



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 5, 2020

Bob MacDonald  
Agent, Proedge Dental Products  
Proedge Dental Products  
7042 South Revere Parkway  
Suite 400  
Centennial, Co 80112

Subject: Label Amendment – Update label to current industrial wording and terminology  
Product Name: BLUTAB Waterline Maintenance Tablets  
EPA Registration Number: 84020-1  
Application Date: July 10, 2019  
Decision Number: 553372

Dear Mr. MacDonald:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080 or via email at [johnson.zebora@epa.gov](mailto:johnson.zebora@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Acting Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Accepted Label

{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  $\leq$  10 cfu/ml]

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

[Maintains  $\leq$  10 cfu/ml in dental unit water line effluent]

[Maintains water quality level of  $\leq$  10 cfu/ml in dental unit water lines]

ACTIVE INGREDIENT

Silver 0.477%

OTHER INGREDIENTS 99.523%

TOTAL 100.000%

CAUTION

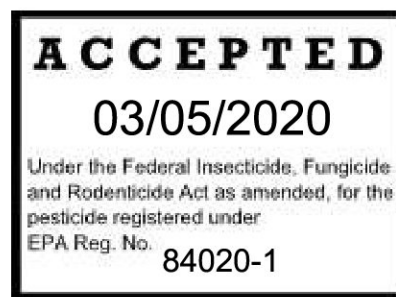
KEEP OUT OF REACH OF CHILDREN

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



{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 quarterly 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  $\leq 10$  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  $\leq 10$  cfu/ml in dental unit water line effluent

Maintains water quality level of  $\leq 10$  cfu/ml in dental unit water lines

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], shock lines with a waterline cleaner or another product recommended by the equipment manufacturer to remove line buildup or deposits. When shocking dental unit water lines, always follow a recognized line shocking/cleaning protocol. Repeat shocking 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] are 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 quarterly 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] are 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 quarterly to establish effectiveness of your maintenance program. If water quality results approach or exceed requirements, 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

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: ProEdge Dental Products  
Centennial 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