

71847-4

8/29/2011

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

AUG 29 2011

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

George Katsigras  
Agent for Medentech Ltd.  
c/o Clearon Corp.  
95 MacCorkle Avenue SW  
South Charleston, WV 25303

Subject: Aquatabs®  
EPA Reg. No. 71847-4  
Application Dated: August 5, 2011  
Receipt Date: August 8, 2011

Dear Mr. Katsigras:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

**Proposed Notification:**

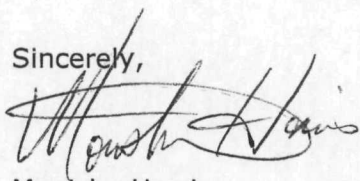
- Label revision in response to Agency letter dated 07/28/2011

**Comments:**

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the product label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact me at [harris.monisha@epa.gov](mailto:harris.monisha@epa.gov) or call (703) 308-0410.

Sincerely,  


Monisha Harris  
Product Manager (32)

Regulatory Management Branch II  
Antimicrobials Division (7510P)

**CONCURRENCES**

SYMBOL	SURNAME	DATE



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 71847-4	2. EPA Product Manager Wanda Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AQUATABS	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Medentech Ltd. c/o Clearon Corp. 95 MacCorkle Avenue S.W. South Charleston, WV 25311 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>28-July-2011</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Fee determination: Fee Category - Not Applicable  
E-mail: katsigrasg@clearon.com

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name George Katsigras	Title Agent	Telephone No. (Include Area Code) 304.720.3924
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name George Katsigras	5. Date 5-August-2011	



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August 5, 2011

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

**SUBJECT: Response to Agency's letter dated July 28<sup>th</sup> 2011 for Aquatabs<sup>®</sup>**  
(EPA Reg. No. 71847-4)

Dear Ms. Wanda Henson:

In response to the Agency's letter dated July 28<sup>th</sup>, 2011, please find enclosed 3 copies of the revised labelling to address the deficiencies identified in that letter.

The following marketing statements have been deleted from the label:

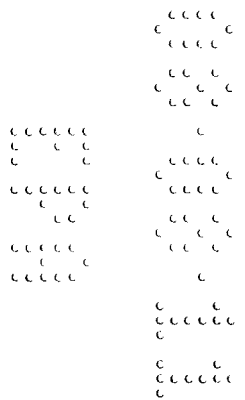
- 1) Achieves EPA microbiological water purifier test standards
- 2) Doesn't contain iodine or chlorite
- 3) Kills 99.9999% of bacteria

In addition, the phrase "equal to or more than 50 pounds" has been added to the extended Environmental Hazards statement's administrative header.

If you have any questions or need more information, please contact me via email, [katsigrasg@clearon.com](mailto:katsigrasg@clearon.com) or by phone at (304) 720-3924.

Sincerely,

George Katsigras  
N.A. Agent for Medentech Ltd.



{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.}

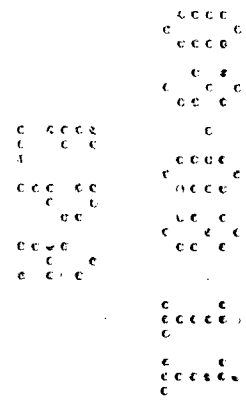
# AQUATABS®

**NOTIFICATION**  
Date Reviewed: 8/29/2011  
Reviewed By: M. Hansen

{Alternate product names:}  
[Platypus Aquatabs®]

{Optional marketing statements. One or more statements may be combined.}

- [Water Purification Tablets]
- [Aquatabs® water purification tablets are effective against giardia cysts, bacteria and viruses.]
- [NSF logo]
- [Certified to NSF/ANSI standard 60]
- [Purifies water for:]
  - [Camping]
  - [Hiking]
  - [Trekking]
  - [International travel]
- [Used globally: over 10 billion liters of water treated annually]
- [Great value]
- [50 tablet pack]
- [Treats up to 100 quarts]
- [30 tablet pack]
- [Treats up to 60 quarts]
- [Fast acting: Water ready to drink 30 minutes after mixing]
- [100% US manufactured active ingredient]
- [Not tested against cryptosporidium]
- [Great tasting drinking water – consistently]



<b>Active Ingredient:</b>	
<b>Sodium Dichloroisocyanurate</b>	16.88%
<b>Other Ingredients:</b>	83.12%
<b>Total:</b>	100.00%

One Aquatabs® tablet will produce a 2.6ppm available chlorine solution when dissolved in two quarts of water

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

See back panel for additional precautionary statements and First Aid.

