

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAY 28 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. David Swain Agent for, c/o ConFirm Monitoring Systems, Inc. SRC, Inc. P. O. Box 1014 Columbia City, IN 46725

Subject: Blu Tab Waterline Maintenance Tablets

EPA Registration Number 84020-1

Your Amendment Dated February 26th, 2010

EPA Received Date March 1st, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to comply with PR Notice 2007-4, is acceptable.

A stamped copy of the labeling is enclosed.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510P) {Front Panel}

BluTab<sup>TM</sup> 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 [0.26 oz. total] [0.74 oz. total]

EPA Reg. No. 84020-1

EPA Establishment No. XXX-XX

ACCEPTED with COMMENTS EPA Letter Dated:

WAY 2 8 2010

inder the Federal Insecticide, inglicide, and Rodenticide Act as indended, for the pesticide, 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

BluTab<sup>TM</sup> 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<sup>TM</sup> 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

ACCEPTED with COMMENTS EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 8 40 20 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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

- Place tablet or tablets (see table below) in empty dental unit water bottle every time you refill the water.

  BluTab<sup>TM</sup> 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<sup>TM</sup> 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 COMMENTATION results approach or exceed requirements, repeat Initial Treatment

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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

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAY 2 8 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 840 20 1

6066

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

50 Tablets
Reorder #BT20
750 mL (24-25 fl. o
50 Tablets
Reorder #BT50

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 4 2010

in the Federal Insecticide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 84020