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

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
75372-1	4/24/17

Term of Issuance:
Conditional

Name of Pesticide Product:
HF Antimicrobial DUWL Iodine Resin Unit

Name and Address of Registrant (include ZIP Code):

Eliot Harrison
Hu-Friedy Manufacturing Co., LLC
c/o Lewis & Harrison
122 C St. NW, Suite 505
Washington, DC 20001

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

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

Date:
4/24/17

EPA Form 8570-

2. You are required to comply with the data requirements described in the DCI identified below:

    a. Iodine GDCI- 046901-1673
    046903-1674
    046904-1441
    046905-1444
    046914-1676
    046923-1677

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 75372-1."

4. Submit one copy of the 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 you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). 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 11/02/2016

If you have any questions, please contact Wanda Henson by phone at (703), or via email at henson.wanda@epa.gov

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
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%

Other Ingredients……54%

Total……100%

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

This product contains 0.5 lb of iodine (I_2) per pound

ACCEPTED

04/24/2017

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-
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

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 until waterlines