



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 24, 2021

Georgia Anastasiou  
Agent  
Hu-Friedy Manufacturing Co., LLC  
c/o Lewis & Harrison  
122 C Street, NW – Suite 505  
Washington, DC 20001

Subject: Label Amendment – Addition of Installation Instructions  
Product: HF Antimicrobial DUWL Iodine Resin Unit  
EPA Registration Number: 75372-1  
Received Date: November 22, 2017  
Action Case Number/Decision Number: 00226684/536752

Dear Georgia Anastasiou:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Wanda Henson by phone at (703) 308-6345, or via email at [henson.wanda@epa.gov](mailto:henson.wanda@epa.gov)

Sincerely,

A handwritten signature in blue ink that reads "Wanda G. Fuller, for". The signature is written in a cursive style.

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

Enclosure

# HF Antimicrobial DUWL Iodine Resin Unit

For Use As An Antimicrobial Agent in Dental Unit Water Lines

Active Ingredient:	
Iodine *	46.0%
<u>Other Ingredients</u>	<u>54.0%</u>
Total	100.0%

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

This product contains 0.5 lb of iodine (I<sub>2</sub>) per pound

**A C C E P T E D**

Jun 24, 2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 75372-1

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**

## 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 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

### If on skin or clothing:

- 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.

### If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling poison control center or doctor, or going for treatment.

[See [side][back][panel][insert][accompanying instructions] for additional precautionary statements, first aid and directions for use.]

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Causes moderate eye irritation. Avoid contact with eyes, skin and clothing. Wear protective eyewear (goggles) and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

### **ENVIRONMENTAL HAZARDS**

The exposed iodine resin pellets are toxic to fish and aquatic organisms. 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.

### **DIRECTIONS FOR USE**

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

HF UWL Iodine Resin Unit is designed for use on dental unit water lines attached to dynamic dental instruments. The product reduces microbial contamination and odor-causing bacteria in dental unit water lines.

Prior to installing HF DUWL Iodine Resin Unit, thoroughly clean dental unit water lines following the manufacturer's instructions or with an appropriate cleaning agent. Insert HF DUWL Iodine Resin Unit into the inlet and outlet fittings of dental unit water lines. Once the product is in place, the supply water will pass through the iodinated resin bed, which will continuously release low levels of antimicrobial iodine. After installation, check water flow and verify that the unit is operational. Create a check-off sheet to monitor volume of water used through unit. Shut off water to the dental unit when not in use.

The lifetime of this product is 240 liters or 365 calendar days (if water usage records are not monitored) or if iodine levels falls to less than 0.5ppm. After this period or level is reached, immediately replace the spent HF Antimicrobial DUWL Iodine Resin Unit product/unit with a new or replacement product/unit. To install the new unit, follow the instructions above for installing a new product.

[If HF Antimicrobial DUWL Iodine Resin Unit is used in conjunction with a bottle water system] The bottle in water bottle systems must be emptied each night and the empty bottle replaced on the manifold. [Prior to] [or] [Before] daily use, wash the inside of the bottle and rinse thoroughly. Wipe down the outside of HF Antimicrobial DUWL Iodine Resin Unit and make sure the intake end is not obstructed. Fill with fresh water each morning before its first use. Replace HF Antimicrobial DUWL Iodine Resin Unit after 240 liters of water usage, if iodine level falls to less than 0.5ppm, or if records of usage are not kept, after 365 calendar days of installation.

Note: Adherence to CDC/ADA guidelines for aseptic procedures including a 2 minute morning flush, a 20-30 second flush between patients, and hand piece sterilization must be continued after the installation of this product.

If package seal is broken or product appears dry, wrap in newspaper and dispose of it in the trash.

#### Troubleshooting

If the water flow after product installation is slow or inhibited, check to ensure that the product was installed properly or if the product has been plugged by debris. For bottle installation ensure that the air supply is turned on at the maximum level (45 psi). In addition, ensure that the product is at the bottom of the water bottle. If there is an air leak from fittings, contact your dental supplier for replacement parts or service. Discoloration of tubing from yellow to blue to green to black is normal and is not a concern. Initial discoloration of water is caused by release initial flush of excess iodine. Operate water until flow appears clear.

