

#### **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

JUL 2 3 2013

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Subject:

Flogenic

EPA Reg.#: 71847-5

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 Flogenic product label (EPA Reg#71847-5). The proposed label dated May 24, 2013 (pin punch 05/29/13).

#### **General Comment:**

Based on the review of the material submitted, the label amendment for product label (EPA Reg#71847-5) 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.

Singerely,

Demson Fuller

Acting Product Manager (32)

Regulatory Management Branch II

Antimicrobials Division (7510P)

Att: Accepted Stamped Label

{DOA: 05242013}

{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.}

## Flogenic

{Alternate product names:}

[Aquascepts EZ]

{Optional marketing statements that may be used with drinking water uses. One or more statements may be combined.}

[Stabilized]

[Chlorinating Tablets]

[1" Tablets]

[Concentrated]

[Concentrate]

[Long Lasting]

[Sanitizer]

[Sanitizes, Clarifies, and protects against Algae]

[Suppresses algae]

[Controls Algae, and Clarifies]

[For Routine Sanitation and Clarification]

[Keeps Water Clear]

[Slow Dissolving]

[Completely soluble]

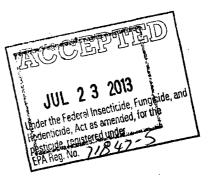
[For Routine Use]

[Chlorinating tablets for water disinfection]

[No mineral scale build-up]

[24-hr chlorine residual for round-the-clock activity]

# KEEP OUT OF REACH OF CHILDREN DANGER



 Active Ingredient:
 .99%

 Trichloro-s-triazinetrione:
 .99%

 Other Ingredients:
 .1%

 Total:
 .100%

FIRST AID			
If in eyes	<ul> <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>		
lf on skin or clothing	<ul> <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>	, ( C )	
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, prefera by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	ibly "	
if swallowed	<ul> <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 doctors.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	6 (r 4) e= 6	
Have the p	roduct container or label with you when calling a poison control center or doctor, or when going treatment.	for	

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

NOTE TO PHYSICIAN

NOTE TO FITTSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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

{71847-5}

{DOA: 05242013

## PRECAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

### DANGER

CORROSIVE.

Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through skin. Harmful if swallowed.

Do not breathe dust or spray mist. Irritating to nose and throat. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), protective clothing, and chemical-resistant gloves when handling this product. 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 pesticide 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 pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes. ponds, streams, estuaries, oceans, or public water 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 sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.]

#### PHYSICAL OR CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Do not mix with other chemicals. Mix with water only, Use only clean dry utensils, Contamination with moisture, dirt, organic matter or other chemicals (including pool chemicals) or any other foreign matter may start a chemical reaction with generation of heat, liberation of hazardous gasses and possible generation of fire and explosion. Avoid any contact with flaming or burning material 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 entire label and use strictly in accordance with precautionary statements and directions.

[Public Systems: A free available chlorine residual of at least 0.2 ppm is attained at the further training the distribution system, as measured by a suitable test kit. Check water frequently as programmed by the National Primary and Secondary Drinking Water Regulations. Contact your local Health Department of further details.]

[\*Drawing-see master

(1)(2)(3)

CCCC

Figure 1. Flogenic (1), 1/2" pipe connector (2), and Flogenic float valve (3)

Flogenic (1) is for connection at the point at which the water discharges to a storage water discharge water discharge to a storage water discharge to a storage water discharge to a storage water discharge water di container is connected to the water supply by way of a ½" pipe fitting (2) or with the frequency float valve (3) depending on what the inຕົ້ນໂປເປລຸ system requires. The standard fitting or float valve is installed first.

To install using the standard fitting.

Turn off the ฟุลโษกูโดพ at the supply. The outlet of the water supply must be a valve or other connector with a ½" pipe ritting. If the water pipe does not end in a 1/2" female pipe thread, a suitable adaptor is required. Connect the Flogenic 12 connector to the water outlet using PTFE pipe tape to get a leak free connection. Turn the device using a 22 mm. whench until the two connecting points are horizontal.]

[\*Drawing-see master

Figure 2, Connect ½" pipe connector (2) to a valve using 22 mm wrench. Seal with PTFE pipe tape. Turn until clips are horizontal.]

[To install the Flogenic float valve

Turn off the water flow at the supply. Replace the current ballcock float valve with the Flogenic float valve.]

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{71847-5}

{Flogenic Master Label Ver.02}

[\*Drawing-see master

Figure 3. Flogenic float valve connector.]

#### (Fitting the Flogenic Cartridge

Remove the Flogenic container from its packaging. Look at the outlet at the bottom of the unit. The bottom of the internal screw must be in line with the wall or use a flat head screw driver to adjust until it is. The screw should now be set. For less chlorination, under 2 ppm, leave the screw as it is.]

{DOA: 05242013

#### [\*Drawing-see master

Figure 4. Adjust screw with screwdriver as shown until 0 threads (a) or 5 threads show (b).1

[Place the Flogenic container on the connector (figure 5) and turn 1/8<sup>th</sup> of a turn clockwise to lock in place. The unit should be horizontal or tilted slightly downward in the direction of flow. Turn on the water flow and allow it to flow for 1 minute. Sample the water and test with the chlorine strips provided. If the amount of chlorine as indicated on the guide is within the required range, >0.2 ppm, the device is ready until it is rechecked 24 hours later. If the amount of chlorine is too low, turn the adjustment screw clockwise ensuring not to over-tighten the screw as this will shear the threads. If the amount of chlorine is too high, turn counterclockwise. Let the water flow for another minute and retest, If the amount of chlorine is within the desired range, leave for 24 hours.]

