



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

**EPA Reg. Number:**

89494-1

**Date of Issuance:**

12/21/17

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

**Term of Issuance:**

Conditional

**Name of Pesticide Product:**

Monarch Lines Cleaner

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

Air Techniques, Inc.  
 1295 Walt Whitman Rd  
 Melville, NY 11747

**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:**

Zeno Bain, Acting Product Manager 33  
 Regulatory Management Branch I  
 Antimicrobials Division (7510P)  
 Office of Pesticide Programs

**Date:**

12/21/17

2. Be aware that proposed data requirements have been identified in a Work Plan and proposed DCI. For more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>
3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 89494-1.”
5. 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 05/04/2017

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

Enclosure: Stamped Label

# Monarch Lines Cleaner

Dental Unit Waterline Cleaner

For Use In Pressurized Self-Contained Water Delivery Systems

Proven formula for dental unit waterline treatment

This solution controls microbial contamination  
while cleaning the dental unit supply tubing.

Ready-to-use

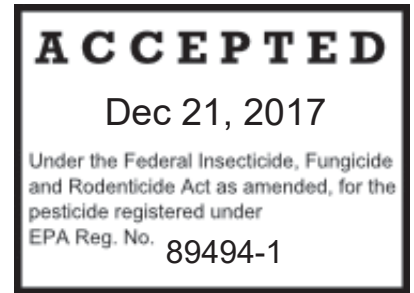
Do not dilute

Active Ingredients:

Chlorhexidine Gluconate 0.12%

Other Ingredients: 99.88%

Total: 100.00%



Keep out of reach of children

CAUTION

See back/side panel for First Aid

Net contents: \_\_\_\_\_ ml/liters/quarts/gallons

EPA Registration No.: 89494-\_\_\_\_\_

EPA Establishment No.: \_\_\_\_\_

### **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. Call a poison control center or doctor or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

IF SWALLOWED: If large quantities are ingested, do not induce vomiting. Drink large quantities of milk or water. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

### **PHYSICAL AND CHEMICAL HAZARDS**

Combustible. Do not use or store near heat or open flame

### **DIRECTIONS FOR USE**

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

#### **Initial Cleaning (Shock Treatment)/New Users**

Week 1 to 3: Use every night

This initial 3-week period makes sure that any microbial build-up in the dental tubing lines is eliminated.

*Note: Remove handpieces and scalers to avoid plugging and clogging instruments due to discharge during first time use.*

#### **Routine Cleaning**

Use once a week. For best results, leave solution in waterlines overnight or over the weekend.

#### **Daily Use**

Monarch Lines Cleaner may be added daily to potable water supplies. Add 1 oz. of Monarch Lines Cleaner per quart to tap or distilled water.

#### **Directions for Dental Unit Waterline Cleaning**

##### **Step 1: Air Purge Dental Unit Waterlines**

1. Turn dental unit OFF. Empty water bottle and place back on dental unit.
2. Turn dental unit ON.
3. Air purge waterlines by activating handpiece hoses and air/water syringes until water is eliminated.

##### **Step 2: Add Monarch Lines Cleaner**

1. Turn dental unit OFF. Remove water bottle and pour 2 fluid ounces (60 ml) of Monarch Lines Cleaner into dental unit's empty water bottle. Place water bottle on dental unit.
2. Turn dental unit ON. Activate handpiece hoses and air/water syringes until Monarch Lines Cleaner exits.
3. Turn dental unit OFF. Allow Monarch Lines Cleaner to treat dental unit supply tubing for at least 6 hours, overnight or over the weekend before proceeding to Step 3.

### Step 3: Flush Dental Unit Waterlines

1. Remove water bottle. Dispose of any excess solution and fill bottle with fresh water.
2. Turn dental unit ON. Flush waterlines for 30 seconds to remove any excess Monarch Lines Cleaner.

Clinical monitoring of water quality can ensure that it meets ADA guidelines of < 200 CFU/ml for dental unit water lines. The ADA guidelines are specific to heterotrophic bacteria, which have no public health effects. This is an analytical method used to measure a variety of bacteria that are common in water. The lower the concentration of bacteria in drinking water, the better maintained the water system. Test water quality quarterly to establish effectiveness of your maintenance program. If water quality results do not meet ADA standards for water quality, repeat Initial Treatment.

For optimal cleaning results, air purge and clean all instruments and tubing, including handpiece, air/water syringe, scaler and waterlines.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal

PESTICIDE STORAGE: Do not store near open flame, at elevated temperature or in intense light.

PESTICIDE DISPOSAL: Wastes resulting from this product may be disposed of on site.

CONTAINER DISPOSAL: Non-refillable 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, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Monarch Lines Cleaner is available in the following packaging configurations:

- 1 gallon / 3.8 L bottle
- 102 fl. oz. / 2.5 L bottle
- 16.9 fl. oz. / 500 mL bottle
- 8 fl. oz. / 250 mL bottle
- 4 fl. oz. / 125 mL bottle

{OPTIONAL MARKETING CLAIMS AND DESCRIPTORS}

[Once-a-week solution for cleaning dental unit waterlines]

[Antimicrobial for independent water supply bottles]

[Shock and maintenance treatment]

[Removes biofilm from dental unit waterlines containing bacteria that cause objectionable tastes and odors]

[Removes biofilm from dental unit waterlines containing odor-causing bacteria]]

[Cleans] [and][deodorizes] in three easy steps]

[Kills][Effective against] odor-causing bacteria

[Kills][Effective against] bacteria that cause objectionable tastes and odors

[For the cleaning and control of microbial contamination in dental unit waterlines]

[For use in any dental unit]

[Inhibits the growth of microbial contamination in dental unit waterlines]

[Keeps microbial contamination in dental unit waterlines in [check] [control]]

[Reduces and maintains the level of microbial contamination in dental unit waterlines]

[Maintains ADA guidelines of < 200 CFU/ml for dental unit water lines.]

[Controls odor-causing bacteria in dental unit water lines]

[Does not corrode waterlines, valves, bottles or equipment]

[Non-corrosive]

[pH-neutral]

[Does not clog waterline]

[Removes microbial buildup in the waterlines]

[Does not stain the waterlines]

[Cleans dental unit waterlines]

[Cleanses dental unit waterlines]

[Purges completely]

[Non-staining]

[Water-soluble]

[Does not affect dental bonding]

[Antibacterial]

[Antimicrobial]

[Antibacterial & Antimicrobial]

[Designed to work with supplemental products such as water cleaning tablets]

[Ready to use]

[No diluting required]

[Doesn't leave residue in water bottle]

[Blue liquid]

[Does not require the use of multiple products such as powders, tablets, cartridges or filters]

[Convenient]

[Easy-to-use]

[Effective weekly cleaner]

[For daily use]

[Recommended for repeated use]

[Mint fragrance]

[No mixing required]

[Fast] [Easy] [and convenient] way to clean waterlines]

[Extremely effective]

[Economical]

[Fast, effective, and efficient application]

[Replaces daily water cleaning tablet]