

JUL 27 2007

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460United States  
Environmental Protection  
AgencyOffice of Pesticide Programs

**Confirm Monitoring Systems, Inc.**  
**109 Inverness Drive East Unit F**  
**Englewood, CO 80112-5105**

**AGENT: SRC**  
**P. O. Box 1014**  
**Columbus City, IN 46725**

**Attention: David Swain, Agent**

**Subject: BluTab Waterline Maintenance Tablets**  
**EPA Registration No. 84020-1**  
**Notification Dated June 26, 2007**

**This will acknowledge receipt of your notification to add U.S. measurements and optional identifier text, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.**

**The Notification dated June 25, 2007 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to the file.**

**Please note that your request for a stamped copy of the label must be handled under the Amendment Process.**

**If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.**

Sincerely

A handwritten signature in black ink that reads 'M Swindell'.

**Marshall Swindell**  
**Product Manager (33)**  
**Regulatory Management Branch 1**  
**Antimicrobials Division (7510P)**

2 8 9

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 84020-1	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BluTab Waterline Maintenance Tablets	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Confirm Monitoring Systems, Inc. 109 Inverness Drive East Unit F Englewood, CO 80112-5105 <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.)

Notification per 98-10 - add U.S. measurements and optional identifier text.

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 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt. 146 mg, 419 mg	No. per container 50 tablets	If "Yes" Package wgt.	<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
			No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 50 Tablets		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" 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 David Swain	Title Agent for Confirm Monitoring Systems, Inc.	Telephone No. (Include Area Code) (268) 244-6270
<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)
Signature 	3. Title Agent for Confirm Monitoring Systems, Inc.	
4. Typed Name David Swain	5. Date June 26, 2007	

# **SRC**

**Scientific & Regulatory**  
Consultants, Inc.

June 26, 2007

Mr. Marshall Swindell, PM 33  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
EPA  
Room S-4900, 4th Floor  
One Potomac Yard  
2777 S Crystal Drive  
Arlington, VA 22202

**SUBJECT: BluTab Waterline Maintenance Tablets EPA Reg. No. 84020-1**

Dear Mr. Swindell:

Enclosed is a notification for the above product, submitted on behalf of our client Confirm Monitoring Systems, Inc. In the past during State review of new registrations, Hawaii has required both a U.S. measurement with a metric measurement on all sections of the label. Therefore, we are notifying you of the addition of U.S. measurements in the Routine Treatment section of the label. These U.S. measurements will be included in parenthesis immediately following the ml measurement.

Also, we are including optional text appearing between front and rear panels. This text is already accepted, but the text appears reading up and down as a quick identifier for separate packaging.

The additions to the label are highlighted with red text on the enclosed label.

Finally, please correct the spelling of the product name which appeared in the June 7, 2007, letter attached to the approved stamped label. The subject line listed the name of the product as "Blue Tab Waterline Maintenance Tablets" instead of the correct spelling of "BluTab Waterline Maintenance Tablets".

This notification is consistent with PR Notice 98-10 since there is no change in the mixing directions affecting the dilution rate.

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 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.



{Front Panel}

BluTab™ Waterline Maintenance Tablets

Dental Unit Waterline Treatment

For the Cleaning and Control of Microbial Contamination in Dental Unit Waterlines

ACTIVE INGREDIENT

Silver 0.477%

OTHER INGREDIENTS 99.523%

TOTAL 100.000%

CAUTION

KEEP OUT OF REACH OF CHILDREN

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 50 tablets

EPA Reg. No. 84020-1

EPA Establishment No. XXX-XX

{Optional Statements – May appear on any panel.}

For the Cleaning and Control of Microbial Contamination in Dental Unit Waterlines

BluTab™ Waterline Maintenance Tablets [This product] is specially formulated and proven to control contamination in dental unit water lines by reducing and inhibiting the re-growth of odor-causing bacteria in the lines. BluTab™ Waterline Maintenance Tablets [This product] is designed to be continuously present in your dental unit water system.

\*Clinical monitoring of water quality can ensure that procedures are performed correctly. Test water quality monthly to establish effectiveness of your maintenance program.

