

70060-25

11/6/2012

1/4



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

November 6, 2012

Georgia Anastasiou
Agent for BASF Corp.
Lewis & Harrison, LLC
122 C Street NW Ste. 505
Washington DC 20001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Aseptrol Dental Water Treatment
EPA Reg.#: 70060-25
Notification Date: October 19, 2012
Receipt Date: October 25, 2012

Dear Ms. Anastasiou:

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

Proposed Notification:

Revise Storage and Disposal Statement in compliance with PR Notice 2007-4 for Aseptrol Dental Water Treatment product (EPA Reg#70060-25). Initial submitted label dated 10/19/12 (pin punch 10/25/12) was revised and updated on 11/05/2012 (pin punch 11/05/12).

General Comment:

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

The submitted revised Storage and Disposal Statement is acceptable. This notification and a copy of this letter have been inserted in your file for future reference.

If you have any questions on this letter, please contact David Liem by email at liem.david@epa.gov or call at 703-305-1284.

Sincerely

A handwritten signature in black ink, appearing to read "Morisha Harris", with a large, stylized flourish underneath.

Morisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Please read instructions on reverse before completing form.

Form Approved, OMB 2070-0060, Approval expires 05-31-98



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment:
- Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70060-25	2. EPA Product Manager Monisha Harris	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 Corporation 100 Park Avenue Florham Park, NJ 07932 PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW <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

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application

Notification - Explain below. Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Notification to update storage and disposal.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§156.10, 156.140, 156.144, 156.146 and 156.156, 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.

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	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	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		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Other _____
 Paper glued
 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, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001	Title: Agent	Telephone No. (Include Area Code): 202-393-3903 x19
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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.

2. Signature <i>Georgia Anastasiou</i>	3. Title Agent for BASF Corporation	6. Date Application Received (Stamped)
4. Typed Name Georgia Anastasiou	5. Date October 19, 2012	

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 505
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

October 19, 2012

HAND DELIVERED

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S4900
2777 S. Crystal Drive
Arlington, VA 22202

**ATTENTION: Monisha Harris
Product Manager (32)**

**SUBJECT: BASF Corporation
Aseptrol Dental Water Treatment (EPA Reg. No. 70060-25)
Notification**

Dear Ms. Harris:


On behalf of BASF Corporation, I am submitting a notification for the product **Aseptrol Dental Water Treatment (EPA Reg. No. 70060-25)**. The purpose of this submission is to update the storage and disposal section in accordance with PR Notice 2007-4.

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

1. Application for Pesticide which includes a sign certification statements in accordance with PR Notice 2007-4;
2. One (1) copy of the revised label with changes highlighted; and,
3. Two (2) copies of the revised label.

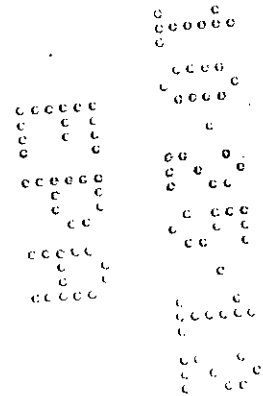
If you have any questions, or require any additional information, please feel free to contact me by phone at 202-393-3903 ext. 19, by fax at 202-393-3906, or by email at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for BASF Corporation

cc: Marie Paquette (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, using tobacco, or using the toilet. 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.

NOTIFICATION
Date Reviewed: 11-12-12
Reviewed By: *[Signature]*

**ASEPTROL®
DENTAL WATER TREATMENT**

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

**[Cleans and Protects 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

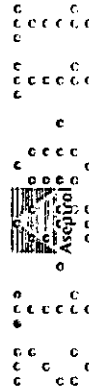
EPA Est. No.

Net Weight:

Manufactured By:
BASF Corporation
100 Park Avenue
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 BASF]

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:

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 or disposal.
PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat. Keep product from contacting air prior to use to avoid deterioration.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL: Non-refillable [container] [pouch] [blister pack] [packet]. Do not reuse or refill this [container] [pouch] [blister pack] [packet]. Offer for recycling, if available. If recycling is not available, dispose [empty pouch] [blister pack] [container] in sanitary landfill or by incineration if burned stay out of smoke.