



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 11, 2018

Michael Overmyer
Anodia Systems
109 Larrimore Lane
Danville, KY 40422

Subject: Label Amendment – Revised to Improve Directions for Use Language
Product Name: Mint-A-Kleen
EPA Registration Number: 85298-2
Application Date: 04/16/2018
Decision Number: 541425

Dear Mr. Overmyer:

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. 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 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.

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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 Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Sincerely,



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

Enclosure: Approved label

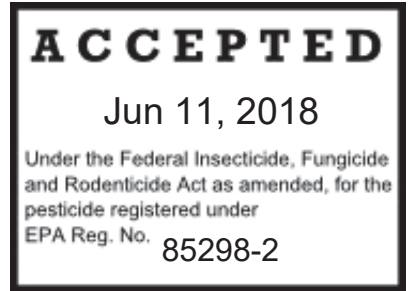
**MINT-A-KLEEN®
EPA FINAL MASTER LABEL**

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 MINT-A-KLEEN® BOTTLE DIRECTLY 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

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

*Note: Each week allow Mint-A-Kleen® to remain in the dental unit waterlines and bottle overnight and over the weekend.

Week 1: Use Mint-A-Kleen® at the end of every business day.

Weeks 2-5: Use Mint-A-Kleen® twice per week at the end of the business day.

After week 5: Use Mint-A-Kleen® once per week.

INITIAL CLEANING PURPOSE: Mint-A-Kleen® preps the dental unit waterlines by gradually penetrating the microbial contamination during this 5 week period. This timely initial cleaning prevents copious amounts of contamination from clogging the waterlines.

ROUTINE WEEKLY CLEANING

- Use Mint-A-Kleen® once per week.
- Use Mint-A-Kleen® at the end of the last business day of the week.
- Leave Mint-A-Kleen® in dental unit waterlines and bottle overnight and over the weekend.
- On Monday morning before dental procedures begin, Air Purge Waterlines again then Flush Waterlines with Water.

DIRECTIONS FOR WATERLINE AND BOTTLE CLEANING:

STEP 1:
AIR PURGE WATERLINES



STEP 2:
ADD MINT-A-KLEEN®



STEP 3:
AIR PURGE WATERLINES



STEP 4:
FLUSH WATERLINES
WITH WATER

STEP 1: AIR PURGE: REMOVE DENTAL UNIT WATER FROM DENTAL UNIT WATERLINES AND BOTTLE

- After the last patient leaves at the end of the business day, turn dental unit OFF.
- Empty water bottle. Now attach this empty water bottle to 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.
- Attach dental water bottle 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 the next step.

STEP 3: (REPEAT STEP 1: AIR PURGE DENTAL UNIT WATERLINES)

- Turn dental unit OFF. Remove water bottle, dispose of any excess Mint-A-Kleen®. Empty water bottle. Now attach this empty water bottle to dental unit.
- Turn dental unit ON.
- Air purge waterlines by activating handpiece hoses and air/water syringes until NO liquid comes out.

STEP 4: FLUSH DENTAL UNIT WATERLINES AND WATER BOTTLE

- Turn dental unit OFF. Remove water bottle from dental unit, dispose of any excess Mint-A-Kleen®.
- Rinse dental water bottle with water. Fill water bottle with water source.
- Turn dental unit ON. Flush waterlines with water for 30 seconds to remove any excess Mint-A-Kleen®.
- 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. Allow Mint-A-Kleen® to remain in the dental waterlines while the dental office is closed for the weekend, holiday break or vacation. Dental Schools that use Mint-A-Kleen® leave Mint-A-Kleen® in their dental waterlines for up to 3 months during their summer breaks.

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 FINAL CARTON INSERT

MINT-A-KLEEN®
PROVEN FORMULA FOR WATERLINE TREATMENT.™

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.

ACTIVE INGREDIENTS

Chlorhexidine Gluconate 0.12%

OTHER INGREDIENTS 99.88%

TOTAL 100.00%

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STEP 2:
ADD MINT-A-KLEEN*



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STORAGE AND DISPOSAL

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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.

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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