

10060-22

11/14/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

November 14, 2012

Georgia Anastasiou
Lewis & Harrison, LLC
Agent for BASF Corporation
122 C Street, N.W. Suite 505
Washington, D.C. 20001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Aseptrol SE Water Purifier Tablets
EPA Registration No.: 70060-22
Notification Date: October 16, 2012
EPA Receipt Date: October 16, 2012

Dear Ms. Anastasiou,

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

Proposed Notification

- Label revisions per PR Notice: 2007-4
- Correct a typographical error.

General Comments

Based on a review of the submitted materials, to update the storage and disposal per PR Notice 2007-4 and to correct a typographical error are **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Monisha Harris

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

CONCURRENCES

SYMBOL	7510P	7510P						
SURNAME	Reed	M. Harris						
DATE	11/14/12	11/14/12						

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EPA

United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment:
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 70060-22	2. EPA Product Manager Monisha Harris	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aseptrol SE Water Purifier Tablets	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) BASF Corporation 100 Park Avenue 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)(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 and correct typographical error.
 Notification of label change per PR Notice 2007-4 and 98-10. This notification is consistent with the guidance in PR Notice 2007-4 and 98-10 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:				2. Type of Container	
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		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* 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 <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"/> 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: Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001	Title: Agent	Telephone No. (include Area Code): 202-393-2903 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 16, 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 16, 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 SE Water Purifier Tablets (EPA Reg. No. 70060-22)
Notification**

Dear Ms. Harris:

On behalf of BASF Corporation, I am submitting a notification for the product **Aseptrol SE Water Purifier Tablets (EPA Reg. No. 70060-22)**. The purpose of this submission is to revise the storage and disposal section in accordance with PR Notice 2007-4 and fix a typographical error for the dilution rate in the directions for use for large quantities of contaminated water. In the past we inadvertently submitted labels that listed the old rate at 55 or 500 gallons. The correct rate should be at 49.5 to 495 gallons which had been previously approved on November 18, 2005 (copy of submission enclosed).

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

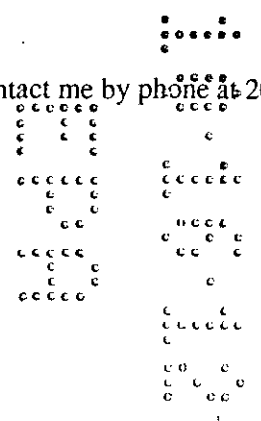
1. Application for Pesticide which includes a sign certification statements in accordance with PR Notices 2007-4 and 98-10;
2. One (1) copy of the revised label with changes highlighted;
3. Two (2) copies of the revised label; and,
4. EPA notification approval dated November 18, 2005.

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)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals
DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through skin or swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and other aquatic organisms.

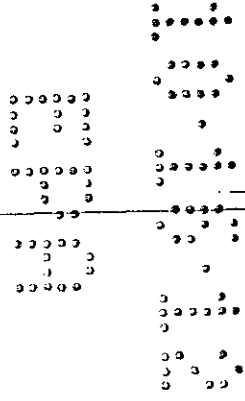
PHYSICAL/CHEMICAL HAZARDS

Keep away from combustible, organic or other readily oxidizable materials.

[contains]



[Aseptrol and the Aseptrol logo are trademarks of BASF]



ASEPTROL-SE WATER PURIFIER TABLETS

Emergency Drinking Water Tablets

[Each tablet treats 1 liter of water]

Note: This product requires a 4-hour treatment time for effectiveness

<u>Active Ingredients</u>	
Sodium Chlorite	6.4%
Sodium Dichloroisocyanurate dihydrate ...	1.0%
<u>Other Ingredients</u>	<u>92.6%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 70060-22

EPA Est. No.

Net Weight:

Manufactured By:
BASF Corporation
100 Campus Drive
Florham Park, NJ 07932

[Protected Under] Patent: 6,699,404

Sodium chlorite in this product is from Spain



[MICROPUR® PURIFICATION]

General Information

Aseptrol-SE Water Purifier Tablets are only for emergency disinfection of drinking water. When used as directed, the tablets make contaminated water suitable for drinking.

Aseptrol-SE Water Purifier Tablets are for use by campers, hikers, militaries, emergency organizations, and anyone needing to drink water of questionable microbiological quality.

[When added to water, Aseptrol-SE Water Purifier Tablets releases chlorine dioxide which is effective against bacteria, viruses and cysts, such as Cryptosporidium and Giardia.

When Aseptrol-SE Water Purifier Tablets are effective against bacteria, viruses and [cysts] {or} [Cryptosporidium and Giardia] there is no need to use a water filter.

{Optional Marketing Language:}

- Improves the taste and odor of [treated] water.
- No aftertaste.
- Uniform tablet dosage.
- Easy to Use [tablets].
- Designed for camper and military use.
- Kills at least 99.99% of bacteria (Klebsiella terrigena) and viruses (Poliovirus and Rotavirus) and 99.9% of cysts (*Giardia muris* and *Cryptosporidium parvum*) within 4 hours.
- Meets EPA microbiological water purifier test standards.
- Drinking Water Purification Tablets for Camping, Backpacking, Hiking, [International] Travel, Fishing, Hunting, Emergency Situations [Emergencies].
- Treats up to [20] [30] Quarts.
- Each Tablet Treats One Quart (One Liter) of Water.

NOTIFICATION

Date Reviewed: 11-14-12
Reviewed By: LIZAVIA

Ultralight Series

- 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.
- EPA Notification 10-16-2012

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Read entire label before applying product and use strictly in accordance with directions and hazard warnings.]

For the Control of Bacteria, Viruses and Cysts

Use Aseptrol-SE Water Purifier Tablets to kill bacteria, viruses and cysts (*Cryptosporidium parvum* and *Giardia muris*) in contaminated water. TO USE: Remove the [250 mg (400 mg)] [Aseptrol-SE Water Purifier Tablet] [tablet] from its foil packaging [with knife or scissors] and quickly insert [the tablet] into [625 ml (1000 ml or 1 liter) or 21 fl. oz. (34 fl. oz.)] {or} [1 quart (1 liter)] of contaminated water. Allow to react for 4 hours, in an opaque container or in the dark, [in order] to generate a use-solution of 4 ppm chlorine dioxide. The treated water is now ready for drinking.

TO USE IN LARGE QUANTITIES OF CONTAMINATED

WATER: Remove [fifteen (15), 5 gram tablets] {or} [one hundred and fifty (150), 5 gram tablets] from there foil packaging and quickly insert them into [49.5 gallons] {or} [495 gallons] of contaminated water. Allow to react for 4 hours, in an area away from sunlight, [in order] to generate a use-solution of 4 ppm chlorine dioxide. The treated water is now ready for drinking.

[Note: Tablets are in childproof package. Please use knife or scissors to open.]

{ Note to Reviewer: For non-refillable containers that only list household/residential uses: }

Storage and Disposal

Store in a cool, dry area away from sunlight and heat and in an area inaccessible to children. Non-refillable [container] [pouch] [blister pack] [packet]. Do not reuse or refill this [container] [pouch] [blister pack] [packet]. Wrap [empty pouch] [blister pack] [container] and put in trash or offer for recycling if available.



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. • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
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.	

{ Note to Reviewer: For non-refillable containers other than household/residential }

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal. PESTICIDE STORAGE: Store in a cool, dry area away from sunlight and heat and in an area inaccessible to children.

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 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.