

85298-2

11/15/2012

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

NOV 15 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

David Swain
c/o Anodia Systems
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

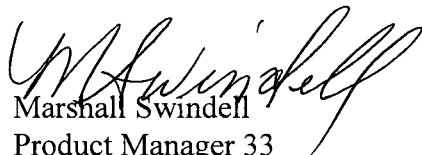
Subject: Mint-A-Kleen
EPA Registration Number 85298-2
Your Notification Dated October 19, 2012
EPA Received Date October 22, 2012

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add a marketing claims regarding the company website, revise the EPA Establishment Number, and remove the typographical error from the instructions, is acceptable.

The notification has been made part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	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 and reformat of label 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@srccconsultants.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
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				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
Certification 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 October 19, 2012	

Scientific & Regulatory Consultants, Inc.

October 19, 2012

Mr. Marshall Swindell, PM 33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

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SUBJECT: Mint-A-Kleen®

EPA Reg. No.: 85298-2

Dear Marshall,

On behalf of our client Anodia Systems (Anodia), enclosed is a submission for Mint-A-Kleen®, (EPA Reg. No. 85298-2). **This is a notification per PR Notice 98-10. Therefore no PRIA fee is required.**

The purpose of this notification is to reformat the label, add a marketing claim regarding the company website, revise the EPA Establishment number and remove a typographical error from the instructions. Anodia is revising their container label to include the Directions for Use and Storage and Disposal on the bottle. The carton insert remains consistent and there is a reference statement from the front panel of the container label to the carton insert. No verbiage has changed with the reformatting of these sections. All changes are marked by yellow highlight on the Master Label enclosed. Two (2) "clean" copies of the final printed label are also enclosed. This notification is consistent with 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 me at (260) 244-6270 or at dswain@srcconsultants.com if you have any questions about this notification.

Sincerely,



David Swain
Agent for Anodia Systems
cc: T. Overmyer

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**MINT-A-KLEEN®
EPA LABEL**

Front Panel

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].

READY TO USE | DO NOT DILUTE

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

Net Contents: 16 FL OZ (473 ML)

**CAUTION
KEEP OUT OF REACH OF CHILDREN**



NOTIFICATION
Date Reviewed: 11/15/13
Reviewed By: [Signature]

Watch our online instructional video at www.MintAKleen.com

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 CLEANER**

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

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.

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

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

Chlorhexidine Gluconate 0.12%

OTHER INGREDIENTS 99.88%

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 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.



Watch our online instructional video at www.MintAKleen.com

If you have any 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

{The following statements, within [] are optional and may appear anywhere on the label, insert, website or collateral literature}

[Mint blue solution is] [formulated without harsh chemicals] [and] [will not corrode, clog, or leave residue in waterlines, bottles or equipment]

[It's economical]

[It's effective and easy to use]

[There's no need for supplemental products; Mint-A-Kleen is ready to use with no mixing, no fuss and no mess.]

[It's proven]

[Mint-A-Kleen is backed by extensive research and is EPA-registered for use as a dental unit waterline cleaner]

[Mint-A-Kleen is a proven liquid formula and protocol that cleans and controls microbial contamination in dental unit waterlines.]

[Mint-A-Kleen uses an active ingredient of 0.12% Chlorhexidine Gluconate to directly contact waterline walls and bottles for thorough treatment, cleaning and protection of waterlines and equipment]

[Proven] [Effective] [Easy to Use] [Economical]

[Mint-A-Kleen is backed by extensive research and years of use in dental offices across the nation.]

[Mint-A-Kleen is a liquid solution designed to directly contact waterline walls and bottles—thoroughly treating, cleaning and protecting them from buildup of microbial contamination]

[Mint-A-Kleen helps dental practices protect waterlines with a convenient three-step, once-per-week process.]

[It does not require the use of multiple products such as powders, tablets, cartridges or filters.]

[Compatible with all dental unit water systems, it comes ready to use with no mixing or water treatment necessary. No fuss, no mess...one trusted product and protocol.]

[Mint-A-Kleen's formula is suitable for patients or staff, and meets EPA requirements for the least stringent toxicity category.]

[Its ingredients do not corrode, clog or leave residue in waterlines, bottles or equipment—meaning that dental offices avoid additional expenses from wear and tear.]

{The following statements, within [] are optional and may appear anywhere on the label, insert, website or collateral literature}

[Fast and ready to use]

[Mint-A-Kleen is the leading liquid cleaner for dental unit waterlines.]

[Compatible with all dental unit water systems, Mint-A-Kleen is proven liquid formula and protocol that cleans and controls microbial contamination in dental unit waterlines.]

[Proven CHG formula in use for over 2 decades]

[Fast and ready to use – no mixing or diluting.]

[Mint-A-Kleen is the leading liquid cleaner for dental unit waterlines.]