UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



United States Environmental Protection Office of Pesticide Programs Agency

FEB - 6 2009

Georgia Anastasiou BASF Catalysts LLC 100 Campus Drive Florham Park, NJ 07932

FILE COPY

Subject:

Aseptrol Dental Water Treatment

EPA Registration Number: 70060-25 Application Dated: January 9, 2009 Receipt Date: January 9, 2009

Dear Ms. Anastasiou:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA Section 3(c) 9.

Proposed Notification

Add optional Marketing Language

General Comment

Based on a review of the material submitted, the following comment applies:

This notification is accepted and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

Wanda Henson

Product Reviewer (32)

Regulatory Management Branch II Antimicrobials Division (7510P)

Please read instructions on reverse befo	ore coi/ ting form.		Form Approv	OMB No. 2070-0	0060, Approval expires 05-31-98	
O EDA	United States		 ☐ Regist		OPP Identifier Number	
EPA Env	rironmental Protection	n Agency	☐ Amend			
	Washington, DC 2046	•	☐ /then:			
Application for Pesticide - Section I						
1. Company/Product Number	Application		oduct Manager		Proposed Classification	
70060-25		Emily M	•		3. Proposed Classification	
4. Company/Product (Name)	PM#			None Restricted		
Aseptrol Dental Water Treatments 5. Name and Address of Applicant (I.	32	dited Boylow Ir	a coordones w	th FIEDA Section 3(a)(3)		
BASF CATALYSTS LLC	6. Expedited Review . In accordance with FIFRA Section 3(c)(3) (b)(l), my product is similar or identical in composition and labeling					
100 CAMPUS DRIVE	to:					
FLORHAM PARK NJ 07932 PLEASE SEND ALL CORI	EPA Reg. No					
"CONTACT POINT" L	Product Name					
Check if this is a new as						
	,	Section	n - II			
Amendment – Explain below.			·—	hels in resnanse to	Agency letter dated	
Resubmission in response to A	Final printed labels in response to Agency letter dated					
Notification - Explain below.			Other - Explain	below	•	
	Explanation: Use additional page(s) if necessary. (For Section I and Section II.)					
NO	TIFICATION TO ADD	OPTION A	AL MARKETIN	G LANGUAGE		
			With PR Notice 98-10			
This notification is consistent with the provision formula of this product. I understand that it is a	violation of 18 U.S.C. Sec. 1001 to v	villfully make any	false statement to EPA.	further understand that	if this notification is not consistent with the	
terms of PR Notice 98-10 and 40 CFR 15	2,46, this product may be in violation	of FIFRA and I n	nay be subject to enforcen	tent action and penaltie:	s under sections 12 and 14 of FIFRA.	
		Section	n - III			
Material This Product Will Be Pa			Mater Caluble Dec	Janian T	2. Turn of Containing	
Child-Resistant Packaging Yes*	Unit Packaging Yes		Water Soluble Packaging Yes		Type of Container Metal	
□ No	│	No No		Plastic		
		No. per	If "Yes"	No. per	Glass	
*Certification must	Unit Packaging wgt.	container	Package wgt.	container	Paper	
be submitted	1 0:(-) 5				Other (Specifiy)	
3. Location of Net Contents Information 4. Size		etail Containe	r	5. Location of On Label	Label Directions	
				1 =	ng accompanying product	
6. Manner in Which Label is Affixed			Other			
	☐ Paper g ☐ Stencile					
		Section	ı - IV			
1. Contact Point (Complete items di	irectly below for identification	of individual to	o be contacted, if ne	cessary, to process	this application)	
Name Title Telephone No, (Include Area						
Georgia Anastasiou, Lewis & Harrison Agent for BASF Catalyst Code 202-393-3903 (ext. 19)						
	Certification			, , , ,		
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. 1 (Received acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both (Stamped)						
under applicable law.	22 3o.odding otdtornom ii	, 20 painoile	uy iiiio or iiripiio	. ccc	1 666 - 1	
2. Signature	3	. Title	and for DASE C	.4adaa4		
Leogia anavasion		Ag	gent for BASF Ca	italyst		
		·				
4. Typed Name		. Date	lanua 0, 200		(())	
Georgia Anastasiou			January 9, 200	•	(((