{for small packaging, the First Aid statements will be depicted in a paragraph instead of a table format}

**First Aid**

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

- If in eyes
  - Hold eye open and rinse slowly and gently with water for 15-20 minutes.
  - Remove contact lens, if present, after the first 5 minutes, then continue rinsing eye
  - Call a poison control center or doctor for treatment advice.

- If swallowed
  - Call a poison control center or doctor immediately for treatment advice
  - Have a person sip on 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.

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.

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

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER**

Corrosive. Causes irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe dust, vapour or spray mist. Wear goggles or face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or smoking. Remove contaminated clothing and wash before reuse.

{for end-use products packaged in containers with sizes of less than 50 pounds}

**Environmental Hazards:** This pesticide is toxic to fish and aquatic organisms.

{for end-use products packaged in container sizes equal to or more than 50 pounds}

**Environmental Hazards:** This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or public 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.

**Physical and Chemical Hazards:**

Contains strong oxidizing agent. Use only clean dry utensils. Mix only into water. Contamination with moisture, dirt, organic matter or other chemicals (including other pool chemicals) or any other foreign matter may start a chemical reaction with generation of heat, liberation of hazardous gases and possible generation of fire and explosion. Avoid any contact with flaming or burning materials such as a lighted cigarette. Do not use this product in any chlorinating device which has been used with any inorganic or unstabilized chlorinating compounds (e.g. calcium hypochlorite). Such use may cause explosion.

**Emergency Handling:** In case of contamination or decomposition do not reseal container. If possible isolate container in open and well ventilated area. Flood with large volumes of water. Dispose of contaminated material in an approved landfill area.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Method of Application**

This product is recommended for disinfecting raw or pre-treated (settled, coagulated and/or filtered) water supplies intended for use as drinking water for humans. The source of water to be treated may be a river, lake, well, cistern or similar system at temperatures as low as 4°C.

Prior to the addition of the sanitizer, remove all suspended material by filtration or by allowing it to settle to the bottom. Decant the clarified, contaminated water to a clean container and add one 8.5mg Aquatabs® tablet to 1/5 gallon (0.75litres) of water to obtain a 6.5ppm (6.5mg/L) available chlorine solution. Mix Well, leave to stand for 30 minutes before drinking.

Aquatabs® are used for the disinfection of individual water systems free of organic debris at room temperature. Add one 8.5mg Aquatabs® tablet to 2 quarts of water to obtain a 2.6ppm (2.6mg/L) available chlorine solution. Mix well, leave to stand for 30 minutes before drinking.

**STORAGE AND DISPOSAL**

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

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**Pesticide Storage:** Keep product dry in a tightly closed container when not in use. Store in a cool, dry, well ventilated area away from heat or open flame.

**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of the Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA regional Office for guidance.

**Container Disposal.** Do not reuse empty container. Rinse empty container thoroughly with water to dissolve all material before discarding. Securely wrap container in several layers of newspaper and discard in trash.

Manufactured by:

Medentech Ltd.

Whitemill Industrial Estate, Clonard Road

Wexford, Ireland

EPA Reg. No. 71847-4

EPA Est. No. \_\_\_\_\_

Net contents: [50][30], 49mg Tablets

[Lot No. \_\_\_\_\_]

[Batch No. \_\_\_\_\_]

[Manufacture: \_\_\_\_\_]

[Expiry Date: \_\_\_\_\_]