



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Antimicrobials Division (7510P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

**EPA Reg. Number:**

84020-2

**Date of Issuance:**

11/7/16

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

**Term of Issuance:**

Unconditional

**Name of Pesticide Product:**

BluTube

**Name and Address of Registrant (include ZIP Code):**

ProEdge Dental Products  
 7248 South Alton Way Unit 9-D  
 Centennial, CO 80112

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 84020-2."

**Signature of Approving Official:**

Demson Fuller, Product Manager 32  
 Regulatory Branch II  
 Antimicrobials Division (7510P)

**Date:**

11/7/16

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/06/2016

If you have any questions, please contact Wanda Henson by phone at (703) 308-6345 or via email at [henson.wanda@epa.gov](mailto:henson.wanda@epa.gov)

Sincerely,



Demson Fuller  
Product Manager – Team 32  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

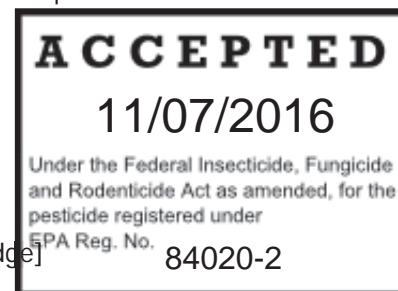
Enclosure

{Administrative Note: Language in {curly brackets} is administrative and will not appear on the final printed label.  
 [Bracketed] text indicates optional text.}

{Front Panel}

**BluTube®**  
 Dental Unit Water Purification Cartridge

[Alternate Brand Name: BluTube Dental Unit Water Purification Cartridge]



Active Ingredient:  
 Iodine\*.....47.5%  
 Other Ingredients.....52.5%  
 Total..... 100.0%

\*Bound to polystyrene divinyl benzene quaternary ammonium anion exchange resin

**KEEP OUT OF REACH OF CHILDREN  
 CAUTION**

<b>FIRST AID</b>	
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on Skin</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: <a href="http://www.npic.orst.edu">www.npic.orst.edu</a> ).	

See side/back panel for additional precautionary statements.

**Net Contents:** [1 cartridge]  
**EPA Reg. No.** 84020-TBD  
**EPA Est. No.**

Manufactured By:  
 ProEdge Dental Products  
 7348 South Alton Way, Unit 9d  
 Centennial, CO 80112

{Administrative Note: Language in {curly brackets} is administrative and will not appear on the final printed label. [Bracketed] text indicates optional text.}

{Back Panel}

## DIRECTIONS FOR USE

**It is a violation of federal law to use this product in any manner inconsistent with its labeling.**

Change the cartridge if the iodine level falls below 0.5 ppm. Use iodine sensitive test strips to verify performance. See the Suggested Use Table to determine when to install a new cartridge.

### Suggested Use Table:

Item #	If Water Records are Kept	If Water Usage Records are Not Kept	If Iodine Concentration is Monitored
WB365	240 Liters	12 months (365 days)	Change when iodine output falls to less than 0.5 ppm
WB270	180 Liters	9 months (280 days)	
WB180	120 Liters	6 months (180 days)	
WB90	60 Liters	3 months (90 days)	

### Initial Treatment

Before starting a treatment program with [BluTube®] [this product], flush lines with a waterline cleaner or another product recommended by the dental equipment manufacturer to remove line build-up or deposits. When flushing dental unit waterlines, always follow a recognized line flushing protocol.

### Routine Use

The BluTube® cartridge is installed on the pick-up tube in your dental unit water bottle. Refer to Installation Instructions for details. It is designed to control microbial contamination in the dental unit waterlines. Once the cartridge is in place, the supply water will pass through the cartridge's iodinated resin bed, controlling microbial contamination in the water delivered by the dental instrument. The treated water can be used as an irrigant/coolant for dental procedures and is appropriate for use in dental instruments like an air/water syringe or high speed handpiece.

### Important:

- Water pressure should not exceed 45 psi.
- Empty the water in the water bottle every night and start with fresh water each day.
- Clinical monitoring of water quality can ensure that the procedures are being performed correctly and are effective. Test water quality regularly to establish effectiveness of your maintenance program.

### BluTube® Installation Instructions

#### TOOLS AND MATERIALS REQUIRED:

- Installation Kit-Includes one female and one male fitting
- Scissors or sharp knife

To obtain maximum bacteriological reduction, dental unit waterlines should be cleaned with an approved dental unit waterline agent prior to initial installation.

