

70060-25

04/22/2008

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



Office of Pesticide Programs

FILE COPY

April 22, 2008

Georgia Anastasiou
Lewis & Harrison
122 C Street, NW #740
Washington, DC 20001

Subject: **Aseptrol Dental Water Treatment**
EPA Registration Number: 70060-25
Application Dated: April 15, 2008
Receipt Date: April 16, 2008

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

- Correct typographical errors in the directions for use and revise company name and address

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,

A handwritten signature in black ink, appearing to read "Wanda G. Henson".

Wanda Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

2/4

 EPA 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 70060-25	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aseptrol Dental Water Treatment	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) BASF CATALYSTS LLC 100 CAMPUS DRIVE FLORHAM PARK NJ 07932 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(l), 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 TO CORRECT TYPOGRAPHICAL ERRORS IN THE DIRECTIONS FOR USE AND REVISE COMPANY NAME AND ADDRESS.
PLEASE SEE COVER LETTER FOR DETAILS

Notification in Accordance With PR Notice 98-10

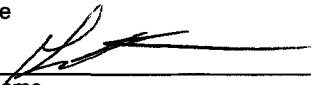
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false 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.

Signature:  Date: **4/15/08**

Section - III

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Georgia Anastasiou, Lewis & Harrison 122 C Street, NW, #740, Washington, DC 20001	Title Agent for BASF Catalyst	Telephone No. (include Area 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. 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)
2. Signature 	3. Title Agent for BASF Catalyst	
4. Typed Name Georgia Anastasiou	5. Date April 15, 2008	

LEWIS & HARRISON

Consultants in Government Affairs

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

telephone 202.393.3903
fax 202.393.3906

3/4

April 15, 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, we are submitting a notification for the product, **Aseptrol Dental Water Treatment (EPA Reg. No. 70060-25)**. The purpose of this notification is to correct typographical errors in the directions for use and revise the company name and address.

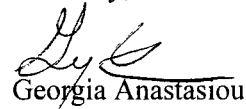
Please note in the amendment that was recently approved on February 20, 2008, we inadvertently submitted an incorrect label that contained five (5) steps for initial treatment. The 4th step which we are removing is a reiteration of the 5th step. We have revised the label to only include four (4) steps for initial treatment. In addition there were a few missing words in the directions which we have added.

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

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)
Barry Speronello (BASF)
Jim Chandler (Vista)

- 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:	<ul style="list-style-type: none"> •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:	<ul style="list-style-type: none"> •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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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 mix with any other chemicals.

**ASEPTROL®
DENTAL WATER TREATMENT**

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

Active Ingredients:
Sodium Chlorite 4.0%
Sodium Dichloroisocyanurate dihydrate ... 1.0%
Other Ingredients: 95.0%
Total: 100.0%

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. Rinse and refill the dental unit water bottle with potable water and flush at least 500 ml (1/2 liter) of water through the lines to remove any residual chemical.~~
- ~~5.4.~~ Flush at least 500 ml of potable water through the lines to remove any residual chemical.

ROUTINE TREATMENT:

1. 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.

h/h