

70060-19

07/08/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

July 8, 2002

Christina M. Swick
Agent for Engelhard Corp
Engelhard Corporation
101 Wood Ave
Iselin, NJ 08830

Subject : Aseptrol S10-Tab
EPA Registration No. 70060-19
Notification Per Notice 98-10

Dear Ms. Swick :

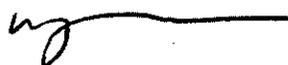
This will acknowledge receipt of your notification the label change (Revision of Aseptrol Logo and Aseptrol trademark statements), submitted under the provision of FIFRA Section 3(c) 9. Based on review of the submitted material the following comments apply.

The statement :

Contains Aseptrol. Aseptrol and the Aseptrol logo are trademarks of Engelhard Corp.

The label changes are acceptable and have been made a part of the file for this product.

Sincerely,



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

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Mitchell						
DATE	07-08-02						



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 70060-19	2. EPA Product Manager Robert Brennis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aseptrol S10-Tab	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</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

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

REVISION OF THE ASEPTROL LOGO AND TEXT

Notification of REVISION OF ASEPTROL LOGO AND TEXT 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: 7/2/02

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 If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Package wgt. container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
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"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Christina M. Swick, Lewis & Harrison, 122 C St. NW, #740, Washington DC 20001	Title Agent for Engelhard Corp.	Telephone No. (Include Area Code) (202) 393-3903
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 Agent for Engelhard Corp.	
4. Typed Name Christina M. Swick	5. Date July 2, 2002	

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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 a 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 a 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.

Have the product container or label with you when calling poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through skin. Harmful if 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 and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms.

(If container size is greater than 50 lbs add the following statement:)

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Aseptrol S10-Tab

Virucidal / Tuberculocidal / Oxidizing Tablets

For Use in Ion Exchange Resin Beds, Laboratory Animal Facilities, Veterinary Hospitals and Clinics, and other Animal Rearing and Confinement Facilities

Active Ingredients

Sodium Chlorite.....	20.8%
Sodium Dichloroisocyanurate dihydrate.....	7.0%
Inert Ingredients.....	72.2%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for first aid and precautionary statements.

EPA Reg. No. 70060-19

EPA Est. No. 70060-

Net Weight:

(Expiration Date:)

Manufactured by:
Engelhard Corporation
Iselin, NJ 08830

[contains]



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

[Sodium Chlorite in this product is from Spain]

Aseptrol S10-Tab, when activated in water, produces a solution of chlorine dioxide (ClO₂) that is effective against: Canine Parvovirus, Hantavirus, Minute Virus of Mice (MVM), Mouse Hepatitis Virus (MHV), Mouse Parvovirus type 1 (MPV-1), Murine Parainfluenza virus type 1 (Sendai), Sialodacryoadenitis virus (SDAV) at 100 ppm. At 200 ppm, **Aseptrol S10-Tab** solution is tuberculocidal, and virucidal against HIV-1 (the virus that causes AIDS).

Aseptrol S10-Tabs have been designed for use in Laboratory Animal Facilities, Veterinary Clinics and Hospitals, Animal Rearing and Confinement Facilities, Research Facilities and Laboratories, and other institutional/industrial applications.

DIRECTIONS FOR USE

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

PREPARATION OF SOLUTION:

100 ppm Chlorine Dioxide (for treatment against animal viruses).

In a clean plastic pail, place either one (1) 6.0 gram **Aseptrol S10-Tab** or four (4) 1.5 gram **Aseptrol S10-Tab** for every gallon of clean potable water. Or, in a plastic spray bottle, place one (1) 1.5 gram **Aseptrol S10-Tab** for every quart (or liter) of clean, potable water. Prepare in a well ventilated area. Once dissolved, this will yield a working solution of 100 ppm of free chlorine dioxide. Once mixed, this solution should be used within 7 days.

200 ppm Chlorine Dioxide (for treatment against tuberculosis bacteria and HIV).

In a clean plastic pail, place two (2) 6.0 gram **Aseptrol S10-Tab** or eight (8) 1.5 gram **Aseptrol S10-Tab** for every gallon of clean potable water. Or, in a plastic spray bottle, place one (1) 1.5 gram **Aseptrol S10-Tab** for every pint (or 500 ml) of clean, potable water. Prepare in a well ventilated area. Once dissolved, this will yield a working solution containing 200 ppm of free chlorine dioxide. Prepare fresh solutions daily.

VETERINARY USE: For use on the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables and catteries. Remove all animals and feed from premises, animal transportation vehicles, enclosures, coops, crates, etc. Remove all bedding, litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with prepared solution and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse.

AS A TUBERCULOCIDE AGAINST TUBERCULOSIS BACTERIA AND VIRUCIDE AGAINST HIV: Apply the 200 ppm use-solution to hard nonporous surfaces such as floors, walls, counters, stainless steel environmental surfaces, bio-safety hoods, sinks, tiles, etc., with cloth, sponge, mop or mechanical sprayer. If mechanical sprayer is used, spray must be coarse. Hold container 6 inches to 8 inches from surface and spray until totally wet. Treated surface must remain wet for 5 minutes before wiping. For heavily soiled areas, a pre-cleaning step is required. The pre-clean step should be done according to the instructions under **VETERINARY USE**. Rinse with potable water after use on surfaces that come in contact with food.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS that involve healthcare settings, or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects soiled with blood or body fluids can be associated with the transmission of HIV-1. **Aseptrol S10-Tab** destroys HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood or other body fluids at 200 ppm and 1 minute contact. **PERSONAL PROTECTION:** The worker should wear disposable latex gloves, gown, mask and eye protection to prevent contamination from soiled items.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of **Aseptrol S10-Tab** solution.

CONTACT TIME: Allow **Aseptrol S10-Tab** solution to contact treated items for 1 minute. This contact time will not control other common types of viruses and bacteria.

DISPOSAL OF INFECTIOUS MATERIALS: Any blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

For Use in Controlling Odor-Causing Microorganisms In Residential and Industrial Ion Exchange Resins Beds During Regeneration

Use Instructions:

1. Close inlet and outlet water valves to prefilter housing or tablet doser housing.
2. Remove bowl from either the prefilter housing or the tablet doser housing.
3. Empty water from bowl.
4. For each cubic foot of Ion Exchange Resin, add 6 grams (0.21 oz.) of **Aseptrol S10-Tab** to the bowl.
5. Replace bowl on housing and open water valves.
6. Proceed with normal regeneration cycle.

Or

1. Remove the cover from the brine tank.
2. For each cubic foot of Ion Exchange Resin, add 6 grams (0.21 oz.) of **Aseptrol S10-Tab** to the brine well of the brine tank.
3. Do not place **Aseptrol S10-Tab** onto dry salt – **MUST BE PLACED IN LIQUID ONLY.**
4. Cover brine tank and proceed with normal regeneration cycle.

(If container size is 5 lbs or less, add the following statement:)

STORAGE AND DISPOSAL

Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration and in an area inaccessible to children. Place empty pouch or blister pack and container in plastic bag and discard in trash.

(If container size is greater than 5 lbs add the following statement:)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration 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: Place empty pouch or blister pack and container in plastic bag and discard in trash.

Notice: Seller expressly warrants that the product conforms to its chemical description. There are no warranties associated with the sale of this product, either expressed or implied, including but not limited to the warranties of fitness for a particular purpose.