



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 13, 2019

Nicole Perkinson  
Authorized Agent for Medentech Ltd. (ToXcel, LLC)  
Medentech Ltd.  
Whitemill Industrial Estate  
Clonard Road, Wexford, Ireland

Subject: Label Amendment – Addition of Marketing Claims and Emergency Contact  
Number  
Product Name: INOVOTABS  
EPA Registration Number: 71847-3  
Application Date: July 2, 2018  
Decision Number: 542795

Dear Ms. Perkinson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

Page 2 of 2  
EPA Reg. No. 71847-3  
Decision No. 542795

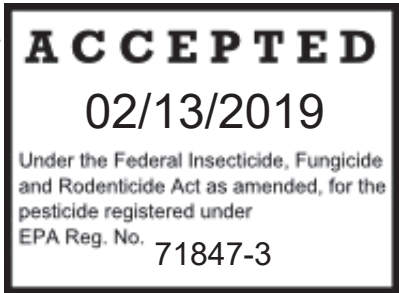
with FIFRA section 6. If you have any questions, please contact Melanie Bolden by phone at (703) 347-0165, or via email at [Bolden.Melanie@epa.gov](mailto:Bolden.Melanie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "D. Fuller", with a long horizontal flourish extending to the right.

Demson Fuller, Product Manager 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure



(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® Inovoject.]**  
**[Inovotabs Effervescent Tablets Only for use with Embrex® *in ovo* vaccination devices]**

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

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

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

[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**

<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 swallowed</b>	<ul style="list-style-type: none"> <li>• Call a 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 a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</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>

<p>Have the product container or label with you when calling a poison control center, doctor, or going for treatment.</p> <p><b>[YOU MAY ALSO CONTACT [1-800-420-9236] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.]</b></p> <p><b>[IN THE EVENT OF A MEDICAL EMERGENCY CALL YOUR POISON CONTROL CENTER AT 1-800-222-1222]</b></p>
<p align="center"><b>NOTE TO PHYSICIAN</b></p> <p align="center">Probable mucosal damage may contraindicate the use of gastric lavage.</p>

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 eggs.
- 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 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**

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