1. Remove shipping caps from both ends of the unit.
2. {Optional} Disconnect dental unit water heating system, if installed.
3. Remove bottle from manifold.
4. Install female fitting, from installation kit into male fitting which is attached to the cartridge.
5. Place the BluTube® cartridge against the bottle pickup tube, aligning the bottoms of the pick up tube and the new unit, allowing enough space (about 1/4") so that cartridge will not touch the bottom of the bottle.
6. Push female fitting into the remaining short section of pickup tube projecting from the manifold and attach the unit.

{Administrative Note: Language in {curly brackets} is administrative and will not appear on the final printed label. [Bracketed] text indicates optional text.}

7. Attach the male fitting from the installation kit into the cut end of the removed portion of pickup tubing. Save this for future dental unit cleaning or purging.
8. Check air pressure to bottle, set at 45 psi.
9. Operate dental unit instruments until all air is purged from the water system

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wear goggles and plastic gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

#### PHYSICAL HAZARDS

Do not allow to freeze. Do not expose to direct sunlight.

### STORAGE AND DISPOSAL

Do not contaminated water, food or feed by storage or disposal.

**Storage:** Store this product in non-metallic containers resistant to the corrosive action of iodine. Keep moist (preferably with deionized water) by storing resin beads with a small layer of water above the settled resin. Do not store in open or unlabeled containers.

**Pesticide Disposal:** This resin contains Iodine (I<sub>2</sub>), which is corrosive to most metals. Do not dispose resin in sewers or storm drains. Place in non-metallic containers and dispose in sanitary landfill approved for pesticide disposal.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration

### {Optional Statements – May appear on any panel.}

- Adherence to the CDC/ADA guidelines for aseptic procedures including a 2-minute morning flush and a 20-30 second flush between patients is recommended.
- Antimicrobial cleaner
- [BluTube® Dental Unit Water Purification Cartridge] [This product] is specially designed and proven to control microbial contamination in dental unit waterlines by reducing and inhibiting the re-growth of odor-causing bacteria in the lines.
- BluTube® is designed to be continuously present in your dental unit water system during appropriate dental procedures.
- BluTube® treated water is not for general consumption.
- BluTube® should not be used as a coolant/irrigation in the performance for Oral Surgical Procedures.
- Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings — 2003. Sterile solutions (e.g., sterile saline or sterile water) should be used as a coolant/irrigation in the performance of oral surgical procedures where a greater opportunity exists for entry of microorganisms, exogenous and endogenous, into the vascular system and other normally sterile areas that support the oral cavity (e.g., bone or subcutaneous tissue) and increased potential exists for localized or systemic infection. Oral surgical procedures involve the incision, excision, or reflection of tissue that exposes the normally sterile areas of the oral cavity. Examples include biopsy, periodontal surgery, apical surgery, implant surgery, and surgical extractions of teeth (e.g., removal of erupted or nonerupted tooth requiring elevation of mucoperiosteal flap, removal of bone or section of tooth, and suturing if needed)
- Cleans [and maintains] dental unit waterlines
- Clinical monitoring of water quality can ensure that procedures are performed correctly. Test water quality monthly to establish effectiveness of your maintenance program.
- [Controls] [Reduces] [Inhibits] odor-causing bacterial contamination in [dental unit waterlines] [effluent] [treatment water]

BluTube® (84020-TBD)  
ProEdge Dental Products

A540 – May 6, 2016, Label Version (4) November 4, 2016

Page 3 of 4

{Administrative Note: Language in {curly brackets} is administrative and will not appear on the final printed label.  
[Bracketed] text indicates optional text.}

- Controls odor-causing bacteria in dental unit water lines.
- Demand release technology.
- Do not use heated water. Heated water can promote bacterial growth and the development of biofilms.
- Empty the water in the water bottle every night and start with fresh water each day. Wipe down the outside of the cartridge daily.
- Fill the bottle with fresh water at the start of each day.
- [For the Cleaning of Microbial Contamination in Dental Unit Waterlines]
- If package seal is broken do not use the cartridge.
- [Inhibits the Growth of Microbial Contamination in Dental Unit Waterlines]
- Kills odor causing bacteria
- Shut off water to the dental unit when not in use.

Reorder No. WB365

Reorder No. WB270

Reorder No. WB180

Reorder No. WB90