



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Scientific & Regulatory Consultants, Inc.
PO Box 1014
Columbia City, IN 46725

FEB 25 2011

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

Subject: BluTab Waterline Maintenance Tablets
EPA Reg. No. 84020-1
Amendment Letter Dated : September 28, 2010

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

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

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely,

A handwritten signature in black ink, appearing to read "M Swindell".

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

Enclosures:

{Front Panel}

BluTab™ Waterline Maintenance Tablets

Dental Unit Waterline Treatment

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

[Inhibits the Growth of Microbial Contamination in Dental Unit Waterlines]

[Maintains dental water line effluent ≤ 10 cfu/ml]

[Keeps Microbial Contamination in Dental Unit Water Lines in [Check] [Control]]

[Reduces and Maintains the Level of Microbial Contamination in Dental Unit Waterlines]

[Maintains ≤ 10 cfu/ml in dental unit water line effluent]

[Maintains water quality level of ≤ 10 cfu/ml in dental unit water lines]

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 [0.26 oz. total] [0.74 oz. total]

EPA Reg. No. 84020-1

EPA Establishment No. XXX-XX

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 25 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for use as a
registered under EPA Reg. No. 84020-1

{Optional Statements – May appear on any panel.}

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

Inhibits the Growth 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]

Maintains dental water line effluent ≤ 10 cfu/ml

Keeps Microbial Contamination in Dental Unit Water Lines in [Check] [Control]

Reduces and Maintains the Level of Microbial Contamination in Dental Unit Waterlines

Maintains ≤ 10 cfu/ml in dental unit water line effluent

Maintains water quality level of ≤ 10 cfu/ml in dental unit water lines

Patent Pending

Reorder No.: BT50

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticides,
registered under EPA Reg. No. 84020-1

{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

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- 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

Storage: Do not contaminate water, food or feed by storage or disposal. Store in a cool dry place.

FOIL POUCH

Disposal: If empty: Place in trash or offer for recycling if available. If partly filled: Call your solid waste agency [or 1-800-CLEANUP] for disposal instructions.

OUTER CONTAINER

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of the empty container in trash.

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

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6/6

{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

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