

71847-3

6/4/2009

1 of 5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

JUN - 4 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Medentech Ltd,  
c/o U. S. Agent of Record, Scientific Coordination, Inc.  
4629 Cherry Valley Drive  
Rockville, Maryland 20853

Subject: Application for Amendments dated April 17, and May 28, 2009  
Innovotabs  
EPA Reg. No.: 71847-3

Dear Tim:

The Agency has reviewed your amendments submitted in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the actions acceptable.

In summary, as a condition of registration, additional efficacy data were required to support the labeled claims. The efficacy data that you submitted, MRID 477357-01, are acceptable. A copy of our review is enclosed. You have also proposed label amendments to improve the clarity of the use directions. The label amendments have been reviewed and are accepted. A copy of your label is enclosed.

In addition, you have submitted a revised basic Confidential Statement of Formula (CSF). This CSF has been reviewed and accepted. Should you have any questions concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

A handwritten signature in cursive script that reads "Emily H. Mitchell".

Emily H. Mitchell, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosures: D364741

[ ] 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 pneumoniae* (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:**

Sodium Dichloroisocyanurate ..... 41.07%

**Inert [Other] Ingredients:**..... 58.93%

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**

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <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>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [You may also contact 1-800-849-3629 for emergency medical treatment information.]	
<b>NOTE TO PHYSICIAN</b>	
Probable mucosal damage may contraindicate the use of gastric lavage	

See back [side] panel for Precautionary Statements  
NET CONTENTS: BATCH NUMBER:

**ACCEPTED**  
JUN - 4 2009  
Under the Federal Insecticide, Fungicide, and  
Rodenticide Act as amended, for the  
pesticide registered under  
71847-3

**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**

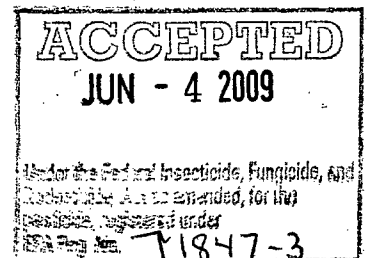
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read the entire label carefully before use.

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 will be wet during the sanitation 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.

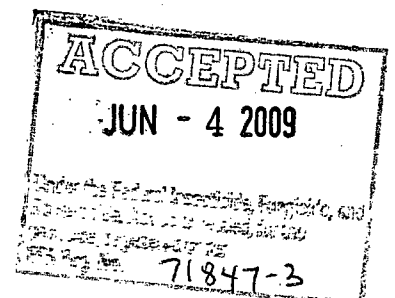


**PREPARATION FOR MIXING INOVOTABS®**

- 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.

**STEP BY STEP INOVOTABS® MIXING DIRECTIONS:**

- 1) Rinse out all containers and clean before daily use
- 2) Use drinking or potable tap water to make the Inovotabs® solution and prepare in a 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 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.



**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

Patent No. US 7,074,363 B2

Tel: 353 53 9160040

Fax: 353 53 9141271

EPA Reg. No. 71847- 3

EPA Est. No. 71847-IRL-001