#### **STORAGE & DISPOSAL**

**STORAGE:** Store at room temperature in original packaging, away from children, pets and direct sunlight. Avoid excessive heat. Do not allow cartridge to freeze. Do not store in open or unlabeled containers.

**DISPOSAL:** Securely wrap cartridge in newspaper and discard in trash.

EPA Reg. No. 75372-1

EPA Est No.

Net Contents:

[Manufactured] [Distributed][by][for]  
Hu-Friedy Manufacturing Co., LLC  
D/B/A Hu-Friedy  
3232 N. Rockwell, St  
Chicago, IL 60618

*Filter Label 4.75" x 0.375"*

Product Name	KEEP OUT OF REACH OF CHILDREN	EPA Reg. No. 75372-1
Active Ingredient: Iodine 46%	CAUTION: See insert for directions & precautions	EPA Est. No.:

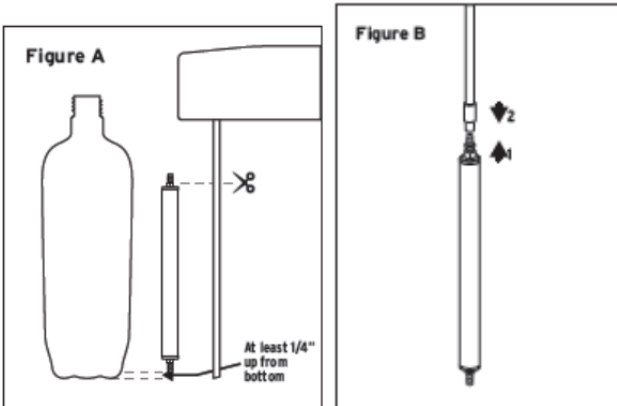
## Installation Instructions

### PRE-INSTALLATION NOTE:

Thoroughly clean dental unit waterlines with an appropriate antimicrobial cleaning agent following manufacturer's instructions before installing the HF Antimicrobial DUWL Iodine Resin Unit for the first time. HF Antimicrobial DUWL Iodine Resin Unit's barb fittings are sized for use with 1/4" O.D. x 1/8" I.D. dental supply tubing. Please note that the filter has no designated inlet or outlet. Either orientation is acceptable.

### FOR USE IN DENTAL BOTTLES:

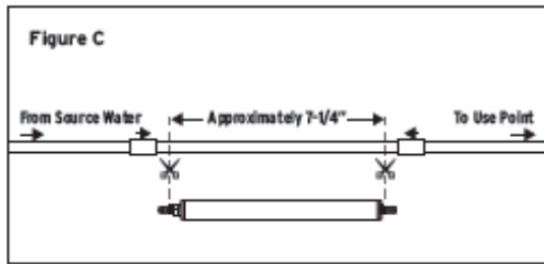
1. Remove bottle from manifold.
2. Hold the HF Antimicrobial DUWL Iodine Resin Unit alongside the riser tube hanging from the manifold and mark the riser tube as shown in Figure A. Be sure to allow for at least a 1/4" gap between the end of the HF Antimicrobial DUWL Iodine Resin Unit and the bottom of the bottle.
3. Cut off the lower section of the riser tube at the top mark using a tubing cutter, sharp knife, or scissors.
4. Push a tubing sleeve onto the riser tube as shown in Figure B, then push the hose barb attached to the HF Antimicrobial DUWL Iodine Resin Unit into the tubing, making sure that it is fully engaged.
5. Slide the tubing sleeve down over the hose barb, and make sure that the barb fitting is firmly threaded into the HF Antimicrobial DUWL Iodine Resin Unit body.
6. Fill the dental bottle with quality potable water and reattach to manifold by sliding the HF Antimicrobial DUWL Iodine Resin Unit through the bottle opening.
7. Pressurize the bottle as normal, then begin discharging all dental appliance lines including handpieces, air/water syringe and quick-disconnect (if present) for a few minutes each. The system is now ready for use.



