

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

70060-19

9/2/2005

page 186

September 2, 2005

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

Subject: Aseptrol S10-Tab  
 EPA Registration No. 70060-19  
 Application Date: August 5, 2005  
 Receipt Date: August 9, 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**

- Addition of Patent Number to label

**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**

SYMBOL	7510C	7510C						
SURNAME	E. B. Henson	Henson						
DATE	9/2/05	9-2-05						



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 <b>70060-19</b>	2. EPA Product Manager <b>Emily Mitchell</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Aseptrol S10-Tab</b>	PM# <b>Team 32</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Engelhard Corporation 101 Wood Ave. Iselin, NJ 08830</b> <b><u>PLEASE SEND ALL CORRESPONDENCE TO</u></b> <b><u>"CONTACT POINT" LISTED BELOW</u></b> <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> 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.)

**ADDITION OF PATENT NUMBER**

**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: 8/5/05

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" 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
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 <b>Christina M. Swick, Lewis &amp; Harrison, 122 C St. NW, #740, Washington DC 20001</b>	Title <b>Agent for Engelhard Corporation</b>	Telephone No. (Include Area Code) <b>(202) 393-3903 x16</b>
---------------------------------------------------------------------------------------------------	-------------------------------------------------	----------------------------------------------------------------

**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.

2. Signature <u>Christina M. Swick</u>	3. Title <b>Agent for Engelhard Corporation</b>	6. Date Application Received <b>(Stamped)</b>
4. Typed Name <b>Christina M. Swick</b>	5. Date <b>August 5, 2005</b>	

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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  
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August 5, 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: Emily Mitchell  
Product Manager 32**

**SUBJECT: Aseptrol S10-Tab (EPA Reg. No. 70060-19)  
Engelhard Corporation  
Notification per PR Notice 98-10**

Dear Ms. Mitchell:

As agent for Engelhard Corporation, I am submitting a Notification pursuant to PR Notice 98-10 for their product, Aseptrol S10-Tab (EPA Reg. No. 70060-19). The purpose of this notification is to add a patent number to the product 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. 16 or by email at [cswick@lewisharrison.com](mailto:cswick@lewisharrison.com).

Sincerely,

*Christina M. Swick*

Christina M. Swick  
Agent for,  
Engelhard Corporation

Cc: Mike Cochran (Engelhard Corporation)

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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**

**Disinfectant/ Virucidal\*/ Tuberculocidal/ Food-Contact Surface Sanitizer  
Oxidizing Tablets**

For Use in Hospitals, Medical, Dental, Industrial, Manufacturing and Institutional Facilities, Ion Exchange Resin Beds, Laboratory Animal Facilities, Clinical and Research Laboratories, Veterinary Hospitals and Clinics and Animal Rearing and Confinement Facilities.

**Active Ingredients**

Sodium Chlorite.....	20.8%
Sodium Dichloroisocyanurate dihydrate.....	7.0%
<b>Other Ingredients.....</b>	<b>72.2%</b>
<b>Total.....</b>	<b>100.0%</b>

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

Patent: 6,699,404

[contains]



Aseptrol®

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

[Sodium Chlorite in this product is from Spain]

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**Aseptrol S10-Tab** is a unique formulation of sodium chlorite that rapidly produces the biocidal agent chlorine dioxide when mixed with water.

\*A 100 ppm use-solution of chlorine dioxide has been shown to be effective against: Canine Parvovirus, Hantavirus, Minute Virus of Mouse (Parvovirus) (MVM-p), Minute Virus of Mouse (Parvovirus) (MVM-i), Mouse Hepatitis Virus (MHV-A59), Mouse Hepatitis Virus (MHV-JHM), Mouse Parvovirus type 1 (MPV-1), Murine Parainfluenza Virus Type 1 (Sendai), Stalodacryoadenitis Virus (Coronavirus) (SDAV) and Theiler's Mouse Encephalomyelitis Virus (TMEV) after 10 minutes of contact.

A 200 ppm use-solution of chlorine dioxide is a broad spectrum disinfectant effective against Human coronavirus and the following gram negative and gram positive bacteria: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Bordetella bronchiseptica*, *Staphylococcus aureus* (MRSA), *Corynebacterium bovis* and *Helicobacter pylori* after 10 minutes of contact. The 200 ppm use-solution is also tuberculocidal against *Mycobacterium bovis* after 5 minutes of contact at 20°C and virucidal against HIV-1 (the virus that causes AIDS) after 1 minute of contact.

**Aseptrol S10-Tabs** can be used as a disinfectant/virucide\*/tuberculocide in Hospitals, Medical, Dental, Industrial, Institutional and Manufacturing Facilities, Laboratory Animal Facilities, Clinical and Research Laboratories, Veterinary Clinics and Hospitals, Animal Rearing and Confinement Facilities, Animal Research Facilities and Laboratories, and other institutional/industrial applications that involve the housing of animals.

**DIRECTIONS FOR USE**

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

**PREPARATION OF USE-SOLUTION:**

**50 ppm Chlorine Dioxide (for sanitization of hard, nonporous food-contact surfaces).**

In a clean plastic pail, place two (2) 1.5 gram **Aseptrol S10-Tab** for every gallon of clean potable water. Or, in a plastic pigmented spray bottle, place one (1) 1.5 gram **Aseptrol S10-Tab** for every two (2) quarts (or two (2) liters) of clean, potable water. Prepare in a well ventilated area. Wait 10 minutes for the 1.5 gram tab to completely dissolve. Once dissolved, this will yield a working solution of 50 ppm of free chlorine dioxide. Once mixed, this solution should be used within 7 days.

