May 26, 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: April 26, 2006

Receipt Date: May 8, 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 of optional marketing language .

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)

YMBOL 17510 C 75/UP	
11/2/0	
URNAMEN Z BORG HANSON	
ATE 5-26-06 5-26-06	

EPA Form 1320-1A (1/90)

Printed on Recorded Page

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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

April 26, 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

Response to Letter Dated April 6, 2006 -Notification per PR Notice 98-10

Dear Ms. Mitchell:

In response to your denial letter dated April 6. 2006 (attached), for the notification of optional marketing language for the product, Aseptrol SE Water Purifier Tablets (EPA Reg. No. 70060-22) we are proposing the following optional highlighted marketing language on the label:

"[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"

Please note as stated in the attached letter we have specified that the chlorine dioxide is introduced when the tablet is in water. In addition we are also proposing other marketing language, which are highlighted in the enclosed label.

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 georgia@lewisharrison.com.

Sincerely.

Georgia Anastasiou

Agent for,

Engelhard Corporation

Please read instructions on reverse before completing form	Form Approved, OMB No 201	70-0060, Approval expires 05-31-98 🗗		
United State	Registration	OPP Identifier Number		
EPA Environmental Protect	ction Agency	265394		
Washington, DC		ſ		
Application for Pesticide - Section I				
Company/Product Number	2 EPA Product Manager	Proposed Classification		
70060-22	Emily Mitchell	o. Troposca Glassification		
Company/Product (Name)	PM#	None Restricted		
Aseptrol SE Water Purifier Tablets	Team 32			
5. Name and Address of Applicant (Include ZIP Code) Engelhard Corporation	6. Expedited Review. In accordance			
Ingelhard Corporation (b)(l), my product is similar or identical in composition and la to:		and labeling		
Iselin, NJ 08830	EPA Reg. No.			
PLEASE SEND ALL CORRESPONDENCE TO				
"CONTACT POINT" LISTED BELOW	Product Name			
Check if this is a new address				
	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 necessar	y. (For Section I and Section II.)			
ADD OPTIONA	L MARKETING LANGUA	GE		
Please reference cover letter				
Notification	on 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 change			
the confidential statement of formula of this product. I understand the understand that if this notification is not consistent with the terms of a				
subject to enforcement action and penalties under sections 12 and 14		violation of FTF KA una 1 may be		
S	Date			
Signature /	Section - III	<u> </u>		
Material This Product Will Be Packaged In	Section - III	<u> </u>		
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging	2. Type of Container		
Yes Yes	Yes	Metal		
□ No	No	Plastic		
If "Yes"	No per If "Yes" No per	Glass		
*Certification must Unit Packaging wgt	container Package wgt container	Paper		
be submitted		Other (Specifiy)		
	·	of Label Directions		
Label Container	On Lab			
6 Manner in Which Label is Affixed to Product Lithe	ograph Other	aling accompanying product		
	ographier glued			
	nciled			
	Section - IV			
Contact Point (Complete items directly below for identification)	tion of individual to be contacted, if necessary, to proce			
Name Georgia Amastasiou, Demis & Franciscu,	Title	Telephone No (Include Area Code)		
122 C Sa ((() /	Agent for Engelhard Corporation	(202) 393-3903 x19		
Certifica I certify that the statements I have made on this form and all acknowledge that any knowingly false or misleading statemen under applicable law.	attachments thereto are true, accurate and complete.	6. Date Application Received (Stamped)		
2, Signature	3. Title			
A Total Name	Agent for Engelhard Corporation	_		
4: Typed Name Georgía Anastasiou	5. Date April 26, 2006	}		
Georgia Allastasiou	/tpi ii 20, 2000			

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.

[centains]



[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

KATADYN'

[MICROPUR® PURIFICATION]

General Lusormation

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.
- 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

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 [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		
If In Eyes:	 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:	 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:	 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. 	
	act container or label with you when calling a center or doctor, or going for treatment.	
	NOTE TO PHYSICIAN	
Probable mucos lavage.	sal damage may contraindicate the use of gastric	

