70060-22

5-15-2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

May 15, 2003

Ms. Christina M. Swick Lewis & Harrison 122 C Street, NW Suite 740 Washington, DC 20001

Subject: Engelhard Inc. Aseptrol SE Water Purifier Tablets EPA Registration Number 70060-22 Application Date: March 4, 2003 Receipt Date: March 3, 2003

Dear Ms. Swick:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Conditions

- 1. The signal word should appear more prominent on the label. Please increase the size.
- 2. Revise the Ingredient statement as follows:

Active Ingredients	
Sodium Chlorite	!%
Sodium Dichloroisocyanurate dihydrate 1.0	
Other Ingredients	
100.0	

3. The complete nomenclature for the terms Crypto and Giardia must appear on the label. The abbreviate form is not acceptable and has been crossed out on the stamped label.

SYMBOL	1510C								
SURNAM									
DATE	NEC3								



General Comments

A stamped copy of the accepted labeling is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,

Robert S. Brennis Product Manager - Team 32 Regulatory Management Branch II Antimicrobials Division (7510C)

• 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 al 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.

ACCEPTED with COMMENTS - EPA Letter Dated:

MAY 1 5 2003

Under the Paderal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70060-22

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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 Chlorite6.4%Sodium Dichloroisocyanurate dihydrate1.0%Inert Ingredients92.6%

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

Sodium chlorite in this product is from Spain

[MICROPUR[®] PURIFICATION]

KATADYN'

General Information

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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} [*Crypto* 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.

- 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 al 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*)] {or} [(*Crypto* and *Giardia*)] 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.

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.

[contains]



[Aseptrol and the Aseptrol logo are trademarks of Engelhard Corporation]

FIRST AID If In Eves: •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 •Take off contaminated clothing. or 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. ACCEPTED with COMMENTS - EPA Letter Dated: MAY 1 5 2003

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 70060-22