LEWIS & HARRISON

122.C Street, N.W., Suite 740 Washington, D.C. 20001

telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs

January 9, 2008

HAND DELIVERED

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202-4501

ATTENTION:

Emily Mitchell

Product Manager 32

SUBJECT:

Aseptrol Dental Water Treatment (EPA Reg. No. 70060-25)

BASF Catalysts, LLC

Notification per PR Notice 98

Dear Ms. Mitchell:

On behalf of BASF Catalysts LLC, I am submitting a notification for the product, Aseptrol Dental Water Treatment (EPA Reg. No. 70060-25). The purpose of this notification is to add the following optional market language:

"Cleans and Protects Dental Unit Waterlines"

Enclosed please find the following documents in support of this submission:

- 1. Application for Pesticide Notification, which includes a signed statement certifying compliance with PR Notice 98-10;
- 2. One (1) copy of the product label with changes highlighted; and,
- 3. Two (2) copies of the final printed label.

If you have any questions, or require any additional information, please feel free to contact me by phone at 202-393-3903 ext. 19 or by email at georgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

Agent for,

BASF Catalysts LLC

cc:

Bernie Franc (BASF)

Janet Cerra (BASF)

- All text in brackets [xxx] is optional and may or may not be included on a final label.
- All text in braces {xxx} is administrative and will not appear on a final label.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing before reuse.

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 eye. •Call a poison control center or doctor for treatment advice.		
If Swallowed:	 Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 		
	ct container or label with you when calling a enter or doctor, or going for treatment.		
NOTE TO PHYSICIAN			
Probable mucos	sal damage may contraindicate the use of		

ENVIRONMENTAL HAZARDS

This product is toxic to fish and other aquatic organisms.

PHYSICAL/CHEMICAL HAZARDS

Keep away from combustible, organic or other readily oxidizable materials. Do not mak with any other chemicals.

gastric lavage.

ASEPTROL® DENTAL WATER TREATMENT

For the Cleaning and Control of Microbial Contamination in Dental Unit Waterlines

[Cleans and Protects Dental Unit Waterlines]

Active Ingredients:

KEEP OUT OF REACH OF CHILDREN

DANGER

See [Side] {or} [Back] Panels for First Aid and Precautionary Statements

EPA Reg. No. 70060-25 EPA Est. No. Net Weight:

> Manufactured By: BASF CATALYSTS, LLC 100 Campus Dr. Florham Park, NJ 07932

> > Patent: 6,699,404

Sodium chlorite in this product is from Spain [contains]



[Aseptrol and the Aseptrol logo are trademarks of Engelhard Corporation]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INITIAL TREATMENT:

- 1. Add two (2) 1.7 gram Aseptrol® Dental Water Treatment tablets for every 750 ml of potable water. Allow the tablets to dissolve.
- 2. Flow about half of the treated water through the dental waterlines and let the treated water sit within the lines for 5 minutes. Purge the remaining water through the lines.
- 3. Repeat steps 1 and 2.
- 4. Flush at least 500 ml of potable water through the lines to remove any residual chemical.

ROUTINE TREATMENT:

- Every week or as needed*, add one (1) 1.7 gram
 Aseptrol® Dental Water Treatment tablet for every
 750 ml of potable water. Allow the tablet to
 dissolve.
- 2. Flow about half of the treated water through the dental waterlines and let the treated water sit within the lines for 5 minutes. Purge the remaining water through the lines.
- 3. Flush at least 500 ml of potable water through the lines to remove any residual chemical.

Note: Periodic cleaning may be done on any day of the week. *Treatment should be done if bacteria count is greater than 500 cfu/ml as recommended by the CDC.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. Store in a cool, dry area away from sunlight and heat and in an area inaccessible to children. Keep product from contacting air prior to use. Place empty foil pouch in trash.



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