



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510-P)
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

71847-~~2~~3

Date of

Issuance:

Nov. 7, 2008

Term of Issuance: **Conditional with comments, expires November 7, 2009**

Name of Pesticide Product:

Inovotabs

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and, submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 71847-G to EPA Registration Number 71847-3.
3. Acceptable data demonstrating efficacy of product utilizing the Sanitizer Test for inanimate, non-food contact surfaces (modified for Inovotabs application) must be submitted by September 7, 2009.

Submit two copies of the finished final printed label prior to releasing this product for sale. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the conditionally approved label is enclosed for your records.

Signature of Approving Official:

Emily H. Mitchell

Emily H. Mitchell
Product Manager 32
Antimicrobials Division (7510P)

Date:

November 7, 2008

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INOVOTABS®

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended for the pesticide,
 EPA Reg. No.

Effervescent Tablets Only for Use in the Pfizer Embrex Inovoject® System
INOVOTABS® is effective in areas where it is of prime importance to reduce cross contamination on the needles in the Pfizer Embrex Inovoject® System.
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.

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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**

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 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
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 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
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-xxx-xxx for emergency medical treatment information.]	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage	

See back [side] panel for Precautionary Statements

NET CONTENTS:

BATCH NUMBER:

[] indicates alternative text

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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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.

Federal Insecticide,
Fungicide, and
Rodenticide Act as
pesticide.

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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 chemical resistant gloves and safety glasses or face shield when making up solution. Wear coveralls over long sleeved shirt and long pants. Wear socks and shoes. 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.

Field testing has shown that Inovotabs reduces *Escherichia coli*. The use of Inovotabs is a supplement to and not a substitute for cleaning and sanitization practices; user must continue to follow Embrex® Inovoject® Systems Clean Up/Shut Down Procedures and Start Up Procedures.

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

Pfizer Embrex Inovoject® System START UP PROCEDURES:

I. Machine Connections

- 1) Attach Pick up plate and stripper weights
- 2) Attach Transfer table to the vaccinator and Egg Removal Equipment (ER) if applicable.
 - a. Mechanical
 - b. Electrical
 - c. Pneumatic

II. Prepare Chemicals

Refer to Pfizer Animal Health Training Placard 3 V1007 (P3) and Placard 6 V1007 (P6)

- 1) Distilled Water, rinse with alcohol (Daily)
- 2) 70% Alcohol (Daily)
- 3) Cleaner (Daily)
- 4) (Daily) Mixed Solution (P3) or Inovotabs® Solution when available (P6)

III. Start AM Cleaning Cycle (13 minutes)

- 1) Check that manifold is in "up" position and that the vaccine pump is open.
- 2) Press Cleaning Cycle.
- 3) Press Number 1(AM).
- 4) Press Needles (Drop Needles and inspect to ensure proper flow at **all** needles).
- 5) When complete the interface will read "AM Cleaning Cycle Complete".
- 6) Vaccine lines are now stored in alcohol and ready for saline and vaccine.

IV. Inovotabs® Solution System set up

- 1) Place solution tube in water.
- 2) Press Solution Dispense and flush with water for **at least** 2 minutes.
- 3) Place solution tube in Inovotabs solution.
- 4) Press Solution Dispense and flush with Inovotabs solution for **at least** 2 minutes.
- 5) Press Solution Dispense after 2 minutes, the system is ready for injection.

V. Prime the Inovoject with Sterile Water/Saline & Vaccine

- 1) Clamp off the main yoke tube to vaccine manifold using forceps.
- 2) Attach a bag of sterile saline/water to the vaccine system. (Be sure to swab spike with alcohol and avoid putting air in the system).
- 3) Squeeze the sterile saline/water through the system (squeeze firmly).
- 4) When finished, clamp off the vaccine line and connect the vaccine bag to the machine ensuring the vaccine bag is completely dry (be sure to swab spike with alcohol and avoid putting air in the system).
- 5) Gently squeeze the vaccine through the system until color can be seen at every needle.
- 6) When primed, close the vaccine pump, turn the manifold, replace the vaccine pump cover, and put the vaccine line in the vaccine sensor.
- 7) Run the QC plate to verify the complete priming of the system.
- 8) The Inovoject is ready to inject.

END STARTUP PROCEDURES for Pfizer Embrex Inovoject® System.

