris, Product Manager (32)

Subject: Label notification: Inovtabs, EPA Reg. No. 71847-3

Dear Ms. Harris,

Please find enclosed an application for a minor label change to the Inovtabs master label (EPA Reg. No. 71847-3). The modifications that have been made to this label are consistent with the provisions PR Notice 98-10. These modifications include removing Pfizer's name from the label, additional words that add clarification to the directions for use and adding Medentec's email address to the label.

Enclosed are:

- Application form (EPA Form 8570-1)
- Certification Statement for Notifications per Notice 98-10
- Copy of the current approved master label
- Copy of the revised label with track changes
- 3 Copies of the revised label without track changes.

If you have any questions or need additional information, please feel free to contact me by phone at 304-720-3924 or via email at Julie.Ownbey@icl-ipa.com.

Kind Regards,

Julie Ownbey

Clearon Corporation/Agent for Medentech.

Regulatory Manager

[] indicates alternate text

INOVOTABS®

Effervescent Sanitizer Tablets Only for Use in the Pfizer Embrex Inovoject System INOVOTABS is an effective sanitizer in areas where it is of prime importance to reduce cross contamination on the needles in the Pfizer Embrex Inovoject System. [Inovotabs has been tested against Staphylococcus aureus (ATCC 6538) and Klebsiella pneumoni (ATCC 4352).] INOVOTABS is for exclusive use in: The Pfizer Embrex Inovoject System. INOVOTABS are a single step effervescent tablet that is dissolved directly into a known volume of water (1 tablet for every 2 quarts or 2 liters of water). Inovotabs dissolve completely and provide a more consistent pH and stable chlorine concentration over time. The chemistry of the Inovotabs allows this product to perform well in the presence of organic challenge and perform consistently in the commercial hatchery environment.

Active Ingredient:

NET CONTENTS:

NET WEIGHT:

Sodium Dichloroisocyanurate	41.07%
Inert [Other] Ingredients:	
Total:	100.00%

Each tablet will produce a minimum of 2221 ppm [free] chlorine when dissolved in two quarts of water.

KEEP OUT OF REACH OF CHILDREN DANGER

	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 inhaled	 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
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 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
	t container or label with you when calling a poison control center or doctor, or ent. [You may also contact 1-800-849-3629 for emergency medical treatment information.]
Deah	NOTE TO PHYSICIAN
	able mucosal damage may contraindicate the use of gastric lavage ee back [side] panel [above] for Precautionary Statements

NOTIFICATION / Date Reviewed: 4/1/2 Proviewed By: 454

BATCH NUMBER: EXPIRATION NUMBER:

PRECAUTIONARY STATEMENTS

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.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Danger: Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or clothing. Avoid breathing dust. Wear rubber gloves and safety glasses or face shield when making up solution. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read the entire label carefully before use.

INOVOTABS® is for exclusive use in the Pfizer-Embrex Inovoject® System at 2 tablets per gallon of water.

DAILY USE OF INOVOTABS®:

- 1) Treated needle surfaces must remain will be wet for the duration during the sanitization phase of the injection cycle.
- 2) Do not keep mixed Inovotabs[®] solution for more than one processing day or when use dilution becomes diluted or soiled. Empty all containers of solution, rinsing the containers thoroughly with tap water.
- 3) Do not use the Inovotabs[®] solution to clean the exterior of the Inovoject[®]. This will result in the removal of anodizing from aluminum components and cause other components to rust prematurely.
- 4) Use Inovotabs® only according to the Directions for Use.
- 5) Medentech and Pfizer make no other claims for use other than those listed on the label.

Note: Water quality and injectables may affect the ability to maintain the process quality of the Embrex Inovoject system-during a normal day's operation. Report any issues to your Customer Service or Technical Service Representative.



PREPARATION FOR MIXING INOVOTABS®

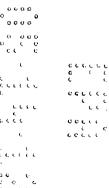
- Add 2 INOVOTABS[®] tablets to 1 gallon of warm water 75°F-104°F (23°C-40°C).
 Lower temperatures will extend dissolution time of the tablets.
- If hatchery water supply is below 64°F (18°C) take measures to ensure water temperature is within an acceptable range at mixing time. This can include storing water overnight so that it rises to room temperature. It is important that the water temperature be raised to at least room temperature; 68°F-77°F (20°C-25°C). It is also critical that water temperature stay at or below 104°F (40°C) as temperatures higher than 104°F may reduce solution efficiency.
- [Higher] Temperatures over 120°F (50°C) can cause release of chlorine to the air and thus reduce chlorine concentration of the sanitizer solution.
- Tablets should be completely dissolved before use.
- Inovotabs solution must be freshly prepared.
- Use within one day.
- Keep in a properly labeled [batch] container to protect against contamination.
- Unused solution should be discarded in accordance with Pesticide Disposal directions on label.
- Inovotabs® must be mixed to yield solution that has a minimum concentration of 2221 ppm of [free] chlorine. This is achieved by dissolving two (2) Inovotabs® per gallon of water.

Formatted: Font: Italic

STEP BY STEP INOVOTABS® MIXING DIRECTIONS:

- 1) Rinse out all containers and clean before daily use
- 2) Use drinking or <u>potable</u> tap water to make the Inovotabs® solution and prepare in an Pfizer Embrex Inovoject® system-approved [batch] container.
- 3) Add 2 tablets per gallon (1 tablet per 2 liters of water).
- 4) Warm water 75°F-104°F (23°C-40°C) may be used. DO NOT BOIL
- 5) Allow tablets to dissolve completely, then [stir] agitate carefully prior to use.
- 6) Be sure the solution is not hot when the Embrex Inovoject® system is injecting eggs.
- 7) Connect the container with freshly prepared Inovotabs® solution to the Inovoject® sanitation and cleaning system by carefully placing the collection tubes in the sanitizer solution and tightening the lid.
- 8) During normal operation additional sanitizer solution may be required. To add additional fluid to the needle punch sanitation system stop the Pfizer Embrex Inovoject® system, remove the sanitizer container and prepare a new batch of Inovotabs® solution or refill the current sanitizer container in place via a secondary [batch] container that was previously prepared with Inovotabs® solution.
- 9) Make a fresh solution at the start of each injection day.
- 10) Follow all appropriate safety guidelines when handling tablets.
- 11) Twist close plastic bag and close lid firmly after withdrawing tablets from container.

Formatted: No underline



Inovotabs, EPA Reg No. 71847-3 Final Label

Page 4 of 4

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry, well-ventilated area. Do not store at temperatures above 104°F (40°C). Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site, in a toilet, or service sink served by a sanitary sewer or an approved waste disposal facility for pesticides. Container Disposal. If empty: Do not reuse or refill empty container. Rinse empty container thoroughly with water to dissolve all material before discarding. Offer for recycling, if available or securely wrap container in several layers of newspaper and discard in trash. Container Disposal. If partly filled: Call your local solid waste agency [or toll free number or website which meets the criteria in paragraph II.E.] for disposal instructions. Never place unused (tablets) product down any indoor or outdoor drain.

Manufactured by:
Medentech Ltd.
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland
info@medentech.com
Patent No. US 7,074,363 B2

Tel: 353 53 9160040 9117900

Fax: 353 53 9141271

EPA Reg. No. 71847-3

EPA Est. No. 71847-IRL-001