

85298-2

9/30/2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 85298-2

Date of Issuance: SEP 30 2010

Term of Issuance:

Conditional

Name of Pesticide Product:

Mint-A-Kleen

NOTICE OF PESTICIDE:

[X] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

David Swain
Anodia Systems
109 Larrimore Lane
Danville, KY 40422

Note: Changes in labeling, differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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 sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. 85298-2".

Signature of Approving Official:

[Handwritten signature of Marshall Swindell]

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

SEP 30 2010

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- b. To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided as a condition of registration within a year of registration or as soon as the study is completed.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 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. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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**MINT-A-KLEEN®
EPA LABEL REVIEW**

I. MANDATORY LABEL COPY

Front of Label:

Mint-A-Kleen®
Simple. Effective. Protective.

CE0245/2

ACTIVE INGREDIENTS	
Chlorhexidine Gluconate	0.12%
OTHER INGREDIENTS	99.88%
TOTAL	100.00%

ACCEPTED
with COMMENTS
in EPA Letter Dated:
SEP 30 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
85248-2

Dental Unit Waterline Cleaner
For the cleaning and control of microbial contamination in dental unit waterlines. For use in any dental unit.

Ready to Use. Do Not Dilute.

Net Contents: 16 fl. oz. (473 ML)

EPA Reg. No. XXX-XX
EPA Establishment No. XXX-XX

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See carton insert for additional precautionary and first aid statements.

Back of Label:

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
Week 2-5: Use bi-weekly

Routine Cleaning

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

Directions for Waterline and Bottle Cleaning:

STEP 1 – AIR PURGE DENTAL UNIT WATERLINES

- Turn dental unit OFF. Empty water bottle and 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, swish Mint-A-Kleen® in bottle and then place water bottle on 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

- Remove water bottle, dispose of any excess Mint-A-Kleen® 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 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.

If you have any questions please contact us directly.

Do not place Mint-A-Kleen® bottle directly on dental unit.

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.

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ACCEPTED
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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act a.
 amended, for the pesticide,
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CARTON INSERT:

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.

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