

71847-4

7/18/2012

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

July 18, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Julie Ownbey
Regulatory Affairs Manager
Medentech Ltd, c/o Clearon Corporation
95 MacCorckle Ave, S W
South Charleston, WA 25303

Subject Aquatabs®
EPA Reg # 71847-4
Application Date June 15, 2012
Receipt Date June 21, 2012

Dear Ms Ownbey

This acknowledges the receipt of your Notification letter of June 20, 2012 in response to the Agency Initiated Letter dated February 4, 2011, regarding the Agency's comments of "Aquatabs" product label (EPA Reg# 71847-4)

General Comments

Based on the review of the material submitted, your response in regard to EPA's letter of February 2, 2011 and proposed revised label (pin punch 6/21/12) are acceptable

This letter in response to initial EPA notification letter dated February 2, 2011 has been inserted in your file for future reference

If you have further questions on this letter, please contact David Liem by email at liem.david@epa.gov or by calling at 703-305-1284

Sincerely

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington DC 20460

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

OPP Identifier Number

Application for Pesticide - Section I

1 Company/Product Number 71847 4	2 EPA Product Manager Monisha Harris	3 Proposed Classification <input 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 Corporaiton 95 MacCorkle Avenue S W South Charleston WV 25303 <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 type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> Me Too Application
<input checked="" type="checkbox"/> Notification Explain below	<input type="checkbox"/> Other Explain below

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

Attached is a label notification for Aquatabs (EPA Reg No 71847 4) which falls under guidance of PR notice 98 10 This notification is consistent with the provisions of PR Notice 98 10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U S C Sec 1001 to willfully make any false statement to EPA I further understand that if this notification is not consistent with the terms of PR Notice 98 10 and 40 CFR 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Section - III

1 Material This Product Will Be Packaged In					
Child Resistant Packaging <input checked="" 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 checked="" type="checkbox"/> No	2 Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If Yes Unit Packaging wgt	No per container	If Yes Package wgt	No per container
3 Location of Net Contents Information <input checked="" 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 Julie Ownbey		Title Regulatory Affairs Manager		Telephone No (Include Area Code) 304 720 3924	
<p align="center">Certification</p> <p>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</p>					6 Date Application Received (Stamped)
2 Signature 			3 Title Regulatory Affairs Manager		
4 Typed Name Julie Ownbey			5 Date June 15, 2012		

Julie Ownbey
Regulatory Affairs Manager
95 MacCorkle Avenue S W
South Charleston WV 25303
julia.ownbey@icl-ipa.com
Phone 304 720 3924
Fax 304 746-4123



June 20 2012

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

Attn Monisha Harris Product Manager (32)

SUBJECT Label notification for Aquatabs (EPA Reg No 71847-4)

Dear Ms Harris

Please find enclosed a label notification for Aquatabs This notification is consistent with EPA s PR Notice 98-10 The purpose of this label notification is to make the following minor revisions

- Update the label with conditions provided by EPA on February 04 2011
 - Revise the precautionary statements to include before eating drinking chewing gum using tobacco or using the toilet
 - Revise the Method of Application to state Mix well for at least 10 minutes leave to stand for 30 minutes before drinking
 - Revise the Pesticide Disposal Section contact your state pesticide
- Move the statement Have the product container or label with you when calling to the last statement within the First Aid Statement
- Add emergency medical treatment information and telephone number under the first aid statement
- Delete a typo 8 5 mg under the Method of Applications
- Add Boating and Great Taste as an optional marketing statement
- Minor formatting changes

Enclosed are

- 8570-1 Application for Registration
- Copy of EPA stamped label dated 02-04-2011
- Copy of the revised label with annotated changes
- 5 Copies of the revised label without annotations

If you have any questions or need additional information please feel free to contact me by phone at (304) 720 3924 or via email Julia.Ownbey@icl-ipa.com

Sincerely

Julie Ownbey
Regulatory Affairs Manager

Handwritten notes and marks on the right side of the page, including several sets of double and triple quotes and other symbols.

(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®

{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]
 - [Boating]
 - [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 is ready to drink 30 minutes after mixing]
- [100% USA manufactured active ingredient]
- [Not tested against cryptosporidium]
- [Great Taste Great tasting drinking water, consistently]

NOTIFICATION
 Date Reviewed 11/15/12
 Reviewed By [Signature]

Active Ingredient	
Sodium Dichloroisocyanurate	16.88%
Other Ingredients	83.12%
Total	100.00%

One Aquatabs® tablet will produce a 2 ppm 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 *Move statement to bottom of table

- | | |
|--------------|---|
| 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
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

Have the product container or label with you when calling a poison control center or doctor or going for treatment YOU MAY ALSO CONTACT 1 800 420 9236 FOR EMERGENCY MEDICAL TREATMENT INFORMATION ✓

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 chewing gum, using tobacco, or using the toilet 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 (0.75 liters) of water to obtain a 6.5ppm (6.5mg/L) available chlorine solution Mix Well for at least 10 minutes, 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 for at least 10 minutes leave to stand for 30 minutes before drinking

✓

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

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 state 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] [___] 49 mg Tablets
[Lot No 1____]
[Batch No _____]
[Manufacture _____]
[Expiry Date _____]