### FOR USE AS AN INLINE FILTER:

1. Depressurize the system that will utilize the HF Antimicrobial DUWL Iodine Resin Unit.
2. Hold the HF Antimicrobial DUWL Iodine Resin Unit alongside the tubing where the installation is desired and mark the section of tubing to be removed, as shown in Figure C.
3. Cut the tubing at the marks using a tubing cutter, sharp knife, or scissors.
4. Push tubing sleeves onto both sections of tubing, then push the hose barbs on each end of the HF Antimicrobial DUWL Iodine Resin Unit into the tubing, making sure that both hose barbs are fully engaged.
5. Slide the tubing sleeves down over the hose barbs, and make sure that both barb fittings are firmly threaded into the HF Antimicrobial DUWL Iodine Resin Unit body.

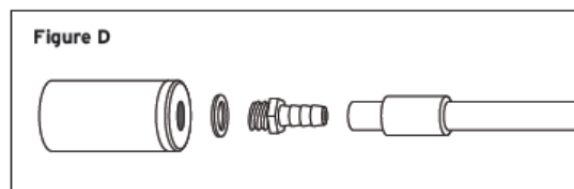
6. Reopen the valve at the water source. Allow water to flow through the new filter by opening any device after the filter. Flow water through each connected device (e.g. handpiece, air/water syringe, scaler, etc.) for several minutes. The system is now ready for use.



### CHANGING THE FILTER

Change the HF Antimicrobial DUWL Iodine Resin Unit after 240 liters or one year (if water usage is not monitored), or if iodine levels fall to less than 0.5 ppm

1. Turn off and depressurize devices attached to filter.
2. Replace the filter via either method:
  - a. Slide back the tubing sleeve(s) and pull the tubing off the barb(s) and remove filter. Install new filter by pushing tubing over the barbs on the new filter, then sliding the sleeves back into place over the barb(s).
  - b. Unthread the barb fitting(s) from the expired filter, leaving the barb(s) in place inside the tubing. Remove the expired filter. Unthread the barb(s) from the new filter. Ensure the seal washer(s) shown in Figure D stay in place and then thread the new filter onto the existing barb(s).



### CLEANING NOTE:

Before cleaning waterlines with any type of antimicrobial agent, always remove the HF Antimicrobial DUWL Iodine Resin Unit first. Replace the section of tubing temporarily, clean and rinse the lines, remove the temporary tubing, and then replace or reinstall the filter.

### NOTE:

The Hu-Friedy Waterline Filter features one barbed fitting that swivels to facilitate easier filter replacement in an inline installation. Before resuming operation after replacing a filter, always ensure that both barbed fittings are threaded securely into the filter body to prevent leaks.

## *OPTIONAL MARKETING LANGUAGE*

- No risk of allergic reaction (isotopic iodine contains no protein)
- Container has no silver or other hazardous waste – disposal as easy as throwing it in the trash
- EPA registered as an antimicrobial dental unit water line product
- Eliminates the need for manual addition of biocides into water systems. This product does it automatically.
- Consistent and accurate dosing.
- [Reduces][Controls][Inhibits] bacterial contamination (odor and fouling bacteria) in dental unit water lines.
- Meets or exceeds ADA guidelines for dental unit water lines.
- Meets or exceeds [ADA recommendation of] < 200 CFU/ml for dental unit water lines.
- One year life with minimal human interaction
- Easily installed in just minutes
- Ability to be used with either municipal or independent reservoir
- No corrosion or etching of metal parts
- No effect on bonding agents
- Ability to be used with current dental unit water bottles
- Shocking not required on monthly (or weekly) basis
- No daily, weekly or monthly protocols
- Works with any size bottle
- Non-corrosive
- Shocking not required on first use (or optional)
- Same product can be used for inline water or independent reservoir
- Less than 5-minute change out time.
- Antimicrobial Cleaner
- Cleans and maintains dental unit waterlines
- Inhibits the growth of microbial contamination in dental waterlines
- Kills odor causing bacteria
- For the cleaning of microbial contamination in dental unit waterlines
- You're on your way to cleaner water!

## *OPTIONAL REMINDER HANG TAG LANGUAGE*

- Equipped With [product name]
- Reminder. Change your filter annually. The lifetime of this product is 240 liters or 365 calendar days (if water usage records are not monitored). Replace [product name] after 240 liters of water usage, or if records of usage not kept, after 365 calendar days of installation.
- Date Installed:
- Installed By:
- Install New [product name]. Date for New Filter:
- Re-order Information: Product Name: Part Code:
- To reorder, call 1-800-HU-Friedy or order through your dental distributor