



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 8, 2017

Nicole Perkinson
Authorized Agent for Medentech Ltd.
Toxicology and Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155

Subject: Label Amendment –Directions for use and marketing claims
Product Name: Aquatabs
EPA Registration Number: 71847-4
Application Date: November 28, 2016
Decision Number: 524209

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.

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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 with FIFRA section 6. If you have any questions, you may contact Donna Kamarei at (703)347-0443 or via email at Kamarei.donna@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Wanda G. Fuller, for". The signature is written in a cursive style.

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

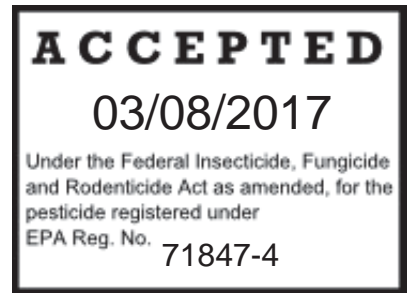
Enclosure

{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.}

AQUATABS®

{Alternate product names:}
[Platypus Aquatabs®]
[MSR Aquatabs®]
[Dental Aquatabs]

{Optional Drinking Water Application marketing statements. One or more statements may be combined.}
[Water Purification Tablets]
[Aquatabs®] [Aquatabs® water purification tablets] are effective against giardia cysts, bacteria and viruses.]
[Used for over 20 years for use in emergency situations by Aid Agencies, Non-Governmental Organizations and Defense Forces around the world.]
[Aquatabs are packed in waterproof foil packs for easy transport during] [emergencies], [travel], [and] [camping].
[Certified to NSF/ANSI standard 60]
[Purifies water for:]
[Camping]
[Hiking]
[Trekking]
[Boating]
[International travel]
[Be ready.] [Be prepared for emergencies:]
[Tornados]
[Floods]
[Earthquakes]
[Winter Storms]
[Hurricanes]
[Purifies water for:]
[Emergency preparedness]
[Used globally: over 10 billion liters of water treated annually]
[Great value]
[50 tablet pack]
[Treats up to 100 quarts]
[30 tablet pack] [30 49mg tablets]
[Treats up to 60 quarts]
[100 tablet pack]
[Fast acting: Water is ready to drink 30 minutes after mixing]
[Active ingredient manufactured in USA]
[Not tested against cryptosporidium]
[Great Taste: Great tasting drinking water, consistently]
[Just 30 minutes treatment time]
[Iodine free]
[May be used with filters]
[Can be used to reduce microcystins from blue green algal blooms in previously treated water to safe levels]



{Optional Dental Waterline marketing statements. One or more statements may be combined.}
[Dental Aquatabs are effective against odor causing bacteria]
[For the cleaning and control of microbial contaminants in dental unit waterlines.]
[Purifies water for dental delivery units, filtration equipment, independent water bottles, scalers and other dental process-water applications.]
[100 tablet pack]

{Optional icons/logos. One or more icon/logo may be combined and/or used in conjunction with marketing statements.}
[Airplane Icon]
[Boat 1 Icon] [Boat 2 Icon]
[Hiking Icon]
[Black NSF/ANSI Standard 60 Logo] [Blue NSF/ANSI Standard 60 Logo]

Active Ingredient:

Sodium Dichloroisocyanurate 16.88%

Other Ingredients: 83.12%

Total: 100.00%

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

KEEP OUT OF REACH OF CHILDREN

WARNING

See [back] [side] panel[s] for additional precautionary statements [First Aid] [storage and disposal] [and] [directions for use]

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

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 the 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.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> <p>YOU MAY ALSO CONTACT [1-800-222-1222] FOR EMERGENCY MEDICAL TREATMENT INFORMATION.</p>	
<p>NOTE TO PHYSICIAN</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

Causes substantial but temporary eye injury. Harmful if swallowed.

Do not get in eyes or on clothing. Wear protective eyewear (goggles with side-shields, safety glasses, or face shield). 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.

