

70060-19

1/27/2006

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January 27, 2006

Eliot I. Harrison
 Lewis & Harrison
 122 C Street, NW
 Suite 740
 Washington, DC 20001

Subject: Engelhard, Inc.
 Aseptrol S10-Tab
 EPA File Symbol No. 70060-19
 Application Date: September 6, 2005
 Receipt Date: September 8, 2005

Dear Mr. Harrison:

This amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Labeling Requests

- 1. To add the following:
 - Sterilization claim
 - Animal room fogging directions
- 2. To add claims against:
 - *Escherichia coli* pathogenic strain 0157:H7
 - Hepatitis B Virus
 - Hepatitis C Virus
 - Newcastle Disease virus
 - Norwalk virus
 - *Staphylococcus aureus* (MSRA)
 - *Enterococcus faecalis* (VRE)
 - Foot and Mouth Disease virus

Conditions

- 1. The first sentence of the Environmental Hazards statement "This product is toxic to fish and aquatic organisms" must be added to containers greater than 50 lbs.
- 2. The type of fogger to be used for Animal Room Disinfection should be identified as an ultra low volume (ULV) fogger .

CONCURRENCES							
SYMBOL	7570C						
SURNAME	Henson						
DATE	1-27-06						

- 3. The proposed reentry language for the treated animal rooms section of the label which reads as:

"Do not allow people to contact or breathe this fog and do not enter until the fog has settled or chlorine odor is not detected (30 - 60 minutes after fogging is completed)."

This reentry language must be revised to include actual monitoring for chlorine dioxide gas and/or ventilation criteria.

- 4. This product is used for surface sterilization. Therefore, the general heading **STERILIZATION** should be changed to read "SURFACE STERILIZATION."

General Comments

The original labels dated September 6, 2005, were discarded. A copy of the efficacy review was faxed to Lewis and Harrison on December 21, 2005. The consultant resubmitted revised labeling based on the review.

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

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

Sincerely,



Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

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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/ Sterilant/
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%
Other 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

Patent: 6,699,404

[contains]

ACCEPTED 
with COMMENTS
EPA Letter Dated:
[Aseptrol and the Aseptrol logo are trademarks of Engelhard Corporation]
JAN 27 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. **70060-19**

[Sodium Chlorite in this product is from Spain]

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), Sialodacryoadenitis Virus (Coronavirus) (SDAV) and Theiler's Mouse Encephalomyelitis Virus (TMEV) after 10 minutes of contact and Foot and Mouth Disease Virus after 30 minutes of contact.

A 200 ppm use-solution of chlorine dioxide is a broad spectrum disinfectant effective against Hepatitis B Virus, Hepatitis C Virus, Newcastle Disease virus, Norwalk virus, Human coronavirus and the following gram negative and gram positive bacteria: *Escherichia coli* pathogenic strain 0157:H7, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Bordetella bronchiseptica*, *Corynebacterium bovis* and *Helicobacter pylori* after 10 minutes of contact. The 200 ppm use-solution is also effective against *Staphylococcus aureus* (MRSA) and *Enterococcus faecalis* (VRE) after 5 minutes of contact, 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.

Aseptrol S10-Tab can also be used as a sterilant in manufacturing facilities, clinical laboratories and Biosafety Level 3 and 4 (BSL-3 and BSL-4) facilities.

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 stored in a tightly covered container and used within 7 days.

100 ppm Chlorine Dioxide (for control of Foot and Mouth Disease Virus and 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 stored in a tightly covered container and used within 7 days.

200 ppm Chlorine Dioxide (for disinfection of hard, nonporous surfaces and instruments, and to kill tuberculosis bacteria, Human coronavirus, HIV, Hepatitis B Virus, Hepatitis C Virus, Newcastle Disease virus and Norwalk virus).

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.

1000 ppm Chlorine Dioxide (for surface sterilization).

In a clean plastic pail or plastic pigmented 1 gallon bottle, place eight (8) 6.0 gram **Aseptrol S10-Tab** for every gallon of clean potable water or eight (8) 1.5 gram **Aseptrol S10-Tab** for every liter of clean potable water. Or, in a plastic pigmented spray bottle, place one (1) 6.0 gram **Aseptrol S10-Tab** for every pint (or 500 ml) of clean, potable water. Prepare in a well ventilated area. Wait 15 minutes for the 6 gram tab to completely dissolve. Once dissolved, this will yield a working solution containing 1000 ppm of free chlorine dioxide. Prepare fresh solutions daily.

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 (30 minutes for Foot and Mouth Disease Virus). 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.

bacteria, HIV-1, Human coronavirus, Hepatitis B Virus, Hepatitis C Virus, Newcastle Disease virus, Norwalk virus, Foot and Mouth Disease Virus 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 (30 minutes for Foot and Mouth Disease Virus). 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.

FOGGING DEVICE FOR ANIMAL ROOM DISINFECTION DIRECTIONS

Remove all animals and feed from animal room, vehicles and enclosures. Remove all litter from floors, walls and surfaces of the room to be treated. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix two (2) 6 gram **Aseptrol S10-Tab** or eight (8) 1.5 gram **Aseptrol S10-Tab** into one gallon of water making a 200 ppm solution of chlorine dioxide. Place fogger in center of room or insert the nozzle of the fogger through a suitable opening into the room. With the Flow Rate setting in HIGH output, apply fog for 15 minutes for each 3000 cubic feet of space in the room, thorough wetting of all surfaces is required. **Do not allow people to contact or breathe this fog and do not enter until the fog has settled or chlorine odor is not detected (30 – 60 minutes after fogging is completed).**

NOTE: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has settled or chlorine odor is not detected (30 – 60 minutes after fogging is completed). If the building must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING FOR ROOM AND MACHINE SURFACES.

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 (30 minutes for Foot and Mouth Disease Virus). 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, Hepatitis B Virus, Hepatitis C Virus, Newcastle Disease virus, Norwalk virus, Foot and Mouth Disease Virus, 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, HBV & HCV 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, HBV and HCV. **Aseptrol S10-Tab** destroys HIV-1, HBV and HCV on pre-cleaned environmental surfaces/objects previously soiled with blood or other body fluids at 200 ppm and 1 minute contact (10 minutes for HBV and HCV).

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 (10 minutes for HBV and HCV). A contact time of 1 minute 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.

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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.

FOOD-CONTACT SURFACE SANITIZER

Use **Aseptrol S10-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.

STERILIZATION

Use **Aseptrol S10-Tab** where sterility conditions are critical for optimum performance, such as manufacturing and laboratory equipment, and in areas where sterilization is required, such as Level 3 and 4 Biosafety Level (BSL-3 and BSL-4) facilities. Use **Aseptrol S10-Tab** on hard, non-porous surfaces such as plastics (polystyrene, polypropylene, polyvinyl chlorides, polyesters) stainless steel, fiberglass, ceramic, metal or glass. Do not use **Aseptrol S10-Tab** as a terminal high-level disinfectant or sterilant on any critical/semi-critical medical device or instrument. Prior to use, thoroughly pre-clean surface to be sterilized. This can be accomplished by rinsing with purified water, mechanical action or by detergent cleaning followed by a water rinse. Pre-cleaned surfaces may be allowed to air dry or may be towel dried but do not dry surfaces using dry heat. Prepare a 1000 ppm use-solution of chlorine dioxide by following the instructions under "Preparation of Use Solution" on this label. Apply the 1000 ppm chlorine dioxide use-solution by either thoroughly soaking the target surface or by immersion. All target surfaces must be exposed to treatment solution for at least 1 hour. Allow to air dry.

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.