

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

70060-22

11/18/2005

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November 18, 2005

Christina M. Swick
 Agent for Engelhard Corporation
 c/o Lewis & Harrison
 122 C St., NW Suite 740
 Washington, DC 20001

Subject: Aseptrol SE Water Purifier Tablets
 EPA Registration No. 70060-22
 Application Date: October 20, 2005
 Receipt Date: October 21, 2005

Dear Ms. Swick:

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

Proposed Notification

- Changes to Directions for Use statement

General Comments

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

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6345.

Sincerely,

Wanda Y. Henson
 Product Reviewer (32)
 Regulatory Management Branch II
 Antimicrobials Division (7510C)

CONCURRENCES

YMBOL	7510C						
JRNAME	E. Ber...						
ATE	11/18/05						

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060, Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other: NOTIFICATION

OPP Identifier Number
265394

Application for Pesticide - Section I

1. Company/Product Number 70060-22	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aseptrol SE Water Purifier Tablets	PM# Team 32	
5. Name and Address of Applicant (Include ZIP Code) Engelhard Corporation 101 Wood Ave. Iselin, NJ 08830 <u>PLEASE SEND ALL CORRESPONDENCE TO "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.)

ADD USE DIRECTIONS FOR LARGER TABLETS

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: Christina M. Swick Date: 10/20/05

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	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
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 <u>Christina M. Swick, Lewis & Harrison,</u> <u>122 C St. NW, #740, Washington DC 20001</u>	Title <u>Agent for Engelhard Corporation</u>	Telephone No. (Include Area Code) <u>(202) 393-3903 x16</u>
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 <u>Christina M. Swick</u>	3. Title <u>Agent for Engelhard Corporation</u>	
4. Typed Name <u>Christina M. Swick</u>	5. Date <u>October 20, 2005</u>	

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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

October 20, 2005

HAND DELIVERED

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

**ATTENTION: Wanda Y. Henson
Product Reviewer (32)**

**SUBJECT: Aseptrol SE Water Purifier Tablets (EPA Reg. No. 70060-22)
Engelhard Corporation
Response to Letter dated October 12, 2005**

Dear Mrs. Henson:

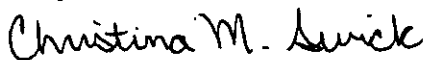
As agent for Engelhard Corporation, I am responding to your letter dated October 12, 2005 (attached) by submitting a product label that has been revised to make the dilution ratio identical for the new and existing Directions For Use.

Enclosed, please find the following documents in support of this Notification:

1. Application for Pesticide Notification (OPP ID No. 265394), 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.

Insofar as Lewis & Harrison, LLC is acting as both the "Company Official" and "Company Contact," please direct all correspondence directly to us. Furthermore, if you have any questions, or require any additional information, please feel free to contact me by phone at 202-393-3903 ext. 16 or by email at cswick@lewisharrison.com.

Sincerely,



Christina M. Swick
Agent for,
Engelhard Corporation

Cc: Mike Cochran (Engelhard Corporation)

- 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 and skin burns. Harmful if absorbed through skin or swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggle, 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 Engelhard Corporation]

**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

Active Ingredients

Sodium Chlorite	6.4%
Sodium Dichloroisocyanurate dihydrate ...	1.0%
<u>Other Ingredients</u>	<u>92.6%</u>
	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. 70060-

Net Weight:

Manufactured By:
Engelhard Corporation
Iselin, NJ 08830

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. Effective against bacteria, viruses and cysts, such as *Cryptosporidium* and *Giardia*.

Since 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.

- Improves the taste and odor of treated water.
- 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.

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- 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.

Directions for Use

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

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 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 area away from sunlight, [in order] to generate a use-solution of 4 ppm chlorine dioxide. The treated water is now ready for drinking.

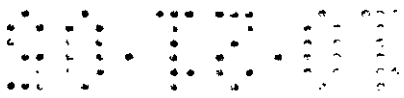
TO USE IN LARGE QUANTITIES OF CONTAMINATED WATER: Remove [fifteen (15), 5 gram tablets] {or} [one hundred and fifty (150), 5 gram tablets] from their foil packaging and quickly insert them into [49.5 gallons] {or} [495 gallons] of contaminated water. Allow to react for 4 hours, in an area away from sunlight, [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.]



Storage and Disposal

Store in a cool, dry area away from sunlight and heat and in an area inaccessible to children. Place empty foil pouch in trash.



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.
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.	

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