{for end-use products packaged in containers 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 greater than or equal to 50 pounds}

[ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of waste. 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 OR CHEMICAL HAZARDS

Contains strong oxidizing agent. Use only clean dry utensils. Mix only into water. Contamination with moisture, dirt, organic matter or other 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 fire or explosion.

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.

{Directions for use applicable for treating drinking water}

[This product] [Aquatabs®] is designed to be used for the disinfection of drinking water. When this product is used as directed, the tablets can provide clean and great tasting water from contaminated sources of water.

[This product] [Aquatabs®] can be used by campers, hikers, militaries, emergency organizations, or anyone needing to drink water from questionable sources or contaminated water.

[For control of Cysts, Bacteria, and Viruses:

[This product] [Aquatabs®] is effective to kill [bacteria (*Raoultella terrigena*)], [viruses (Poliovirus and Rotavirus)], [and] [cysts (*Giardia muris*)] in contaminated water.]

{Directions for Use applicable for treating water from the following sources ($\geq 4^{\circ}\text{C}$ (40°F)): Rivers, lakes, wells, cisterns, or similar systems.}

[TREATING WATER FROM RIVERS, LAKES, WELLS, CISTERNS, OR SIMILAR SYSTEMS ($> 4^{\circ}\text{C}$ (40°F))

Prior to use, remove all suspended material [by filtration] [or] [by straining through a doubled over T-shirt/cloth] [or] [allow to settle to the bottom of an initial container]. Afterwards, move contaminated water to a new, clean container for treatment.

To Use: Remove one [Aquatab®] [tablet] from its [packaging] [container], and quickly insert into [1/5 gallon] [0.75 liters] [25.6 fl.oz.] of contaminated water (6.5 ppm (6.5 mg/L) available chlorine). Mix well for at least 10 minutes, then allow to stand for 30 minutes before drinking. The treated water is now ready for drinking.]

{Directions for Use applicable for treating individual water systems at room temperature.}

[TREATING INDIVIDUAL WATER SYSTEMS AT ROOM TEMPERATURE

To Use: Remove one [Aquatab®] [tablet] from its [packaging] [container], and quickly insert into 2 quarts [1/2 gallon] [0.5 gallon] [64 fl. oz.] of contaminated water (2.6 ppm (2.6 mg/L) available chlorine). Mix well for at least 10 minutes, then allow to stand for 30 minutes before drinking. The treated water is now ready for drinking.]

{Directions for use applicable for treating dental process-water}

[This product] [Dental Aquatabs] are designed to be used for the treatment of dental process-water. When this product is used as directed, the tablets can produce clean and great-tasting water from contaminated sources of water.]

[This product] [Dental Aquatabs] is effective against microbial contaminants

[TREATING DENTAL PROCESS-WATER AT ROOM TEMPERATURE]

To Use: Remove one Dental Aquatabs [tablet] from packaging and quickly insert into [1/5 gallon] [0.75 liters] or up to [2 quarts] [1.5 - 2 litres] of water. Ensure tablet is fully dissolved before use.

[One Dental Aquatabs tablet will produce a 2.6 ppm available chlorine solution when dissolved in [two quarts] [2 litres] of water.]

STORAGE AND DISPOSAL

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

Pesticide Storage:

Store in a cool, dry area away from sunlight and heat and in an area inaccessible to children.

Pesticide Disposal:

Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

Container Handling:

Nonrefillable [container] [pouch] [pack] [blister pack] [packet]. Do not reuse or refill this [container] [pouch] [pack] [blister pack] [packet]. Offer for recycling, if available.

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.

[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. 71847-4

EPA Est. No. _____

[Material][Label] No. _____

Net contents: [___], 49 mg Tablets

[Lot No. _____]

[Batch No. _____]

[Manufacture Date: _____] [Expiry Date: _____]

{OPTIONAL ICONS/LOGOS}



[Airplane Icon]



[Boat 1 Icon]



[Boat 2 Icon]



Certified to NSF/ANSI 60

[Black NSF/ANSI Standard 60 Logo]



Certified to NSF/ANSI 60

[Blue NSF/ANSI Standard 60 Logo]



[Hiking Icon]