

85298-2

1/19/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

Anodia Systems  
109 Larrimore Lane  
Danville, KY  
40422

JAN 19 2011

Attention: David Swain

**Subject: Mint-A-Kleen ®**  
EPA Registration No: 85298-2  
Notification Dated December 15, 2010

This will acknowledge receipt of your Notification to update the container handling statement per PR Notice 2007-4 and make other minor changes to the product label, submitted under the provision of FIFRA Section 3(c)(9).

**Proposed Notification:**

Revise label per PR Notice 2007-4 and additional minor changes

**General Comments:**

Based on a review of the submitted material, the following comments apply:

The Notification dated December 15, 2010 is acceptable, to revise the minor label to add the following marketing verbiage, "**Proven formula for waterline treatment**" This information has been added to your file.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell  
Product Manger (33)  
Regulatory Management Branch I  
Antimicrobial's Division (7501P)

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Please read instructions on reverse before completing form.

Form Approved, No. 2070-0080, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 85298-2	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Mint-A-Kleen®	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Anodia Systems 109 Larrimore Lane Danville, KY 40422 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of addition of marketing verbiage through PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please contact David Swain at dswain@srconsultants.com or at 260-244-6273 (fax) with any questions.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 16 oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Swain	Title Agent for Anodia Systems	Telephone No. (Include Area Code) (260) 244-6270
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received  (Stamped)
Signature 	3. Title Agent for Anodia Systems	
4. Typed Name David Swain	5. Date December 15, 2010	



**MINT-A-KLEEN®  
EPA LABEL**

**I. MANDATORY LABEL COPY**

**Front of Label**

**Mint-A-Kleen®**

Proven formula for waterline treatment.

**Dental Unit Waterline 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.

Net Contents: 16 FL OZ (473 ML)

**CAUTION**

**KEEP OUT OF REACH OF CHILDREN**

**Back of Label**

**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**

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

**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](mailto:info@AnodiaSystems.com)  
[www.AnodiaSystems.com](http://www.AnodiaSystems.com)

**EPA Reg. No. 85298-2      EPA Establishment No. 5464-IL-001**

**CARTON INSERT**

**Mint-A-Kleen®**

Proven formula for waterline treatment.

**DENTAL UNIT WATERLINE CLEANER**

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

**ACTIVE INGREDIENTS**

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**TOTAL** 100.00%

Net Contents: 16 FL OZ (473 ML)

**CAUTION**

**KEEP OUT OF REACH OF CHILDREN**

**READY TO USE | DO NOT DILUTE**

**DO NOT PLACE MINT-A-KLEEN® BOTTLE DIRECTLY ON 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

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.

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\* 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.

**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.

If you have any questions, please contact us directly.

Anodia Systems

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