DAILY USE OF INOVOTABS®:

- 1) Treated needle surfaces must remain wet for the duration 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 due to an increase in the number of partial needle plugs experienced during a normal day's operation. Report any issues to your Customer Service or Technical Service Representative.

ACCEPTED
 WITH COMMENTS
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under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 and the Federal Food, Drug,
 and Cosmetic Act

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PREPARATION AND MIXING INSTRUCTIONS:

- Add 2 INOVOTABS® tablets to 1 gallon of warm water 75°F-104°F (23°C-40°C). This 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.
- Water temperature must be between 75°F-104°F (23°C-40°C) to obtain optimal dissolution of the tablets. Lower temperatures will extend dissolution time of the tablets. Tablets should be completely dissolved before use.
- 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 solution.
- 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 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® system by carefully placing the collection tubes in the solution and tightening the lid.
- 8) During normal operation additional solution may be required. To add additional fluid to the system stop the Pfizer Embrex Inovoject® system, remove the container and prepare a new batch of Inovotabs® solution or refill the current 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.

**Pfizer Embrex Inovoject ® System
SHUT DOWN PROCEDURES:**

I. Run QC Plate after the last buggy of hatchling eggs

II. Clean the Pick-Up Plate

- 1) Disconnect transfer table air connector.
- 2) Unlatch all of the pick up plate latches and remove the stripper weights.
- 3) E-stop the Inovoject® (the plate will drop).

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United States Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the FIFRA Act of 1972,
and registered under EPA Reg. No.

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- 4) Hose off the pick up plate thoroughly, rinsing the suction cups at least 3 times (until all visible organic matter is removed).
- 5) Place pick up plate in the Cleaning Tank with 240mls of chlorinated non-foaming tray wash.
- 6) Check to ensure that air is bubbling through all of the suction cups.
- 7) Leave in the tank for 30 minutes if warm water and 60 minutes if cold water.
- 8) When complete rinse off the pick up plate and the cleaning tank to remove chlorine.

III. Running the PM Cleaning Cycle (22 Minutes)

- 1) Separate the transfer table prior to starting the cycle.
- 2) Connect spike to the cleaning cart line.
- 3) Turn manifold to the cleaning "up" position and open the vaccine pump.
- 4) Press Cleaning Cycle.
- 5) Press Button #2 button for PM cycle.
- 6) Drop the needles to check for proper flow, and verify that all of the needles are straight. (This needs to be completed in the first step of the cycle).
- 7) Cycle will go through 6 steps.
- 8) When complete the interface will read "PM Cleaning cycle complete".

IV. Inovotabs® Solution System Shut Down

- 1) Remove solution pump tube from the Inovotabs solution and dump the remaining solution.
- 2) Place solution tube in water.
- 3) Press Solution Dispense and flush with water for **at least 2 minutes**.
- 4) Place solution tube in the alcohol container.
- 5) Press Solution Dispense and flush with Alcohol for 2 minutes.
- 6) Press Solution Dispense after 2 minutes, to stop the pump, the system is stored in alcohol.

V. Clean the Transfer Table

- 1) Hose off the machine with a garden hose spray nozzle. **No High Pressure Washers.**
- 2) Remove the main vacuum hose, flush with water, drain and place in the cleaning tank.
- 3) Scrub all surfaces with a scrubbing pad and dishwashing detergent.
- 4) Key areas to scrub are the pick up plate, vacuum hose elbow, and the pulleys beneath the table.
- 5) Rinse the table and air dry.

VI. Clean the Vaccinator

- 1) After the PM cleaning cycle has completed, **unplug the vaccinator.**
- 2) Hose off the machine with a garden hose spray nozzle. **No High Pressure Washers.**
- 3) Do not get water in the vaccine pump, and do not spray the interface or sensors.
- 4) Scrub all surfaces with a scrubbing pad and dishwashing detergent.
- 5) Key areas to scrub are the tooling and the pulleys.
- 6) Rinse the vaccinator and air dry.
- 7) Remove the air hose from the machine.
- 8) Dump the distilled water container and store in alcohol.

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in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended by the FIFRA Act of 1990,
registered under EPA Reg. No.

END SHUT DOWN PROCEDURES For Pfizer Embrex Inovoject® System.

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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 product down any indoor or outdoor drain.

Manufactured by:
Medentech Ltd.
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland
Tel: 353 53 9160040 Fax: 353 53 9141271

EPA Reg. No. 71847- EPA Est. No. 71847-IRL-001

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, this pesticide,
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