

71847-3

7/2/2013

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

July 2, 2013

Medentech Ltd.
c/o Clearon Corporation
95 MacCorkle Avenue S.W.
South Charleston, WV 25303

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Inovotabs®
EPA Reg.#: 71847-3
Application Date: May 24, 2013
Receipt Date: May 29, 2013

Dear Mr. Howell:

This acknowledges the receipt of your Amendment application dated May 24, 2013 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Proposed Amendment:

Amend by adding administrative directions, reformatted the Directions for Use, correct grammatical/spelling errors and various minor other changes for Inovotabs® product label (EPA Reg#71847-3). The original proposed label dated May 24, 2013 (pin punch 05/29/13) was updated on June 26, 2013 (pin punch 06/26/13).

General Comment:

Based on the review of the material submitted, the label amendment for Inovotabs® product label (EPA Reg#71847-3) is **acceptable**.

A copy of the accepted stamped label is enclosed for your record. Submit one copy of your final printed label/labeling before distributing or selling the product bearing the revised label/labeling. This amendment, a stamped label with comment, and a copy of this letter have been inserted in your file for future reference.

If you have any questions or comments concerning this letter, please contact David Liem by email at liem.david@epa.gov or call (703) 305-1284.

Sincerely,

A handwritten signature in black ink, appearing to read "Demson Fuller".

Demson Fuller
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Att: Accepted Stamped Label

{All text in brackets [xxx] is optional and may or may not be intended on a final label.}
{All text in braces {xxx} is administrative and will not appear on a final label.}

INOVOTABS®

[Effervescent Sanitizer Tablets Only for Use in the Embrex® Invoject.]

[INOVOTABS® is an effective sanitizer in areas where it is of prime importance to reduce cross contamination on the needles in the Embrex® Invoject.]

[INOVOTABS® has been tested against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352).]

[INOVOTABS® is for exclusive use in: The Embrex® Invoject.]

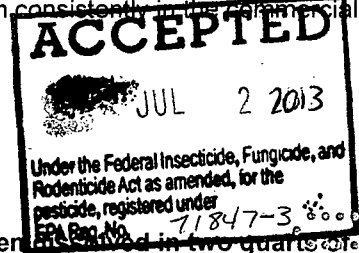
[INOVOTABS® are a single step effervescent tablet that is dissolved directly into a known volume of water (1 tablet for every 2 quarts or 2 liters of water). Inovotabs® dissolve completely and provide a more consistent pH and stable chlorine concentration over time. The chemistry of the Inovotabs® allows 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%

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

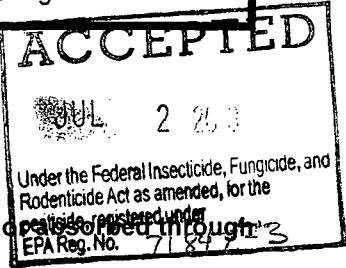
If in eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: 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 a 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.
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.

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

YOU MAY ALSO CONTACT [1-800-420-9236] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.

NOTE TO PHYSICIAN
Probable mucosal damage may contraindicate the use of gastric lavage.

See [back] [side] panel[s] for additional precautionary statements [and first aid].



**PRECAUTIONARY STATEMENTS
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 protective eyewear (safety glasses or face shield) when making up solution. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

{For end-use products packaged in containers with sizes of less than 50 pounds.}
[This product is toxic to fish and aquatic organisms.]
{For end-use products packaged in containers with sizes of greater than or equal to 50 pounds.}
[This product is toxic to fish and aquatic organisms. 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.]

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 and use strictly in accordance with precautionary statements and directions.

[INOVOTABS® is for exclusive use in the Embrex® Inovoject 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 the solution 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 Embrex® 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 Zoetis, Inc. 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 during a normal day's operation. Report any issues to your Customer Service or Technical Service Representative.]

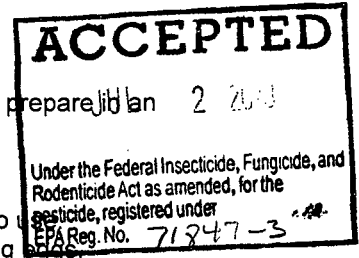
[PREPARATION FOR MIXING INOVOTABS®

- Add 2 INOVOTABS® tablets to 1 gallon of warm water 75-104°F (23-40°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; 68-77°F (20-25°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 proper [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 an Embrex® Inovoject approved [batch] container.
- 3) Add 2 tablets per gallon (1 tablet per 2 liters of water).
- 4) Warm water 75-104°F (23-40°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 is injecting.
- 7) Connect the container with freshly prepared Inovotabs® solution to the Embrex® 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 Embrex® Inovoject, 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 at a temperature below 104°F (40°C).

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site, in a toilet, or a service sink served by a sanitary sewer or an approved waste disposal facility for pesticides.

{Nonrefillable container – household/residential use; size: 50 pounds or less.}

[Container Handling

Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

{Nonrefillable container – single-use, non-resealable package; size: 50 pounds or more, less than 50 pounds.}

[Container Handling

Nonrefillable container. Do not reuse or refill this container. Rinse and discard empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

{Nonrefillable container – Dry Granulated Product – single-use, non-resealable package; size: 50 pounds or more, less than 50 pounds.}

[Container Handling

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance to local, state and federal regulations. When completely empty, offer for recycling, if available.]

{Nonrefillable container – Fiber Drums with Liners; size: 50 pounds or more.}

[Container Handling

{71847-3}

{INOVOTABS® Master Label Ver.02}

{DOA: 06262013}

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Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance to local, state and federal regulations. When completely empty, offer for recycling, if available,]

{Nonrefillable container- non-household/residential use; size: 50 pounds or less, 50 pounds or more.}

[Container Handling

Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

[WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with label directions under normal conditions of use, but to the extent consistent with applicable law, neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, expressed or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.]

Manufactured by:

Medentech Ltd.
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland

EPA Reg. No. 71847-3

EPA Est. No. _____

[Material][Label] No. _____

NET CONTENTS: _____ [lbs.] [kg.]

[Batch][Lot] No. _____

Patent No. US 7,074,363 B2

