



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 13, 2020

Abigail Wacek
Authorized Representative for ProEdge Dental Products
ProEdge Dental Products
7042 South Revere Parkway, Suite 400
Centennial, CO 80112

Subject: Label Amendment – Addition of label claims and minor adjustments to label
Product Name: BluTube
EPA Registration Number: 84020-2
Application Date: August 14, 2019
Decision Number: 556828

Dear Ms. Wacek:

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

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with FIFRA section 6. If you have any questions, please contact Melanie Bolden by phone at (703) 347-0165, or via email at Bolden.Melanie@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Demson Fuller".

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

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

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**

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• 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.• Call a poison control center or doctor for treatment advice.
If on Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
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: www.npic.orst.edu).	

See [box] [inside] [side][/][back] [panel] for [Directions for Use], [First Aid and] additional precautionary statements.

Net Contents: [1 cartridge] [2 cartridges]

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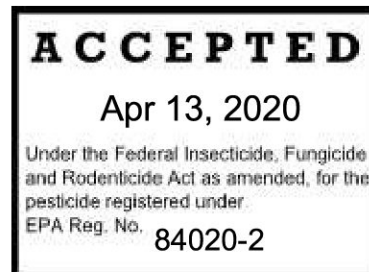
Manufactured By:

ProEdge Dental Products

7042 S Revere Parkway, Suite 400Centennial, CO 80112

[888.843.3343]

[proedgedental.com]



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DIRECTIONS FOR USE

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

Change the [Product Name] 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 [Product Name] cartridge.

Suggested Use Table: {Note to reviewer: Label may include some or all of the following in the table.}

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

Initial Treatment

Before starting a treatment program with [Product Name] [this product], shock lines with a waterline cleaner or another product recommended by the dental equipment manufacturer to remove line build-up or deposits. When shocking dental unit waterlines, always follow a recognized line shocking protocol. Never shock through the [Product Name] cartridge.

Routine Use

The [Product Name] cartridge is installed on the pick-up tube in your dental unit water bottle. Refer to Installation Instructions below for details. [Product Name] [This product] [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 monthly to establish effectiveness of your maintenance program. If results indicate that water quality is acceptable for two consecutive months, the frequency of testing may be reduced, but should not be less than every three months. If water quality results do not meet ADA standards for water quality, repeat Initial Treatment.

BluTube® Installation Instructions

{Note to Reviewer: This section may include graphic presentations of the installation instructions. As per PR Notice 98-10, these graphics will present the same information as provided in narrative form below.}

TOOLS AND MATERIALS REQUIRED:

- Installation Kit-Includes one female and one male fitting

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- Scissors or sharp knife

[To obtain maximum odor-causing 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/cartridge.
2. {Optional} Disconnect dental unit water heating system, if installed.
3. Remove water bottle from dental unit manifold.
4. Install female fitting from installation kit into male fitting at the small end of the cartridge.
5. Place the [Product Name] cartridge against the bottle pickup tube, aligning the bottoms of the pickup tube and the new unit, allowing enough space (about 1/4") so the 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.
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 OR CHEMICAL HAZARDS

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

ENVIRONMENTAL HAZARDS

[For products > 50 pounds]

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

[For products ≤ 50 pounds]

This pesticide is toxic to fish and aquatic invertebrates

STORAGE AND DISPOSAL

Do not contaminate 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 (I₂), 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.}

- 6 Month BluTube® A
- 6 Month BluTube® B

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- 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
- 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]
- 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.
- "Dummy" straw to make shocking easy
- 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
- Maintains water quality level of < 200 CFU/mL in dental unit waterlines
- Pickup tubing to help with install
- [Product Name] treated water is not an appropriate coolant/irrigant for surgical procedures. Sterile water or sterile saline is the only appropriate coolant/irrigant for surgical procedures.
- [Product Name] [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.
- [Product Name] [This product] is designed to be continuously present in your dental unit water system during appropriate dental procedures.
- [Product Name] [This product] treated water is not for general consumption.
- [Product Name] [This product] should not be used as a coolant/irrigation in the performance for Oral Surgical Procedures.
- [Product Name] treated water is not an appropriate coolant/irrigant for surgical procedures. Sterile water or sterile saline is the only appropriate coolant/irrigant for surgical procedures.
- The [Product Name] is for use on dental unit water lines attached to [the] dynamic dental instruments [,] [i.e.,] [high-speed handpiece] [,] [three-way air/water syringe] [,] [and] [ultrasonic scaler]. This cartridge [in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments] reduces odor-causing bacteria from the water supplied [through] [to] the instruments to less than [200] [500] CFU/mL, a level that will meet or exceed the current [American Dental Association (ADA)] [ADA] recommendations for water quality.
- The [Product Name] is for use on dental unit water lines attached to [the] dynamic dental instruments [,] [i.e.,] [high-speed handpiece] [,] [three-way air/water syringe] [,] [and] [ultrasonic scaler]. This cartridge [in conjunction with currently recommended practices regarding sterilization and flushing of dental instruments] maintains the quality of water supplied [through] [to] the instruments [at] [to] less than [200] [500] CFU/mL, a level that will meet or exceed the current [American Dental Association (ADA)] [ADA] recommendations [for water quality].
- Questions? [phone number] [email address]
- Shut off water to the dental unit when not in use.
- Shocking: When shocking lines, follow the recommendations provided by the dental unit manufacturer and use an approved cleaner. Remove the [Product Name] and shock waterlines

BluTube® (84020-2)

ProEdge Dental Products

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- with the provided pickup tube. Once the waterlines are shocked, reconnect the [Product Name] and retest water to ensure remediation was effective.
- The [Product Name] is intended for use on dental unit water lines attached to dental instruments such as air/water syringes and high speed handpieces. This cartridge reduces the number of odor-causing bacteria in water supplied to the instruments to less than [200] [500] CFU/mL, below the current dental water line bioburden standard recommended by the [American Dental Association (ADA)] [ADA].
 - This cartridge reduces the number of odor-causing bacteria in water supplied to the instruments to less than 200 CFU/mL, which is [below] the current dental water line bioburden standard recommended by the [American Dental Association (ADA)] [ADA].
 - Used according to labeling, this cartridge reduces odor-causing bacteria from the water supplied through the instruments to a level that will meet or exceed the current [American Dental Association (ADA)] [ADA] recommendations for water quality having a maximum of 500 CFU/mL.

Reorder No. {Insert Item #}

{Note to the Reviewer: The following information will be printed directly on the Dental Unit Water Purification Cartridge. The full product label will accompany the cartridge at the point of sale.}

BluTube®

[Dental Unit Water Purification Cartridge]

Active Ingredient: Iodine 47.5%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See box for Directions for Use, First Aid, and additional precautionary statements

EPA Reg. No.: 84020-2

EPA Est. No.: