



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 3, 2018

Michael Overmyer
COO of Anodia Systems
Anodia Systems
109 Larrimore Lane
Danville, KY 40422

Subject: Notification per PRN 98-10 – Simplifying verbiage and other minor label edits
Product Name: Mint-A-Kleen
EPA Registration Number: 85298-2
Application Date: February 20, 2018
Decision Number: 539746

Dear Mr. Overmyer:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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 have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zeno Bain', with a stylized flourish at the end.

for

Zeno Bain, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

MINT-A-KLEEN®
EPA MASTER LABEL **UPDATES**

Front Panel

Mint-A-Kleen®

Proven formula for waterline treatment.™

Dental Unit Waterline and Water Bottle Cleaner

ACTIVE INGREDIENTS

Chlorhexidine Gluconate 0.12%

OTHER INGREDIENTS 99.88%

TOTAL 100.00%

See carton insert for additional [Precautionary Statements], [First Aid], [Directions for Use], [and] [Storage and Disposal].

READY TO USE | DO NOT DILUTE

DO NOT **ATTACH PLACE MINT-A-KLEEN® BOTTLE DIRECTLY ON **TO** DENTAL UNIT.**

Net Contents: OZ (ML)

[4 FL OZ (118ML)]; [8 FL OZ (236 ML)]; [12 FL OZ (355 ML)]; [16 FL OZ (473 ML)];
[20 FL OZ (591 ML)]; [32 FL OZ (946 ML)]; [64 FL OZ (1.9 L)]; 1 GALLON (3.8 L)]

CAUTION
KEEP OUT OF REACH OF CHILDREN



Watch our online instructional video at www.MintAKleen.com

PATENT PENDING.

MADE IN USA

Questions? Please contact us directly:

Anodia Systems
109 Larrimore Lane
Danville, KY 40422
P: 866.246.2548
F: 866.926.8246
E: info@AnodiaSystems.com
www.AnodiaSystems.com

NOTIFICATION

85298-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/03/2018

BACK PANEL**DENTAL UNIT WATERLINE AND BOTTLE CLEANER**

For the cleaning and control of microbial contamination in dental unit waterlines and bottles. For use in any dental unit.

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Initial Cleaning

Week 1: Use every night.

Weeks 2-5: Use ~~bi-weekly~~ twice per week.

After week 5: Use once per week.

Routine Cleaning

Use once per week. For optimal results, use at the end of the last business day of the week.

Leave Mint-A-Kleen in dental unit waterlines and bottle over the weekend. Flush on Monday morning before dental procedures begin.

Directions for Waterline and Bottle Cleaning:**STEP 1: AIR PURGE DENTAL UNIT WATERLINES**

- Turn dental unit OFF. Empty water bottle. Now attach this empty water bottle to ~~place back on~~ dental unit.
- Turn dental unit ON.
- Air purge waterlines by activating handpiece hoses and air/water syringes until water is eliminated.

STEP 2: ADD MINT-A-KLEEN®

- Turn dental unit OFF. Remove water bottle, pour 4 ounces of Mint-A-Kleen® into dental unit's empty water bottle. Place sterile 2x2 gauze on dental water bottle's opening. Turn dental water bottle upside down 3 times with gauze in place. This allows Mint-A-Kleen® to coat this dental water bottle's interior walls. Using the same 2x2 gauze, wipe down the pick-up tube. ~~swish Mint-A-Kleen® in bottle and then place~~ Attach dental water bottle ~~on~~ to dental unit.
- Turn dental unit ON. Activate handpiece hoses and air/water syringes until Mint-A-Kleen® exits.
- Turn dental unit OFF. Allow Mint-A-Kleen® to treat waterlines and bottle for at least 12 hours before proceeding to Step 3.

STEP 3: FLUSH DENTAL UNIT WATERLINES

- ~~Dental Unit is OFF.~~ Remove water bottle, dispose of any excess Mint-A-Kleen®. Rinse dental water bottle with water. ~~and~~ Fill water bottle with water source.
- Turn dental unit ON. Flush waterlines with water for 30 seconds to remove any excess Mint-A-Kleen®.
- ~~Continue with~~ Begin dental procedures.

* Note: For optimal cleaning, air purge and clean all instruments and tubing that contain water using the aforementioned protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.

STORAGE AND DISPOSAL

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

Storage: store in a cool dark room away from heat or open flame.

Disposal: wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility

Container: non-refillable container. Do not reuse or refill container. Rinse with water and place in trash or offer for recycling if available.

EPA Reg. No. 85298-2 EPA Establishment No. 85298-KY-001

MASTER CARTON INSERT UPDATES

Mint-A-Kleen®

Proven formula for waterline treatment.™

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TOTAL 100.00%

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CAUTION

KEEP OUT OF REACH OF CHILDREN

READY TO USE | DO NOT DILUTE

DO NOT ATTACH PLACE MINT-A-KLEEN® BOTTLE DIRECTLY ON TO DENTAL UNIT.

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

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- Turn dental unit ON. Flush waterlines with water for 30 seconds to remove any excess Mint-A-Kleen®.
- ~~Continue with~~ **Begin** dental procedures.

* Note: For optimal cleaning, air purge and clean all instruments and tubing that contain water using the aforementioned protocol, including but not limited to: handpiece, air/water syringe, scaler, quick disconnect line.

STORAGE AND DISPOSAL

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Container: non-refillable container. Do not reuse or refill container. Rinse with water and place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS:

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if inhaled or swallowed. Avoid contact with eyes or clothing or breathing vapor. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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 for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

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

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

PHYSICAL OR CHEMICAL HAZARDS

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



Watch our online instructional video at www.MintAKleen.com

If you have any questions, please contact us directly.

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