

85298-2

7/13/2011

1009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Anodia Systems
109 Larrimore Lane
Danville KY 40422

JUL 13 2011

Attention David Swain
Agent for Anodia Systems

Subject Mint A Kleen – Notification for additional optional marketing language
EPA Reg No 85298 2
Notification Application Dated June 21 2011

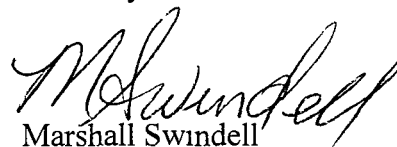
This will acknowledge receipt of your notification for the aforementioned product label submitted under the provisions of Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Section 3© (9) Based on a review of the submitted material the following apply

- The Agency accepts the notification The proposed optional marketing language on pages 4 and 5 is acceptable

Should you wish to retain a reference to the company s website on your label then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency If the website content is false or misleading the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E) 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 Although EPA has not yet determined the extent to which it will routinely review company websites if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process the website may be referred to the EPA s Office of Enforcement and Compliance Assurance

The Notification is in compliance with PR Notice 98 10 and is acceptable This information has been made a part of your file If you have any questions concerning this letter please contact Abigail Downs at (703) 305 5259

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510CP)



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"/> Non s <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 FIFRA Please contact David Swain at dswain@srcconsultants 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	If Yes Unit Packaging wgt No per container		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If Yes Package wgt	No per container		
3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4 Size(s) Retail Container 16		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 <input type="checkbox"/> Paper glued <input type="checkbox"/> 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 June 21 2011	



June 21 2011

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

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 add marketing verbiage located on last pages of enclosed Master Label A previous notification dated May 30 2011 was denied due to comparative claims and the use of the term gentle According to the EPA denial letter (attached) dated June 6 2011 the other new claims were acceptable This notification removes the disallowed claims and keeps the other acceptable claims from the May 30 2011 submission 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 FPA 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@srconsultants.com if you have any questions about this notification

Sincerely
[Signature]
David Swain
Agent for Anodia Systems

cc T Overmyer

**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
www.AnodiaSystems.com

EPA Reg No 85298 2 EPA Establishment No 5464 IL 001

6049

CARTON INSERT

Mint A Kleen^o

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^o 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^o

Turn dental unit OFF Remove water bottle pour 4 ounces of Mint A Kleen^o into dental unit's empty water bottle swish Mint A Kleen^o 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^o exits

Turn dental unit OFF Allow Mint A Kleen^o 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^o 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^o

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

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

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]

9089

{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]