**100 ppm Chlorine Dioxide (for control of animal viruses\*).**

In a clean plastic pail or plastic pigmented 1 gallon bottle, place either one (1) 6.0 gram **Aseptrol S10-Tab** or four (4) 1.5 gram **Aseptrol S10-Tab** for every gallon (4 liters) of clean potable water. Or, in a plastic pigmented 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. Wait 10 minutes for the 1.5 gram tab and 15 minutes for the 6 gram tab to completely dissolve. Once mixed, this solution should be used within 7 days.

**200 ppm Chlorine Dioxide (for disinfection of hard, nonporous surfaces and instruments, and to kill tuberculosis bacteria, Human coronavirus and HIV).**

In a clean plastic pail or plastic pigmented 1 gallon bottle, place two (2) 6.0 gram **Aseptrol S10-Tab** or eight (8) 1.5 gram **Aseptrol S10-Tab** for every gallon (4 liters) of clean potable water. Or, in a plastic pigmented 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. Wait 10 minutes for the 1.5 gram tab and 15 minutes for the 6 gram tab to completely dissolve. Once dissolved, this will yield a working solution containing 200 ppm of free chlorine dioxide. Prepare fresh solutions daily.

**HEALTH-CARE and VETERINARY FACILITIES**

Use **Aseptrol S10-Tab** to disinfectant pre-cleaned surfaces and to decontaminate instruments in hospitals, medical and dental offices, veterinary offices and clinics and hospitals and related facilities. Apply a 200 ppm chlorine dioxide use-solution to hard, non-porous surfaces and/or instruments thoroughly wetting surfaces with a cloth, mop, sponge or sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface and spray until totally wet. Do not breathe spray. Allow to air dry. The 200 ppm chlorine dioxide use-solution is effective against gram negative and gram positive bacteria, HIV-1, Human coronavirus, animal viruses\* and tuberculosis bacteria.

This product is not be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to decontaminate pre-cleaned critical or semi-critical medical devices prior to sterilization or high-level disinfection.

**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.

**SPECIAL INSTRUCTIONS FOR CLEANING AND DISINFECTING AREAS WHICH MAY BE INFESTED WITH HANTAVIRUS**

Infection with Hantavirus occurs by inhalation of infectious materials. Persons involved in the clean-up must wear coveralls (disposable, if possible), rubber boots or disposable shoe covers, rubber or plastic gloves, protective goggles, and an appropriate respiratory protection device, such as a half-mask air-purifying (or negative-pressure) respirator with a high-efficiency particulate air (HEPA) filter or a powered air-purifying respirator (PAPR) with HEPA filters.

All potential infective waste material (including respirator filters) from clean-up operations that cannot be burned or deep buried on site must be double bagged in appropriate plastic bags. The bagged material must then be labeled as infectious (if it is to be transported) and disposed of in accordance with local requirements for infectious waste.

Rodent dropping and visible dust may be reservoirs for Hantavirus. If you are cleaning out a building that has been closed up, such as a cabin, shed, or garage:

- A. Air out building for at least 30 minutes by opening windows and doors.
- B. Leave the building while it is airing out.
- C. Do not vacuum, sweep or dust. This may spread the virus through the air.
- D. Thoroughly wet the contaminated areas with **Aseptrol S10-Tab** and allow to stand undisturbed for 10 minutes.
- E. Carefully remove non-salvageable contaminated material and dispose by burial or burning. Contact your local and state health department for additional disposal methods.
- F. Treat the surface again following the label directions and allow to stand undisturbed for 10 minutes.

For additional guidance visit CDC website at [www.cdc.gov/hantavirus](http://www.cdc.gov/hantavirus).

### INSTITUTIONAL AND INDUSTRIAL FACILITIES

Use Aseptrol S10-Tab to disinfectant pre-cleaned surfaces in institutional and industrial facilities such as office buildings, food-processing plants, schools, hotels and motels, recreational facilities, recreational centers, institutional kitchens, supermarkets, grocery stores, boats, public facilities and military installations. Apply a 200 ppm chlorine dioxide use-solution to hard, non-porous surfaces thoroughly wetting surfaces with a cloth, mop, sponge or sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface and spray until totally wet. Do not breathe spray. Allow to air dry. A potable water rinse is required for any surface that may come into contact with food.

### LABORATORY ANIMAL FACILITIES, ANIMAL REARING FACILITIES AND ANIMAL RESEARCH FACILITIES AND LABORATORIES

Use Aseptrol S10-Tab to disinfect and kill tuberculosis bacteria, HIV-1, Human coronavirus and animal viruses\* on hard non-porous surfaces such as floors, walls, counters, stainless steel environmental surfaces, bio-safety hoods, sinks, tiles, cages, coops, crates, kennels, instruments and utensils. Pre-clean surfaces and then apply either a 100 ppm chlorine dioxide solution (for animal viruses\*) or 200 ppm chlorine dioxide solution (for disinfection, HIV-1, Human coronavirus and TB control). Apply the use-solution with a cloth, mop, sponge or sprayer or by immersion. Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface and spray until totally wet. Do not breathe spray. Allow to air dry.

### 3D-CONTACT SURFACE SANITIZER

Use Aseptrol S-10 Tab to sanitize hard, nonporous food-contact surfaces and utensils in food processing plants, breweries, bottling plants, restaurants and other food-handling establishments.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush surfaces with a good detergent or compatible cleaner followed by a potable water rinse before application of the sanitizer solution.

Apply a use-solution of 50 ppm chlorine dioxide to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, coarse sprayer or by immersion. Surfaces must remain wet for at least 60 seconds and then followed by adequate draining and air drying. Do not rinse. Prepare a fresh solution for each use.

### 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.  
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.**

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