



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 13, 2022

Mandi Daun
Lewis & Harrison, LLC
Consultant for Air Techniques, Inc.
Electronic Transmittal: mdaun@lewisharrison.com

Subject: PRIA Label Amendment – Rearranging directions for daily use on label and making daily use optional
Product Name: Monarch Lines Cleaner
EPA Registration Number: 89494-1
Received Date: 5/1/2019
Action Case Number: 00222362

Dear Mandi Daun:

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.

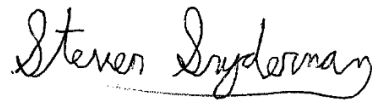
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 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 Steven Snyderman by phone at (202) 564-0910, or via email at snyderman.steven@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

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][inside] panel for First Aid

Net contents: _____ ml/liters/quarts/gallons

EPA Registration No.: 89494-1

EPA Establishment No.: _____

[Manufactured for][Produced for]:



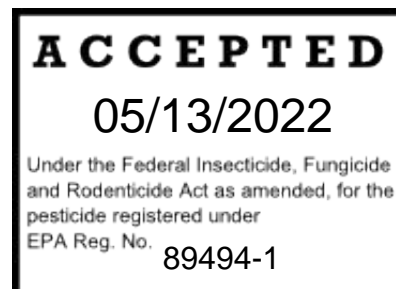
Air Techniques, Inc.

1295 Walt Whitman Road

Melville, NY 11747-3062

www.airtechniques.com

Phone: 800.247.8324



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.

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.

[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.]

STORAGE AND DISPOSAL

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

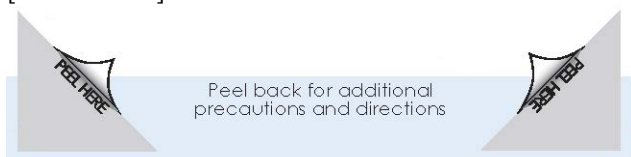
PESTICIDE STORAGE: Do not store near open flame, at elevated temperature or in intense light.

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.

[Peel back for additional precautions and directions]

[PEEL HERE]



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]

