

84020-1

05/02/2007

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U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg.
Number:
84020-1

Date of
Issuance:
MAY - 2 2007

Term of Issuance:

Conditional

Name of Pesticide Product:

BluTab Waterline
Maintenance Tablets

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Scientific & Regulatory Consultants, Inc.

P.O. Box 1014

Columbia City, IN 46725

Attention: Sally Hayes, Agent for ConFirm Monitoring Systems, Inc.

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA Registration Number to read, "EPA Reg. No. "84020-1".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

MAY - 2 2007

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EPA Reg. No. 84020-1

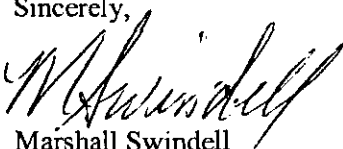
- b. On page two of your label, the statement “ *Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets[This product] will help maintain dental unit water line effluent at levels <500 CFU/mL*” needs to be removed. Claims that include language to Colony Forming Units (CFU) could give the impression that this product is intended to treat pathogenic organisms. This claim would be considered misleading and therefore, unacceptable. Optional language that could be inserted is “BluTab™ Waterline Maintenance Tablets has been specially formulated and clinically proven to control odor causing bacteria and clean dental unit water lines”.
- c. On page two of your label, the statement “ *Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets[This product] will help maintain dental unit water line effluent at levels <200 CFU/mL*” needs to be removed. Claims that include language to Colony Forming Units (CFU) could give the impression that this product could have intentions to treat pathogenic organisms. This claim would be considered misleading and therefore, unacceptable. Optional language that could be inserted is “BluTab™ Waterline Maintenance Tablets has been specially formulated and clinically proven to control odor causing bacteria and clean dental unit water lines”.
- d. On page two of your label, the statement “ *Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets[This product] will help maintain dental unit water line effluent at CDC recommended levels*” needs to be removed. Claims that make reference to the Center of Disease Control (CDC) has acceptable CFU levels for human consumption and/or contact in water type units. Consequently, this could give the impression that the product can treat pathogenic organisms. This reference is unacceptable. Optional language that could be inserted is “BluTab™ Waterline Maintenance Tablets has been specially formulated and clinically proven to control odor causing bacteria and clean dental unit water lines”.
- e. On page two of your label, the statement “ *Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets[This product] will help maintain dental unit water line effluent at ADA recommended levels*” needs to be removed. The American Dental Association (ADA) has acceptable CFU levels for human contact in water units found in dental facilities. Consequently, this could give the impression that the product can treat pathogenic organisms. This reference is unacceptable. Optional language that could be inserted is “BluTab™ Waterline Maintenance Tablets has been specially formulated and clinically proven to control odor causing bacteria and clean dental unit water lines”.
- f. On page two of your label, the statement “*To be use in conjunction with CDC/ADA flushing recommendations*” needs to be removed. Claims that make reference to the ADA and the CDC have concerns similar to what was stated above.
- g. On page two, in the first bullet item that starts “BluTab™ Waterline...”, between the words “of” and “bacteria” add the wording “odor causing”.
- h. On page two, in the last bullet item that starts “[Controls][Reduces]...”, between the words “[*Inhibi*]” and “bacterial”, add the wording “odor causing”.
- i. On page three, under Routine Treatment (Directions for 419 mg tablets) , No. 3, in the third bullet of that section, the statement, No. 3, in the second bullet of that section, the

statement " *If water quality results approach or exceed the CDC recommended bacteria counts, repeat Initial Treatment*" needs to be removed. Claims that make reference to the CDC have concerns similar to what was stated above.

- j. On page three, under Routine Treatment (Directions for 419 mg tablets) , No. 3, in the third bullet of that section, the statement "*Adhere to CDC guidelines including a 2 minute morning flush, a 20-30 second flush between patients and hand piece sterilization*" needs to be removed. Claims that make reference to the CDC have concerns similar to what was stated above.
- k. On page three, under Routine Treatment (Directions for 146 mg tablets) , No. 3, in the second bullet of that section, the statement "*Adhere to CDC guidelines including a 2 minute morning flush, a 20-30 second flush between patients and hand piece sterilization*" needs to be removed. Claims that make reference to the CDC have concerns similar to what was stated above.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

 Marshall Swindell
 Product Manager Team-33
 Regulatory Management Branch I
 Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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{Front Panel}

BluTab™ Waterline Maintenance Tablets

Dental Unit Waterline Treatment

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. XXX-XX

EPA Establishment No. XXX-XX

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAY - 2 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 84080-1

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{Optional Statements – May appear on any panel.}

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 bacteria in the lines. BluTab™ Waterline Maintenance Tablets [This product] is designed to be continuously present in your dental unit water system.

odor (w/s.n)

Proper maintenance and the routine use of BluTab™ Waterline Maintenance Tablets [This product] will maintain dental unit water line effluent at levels <200 CFU/ml.

Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets [This product] will maintain dental unit water line effluent at levels <200 CFU/ml.

Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets [This product] will maintain dental unit water line effluent at levels <200 CFU/ml.

Proper maintenance of equipment and the routine use of BluTab™ Waterline Maintenance Tablets [This product] will maintain dental unit water line effluent at levels <200 CFU/ml.

*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.

[Redacted]

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

Patent Pending

odor (w/s.n)

Reorder No.: BT50

ACCEPTED
with COMMENTS
in EPA Letter Dated:
4/02/06 - RFE

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the purpose of registration under FIFRA.

84020-R

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.

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{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	1
4L (1.06gal)	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.

[REDACTED]

{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 (mL)	Tablets
700-750	1
1500	2
2000	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.

ACCEPTED
with COMMENTS

MAY - 2 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84020-R

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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 the CDC recommended bacteria counts, repeat Initial Treatment.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY - 2 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No

84020-R