#### [\*Drawing-see master

Figure 5. Place Flogenic container on connector and turn 1/8<sup>th</sup> of a turn until it clicks in place 1

[Retest the chlorine in the storage tank and at the end of the line after 24 hours. The chlorine level in the storage tank must be in the range of at least 0.2 ppm. There must be a residual chlorine level of at least 0.2 ppm at the furthest point on the line. If the amount of chlorine is too low or too high, adjust the screw as shown above and test again after 24 hours until the system is in the correct range. Make a note of the final setting and use it to set the device when it is replaced.

#### Replacing the Flogenic cartridge

When the tablets can no longer be seen in the unit, it should be replaced. Alternatively, the provided can be used to determine if the unit requires replacement.

garfriage. Note the screw setting To replace the cartridge, first turn off the water at the source. Remove the spent the spent device by counting the number of threads visible when looking into the device through the outlet. Use a flat head screw driver to set the screw on the new cartridge by turning the screw one full turn clockwise 2013 ach visible thread. Follow steps as above for fitting Flogenic Cartridge.] the Federal Insecticide, Fungicide, and

#### STORAGE AND DISPOSAL

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

#### **PESTICIDE STORAGE**

Store in a dry, cool and well-ventilated area. Avoid moisture getting into container. Keep off wet floors. In case of spillage, wash with large amounts of water. After each use, keep container tightly closed, OXIDIZING MATERIAL. Keep away from flames, sparks, and all sources of heat. Avoid contact with organic material.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of 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.

{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.}

#### *ICONTAINER 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.]

{Page 3 of 8}

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pesticide regist EPA Reg. No.

{Flogenic Master Label Ver.02}

{DOA: 05242013}

{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.]

#### **EMERGENCY HANDLING**

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

#### SPILLS

When handling or dealing with spills, use goggles with side-shields, or face shield; protective clothing; including chemical-resistant gloves and boots; use a dust respirator if dusting occurs. Sweep up dry spills and dispose of as described for pesticide disposal. If contents are contaminated or decomposing, do not reseal container; isolate unsealed container in the open or in a well-ventilated area; flood with large volumes of water if necessary.

#### *IWARRANTY*

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. 71847-5	
EPA Est. No.	
[Material][Label] No.	
NET CONTENTS:	[lbs.][kg.]
[Batch][Lot] No.	



{DOA: 05242013}

#### {Individual Container Label}

## Flogenic

#### KEEP OUT OF REACH OF CHILDREN

#### **DANGER**

See [outside container] or [accompanying label] for Precautionary Statements, Storage and Disposal, and Directions for Use

EPA Reg. No. 71847-5

EPA Est. No.

[Material][Label] No.

Net Contents: \_\_\_\_ [Batch][Lot] No. [lbs][kg.]

Medentech Ltd.

Whitemill Industrial Estate, Clonard Road Wexford, Ireland



## **Master Drawings**

Figure 1

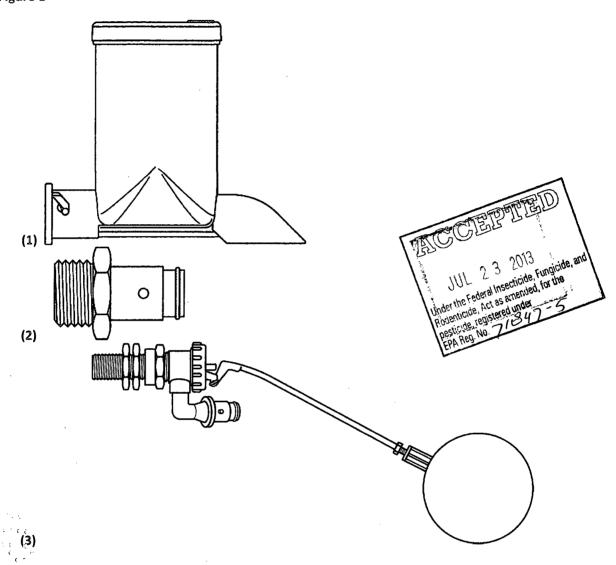


Figure 2

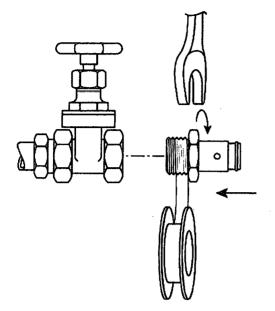


Figure 3

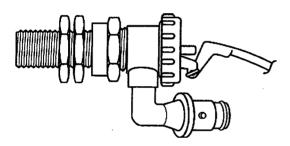


Figure 4

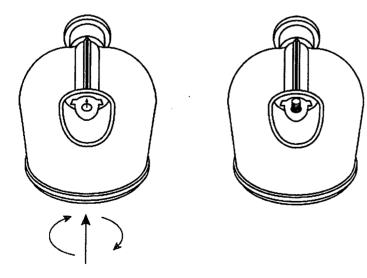




Figure 5

