70060 - 22

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

page 13

March 7, 2006

Georgia Anastasiou 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: February 3, 2006 Receipt Date: February 7, 2006

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

addition and clarification of mixing directions in Directions For Use

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 (I Antimicrobials Division (7510C)

	CONCURRENCES	
SYMBOL 7510C 7510C		
BURNAME E. Beig Henson		
DATE 3/7/06 3/7/06		
EPA Comp. 1220 14 (1/00)	Briston Complet Brown	OFFICIAL FILE COPY

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Please read instructions on reverse before	completing form.		Form Appro	oved, OMB No. 2070-	0060, Approval e	xpires 05-31-98		
O EDA	United States		☐ Registration		OPP Identifier Number			
EPA Enviro	-l		_	ndment	265394			
	Washington, DC 20		_	r: NOTIFICATIO	i i			
Application for Pesticide - Section I								
1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification								
70060-22			ily Mitchell		J. Floposed	Classification		
Company/Product (Name)		PM#			None	Restricted		
Aseptrol SE Water Purifier Table		Team 32		<u> </u>				
5. Name and Address of Applicant (Inclu Engelhard Corporation	ide ZIP Code)			In accordance w				
101 Wood Ave.		(b)(I), my product is similar or identical in composition and label to:			and labeling			
Iselin, NJ 08830		EPA Reg. No.						
PLEASE SEND ALL CORRES	SPONDENCE TO	_						
<u>"CONTACT POINT" LIS</u>	TED BELOW	Product I	Product Name					
Check if this is a new addre	ess							
		Section	- 11					
Amendment – Explain below.			Final printed	labels in response to	Agency letter dat	ted		
Resubmission in response to Agen	ncy letter dated		"Me Too" App	olication				
Notification - Explain below.			Other - Expla					
Explanation: Use additional pa	ige(s) if necessary.	(For Section	l and Section	i II.)				
				·	<u> </u>			
Revise	Directions For l	Jse in Accor	dance with	PR Notice 98-1	0	1		
		N						
						 4		
This notification is consistent with the provision			ith PR Notice 98-		have been made to	n the laheling or		
the confidential statement of formula of this p	roduct. I understand that	it is a violation of	18 U.S.C. Sec. 100	01 to willfully make any	false statement to	EPA. I further		
understand that if this notification is not const subject to enforcement action and penalties u			! 40 CFR 152.46, ti	his product may be in vi	olation of FIFRA a	ınd I may be		
2 / _			3 ~~					
Signature:			3-06					
V		Section	- 111					
Material This Product Will Be Packa Child-Resistant Packaging	ged In: Unit Packaging		Water Soluble F	Packaging	2. Type of Cont	tainer		
Yes*	Yes		Yes	ackaging	Metal	261		
No No	☐ No	·	□ No		Plastic			
∵	If "Yes"	No. per	if "Yes"	No. per	Glass			
*Certification must	Unit Packaging wgt.	container	Package wgt.	container	Paper	i		
be submitted					Other (Spe	cifiy)		
3. Location of Net Contents Information		Retail Container			Label Directions			
Label Container				On Label				
6. Manner in Which Label is Affixed to	Product Lithog	ranh	☐ Other	On labelin	g accompanying	product		
O. Mainter in vehicit Laber is Anixed to		glued						
	☐ Stenc	_		···				
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, Title Telephone No. (Include Area Code)								
122 C St. NW, #740, Washington DC 20001 Agent for Engelhard Corporation (202) 393-3903					3903 x19 , , ,			
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. Eate Application Received Received (Stamped)								
2. Signature	i	3. Title		4 :) 1 o 1 s "		
4. Typed Name		Agent for Engelhard Corporation 5: Date		ration				
Georgia Anastasion		5: Date February 3, 2	006					

:

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

February 3, 2006

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:

Emily Mitchell

Product Manager 32

SUBJECT:

Aseptrol SE Water Purifier Tablets (EPA Reg. No. 70060-22)

Engelhard Corporation

Notification per PR Notice 98-10, II.M.1

Dear Ms. Mitchell:

As agent for Engelhard Corporation, I am submitting a Notification pursuant to PR Notice 98-10 for their product, Aseptrol SE Water Purifier Tablets (EPA Reg. No. 70060-22). The purpose of this notification is to revise the mixing directions in accordance with the request of the California Department of Pesticide Regulation. The directions have been revised so that the mixed solution is now placed in an opaque container or in the dark for the four-hour reaction time.

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. 19 or by email at geoorgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

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 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

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

[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. 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.

{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, Hiking, International Travel, Emergency Situations.
- Treats up to [20] [30] Quarts.
- Each Tablet Treats One Quart (One Liter) of Water.

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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. [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.)] [1 quart (1 liter)] of contaminated water. Allow to react for 4 hours—in—an area away from—sunlight,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 [55 gallons] {or} [500 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
•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.
 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.

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.