Controls odor-causing bacteria in dental unit water lines.

[Controls] [Reduces] [Inhibits] odor-causing bacterial contamination in [dental unit water lines] [effluent water]

Patent Pending

Reorder No.: BT50

{Back Panel}

Directions for use:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. READ ENTIRE LABEL BEFORE USING THIS PRODUCT.

Initial Treatment

Before starting a treatment program with BluTab™ Waterline Maintenance Tablets [this product], flush lines with a waterline cleaner or another product recommended by the equipment manufacturer to remove line buildup or deposits. When flushing dental unit water lines, always follow a recognized line flushing/cleaning protocol. Repeat flushing to clean lines every 2 months or more frequently when water quality results indicate.

{Directions for 419mg tablets}

Routine Treatment

- 1) Place tablet or tablets (see table below) in empty dental unit water bottle every time you refill the water. BluTab™ Waterline Maintenance Tablets [This product] is intended for use with potable water (including tap or distilled).
- 2) Fill bottle with desired volume of water and connect to dental unit. Tablet dissolves in a few minutes.

Water Volume	Tablets
2L (68 fl. oz.)	1
4L (135 fl. oz.)	2

- 3) BluTab™ Waterline Maintenance Tablets [This product] may be left in the waterlines overnight and for extended periods of non-use. Use water solution until it is expended or up to 28 days. It is not necessary to purge lines at the end of each day.

Clinical monitoring of water quality can ensure that procedures are being performed correctly and are effective. Test water quality monthly to establish effectiveness of your maintenance program. If water quality results approach or exceed requirements, repeat Initial Treatment.

{Directions for 146mg tablets}

Routine Treatment

- 1) Place tablet or tablets (see table below) in empty dental unit water bottle every time you refill the water. BluTab™ Waterline Maintenance Tablets [This product] is intended for use with potable water (including tap or distilled).
- 2) Fill bottle with desired volume of water and connect to dental unit. Tablet dissolves in a few minutes.

Water Volume	Tablets
700-750 (24-25 fl. oz.)	1
1500 (51 fl. oz.)	2
2000 (68 fl. oz.)	3

- 3) BluTab™ Waterline Maintenance Tablets [This product] may be left in the waterlines overnight and for extended periods of non-use. Use water solution until it is expended or up to 28 days. It is not necessary to purge lines at the end of each day.

Clinical monitoring of water quality can ensure that procedures are being performed correctly and are effective. Test water quality monthly to establish effectiveness of your maintenance program. If water quality results approach or exceed requirements, repeat Initial Treatment

Note: Bracketed [ ] information is optional text/picture/diagram. Text separated by a comma (,) denotes—and/or—options. Braced { } text is for administrative purposes only and will not appear on the printed label.

## Precautionary Statements:

## Hazards to Humans and Domestic Animals

**CAUTION:** Tablet may cause moderate eye irritation. Avoid contacting tablet with eyes or clothing. Wash thoroughly with soap and water after handling tablets and before eating, drinking, chewing gum, or using tobacco.

## First Aid

**If in Eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes and continue rinsing.

Call a poison control center or doctor for treatment advice.

**Hotline Number:** In case of emergency call toll free [1-xxx-xxx-xxxx]. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

## Storage and Disposal

**Pesticide Storage:** Store at room temperature out of direct sunlight or prolonged temperatures above 30°C (or 86°F). Do not contaminate water, food, or feed by storage and disposal.

**Pesticide Disposal:** Pesticide wastes are toxic. Improper disposal of excess pesticide 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 hazardous waste representative at the nearest EPA regional office for further guidance.

**Pesticide Container Disposal:** Do not reuse this container. Place in trash or offer for recycling if available.

**Distributed by:** ConFirm Monitoring Systems, Inc.  
Englewood, CO 80112



{Optional quick identifier text for separate packaging, appearing between panels}

2 Liter (68 fl. oz.)  
50 Tablets  
Reorder #BT20

750 mL (24-25 fl. oz.)  
50 Tablets  
Reorder #BT50