

December 24, 2003

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

Subject: Engelhard Corporation
Aseptrol S10-Tab
EPA Registration Number 70060-19
Application Date: October 24, 2003
Receipt Date: October 24, 2003

Dear Mr. Harrison:

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:

- Addition of Hard, Non-Porous Disinfectant claims and associated use sites
- Reinsert deleted ion exchange resin directions for use
- Revised use direction language per the state of California

Conditions

1. Revise the Ingredient statement as follows:

Active Ingredient

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

2. The statement "Wait 10 minutes for the 1.5 gram tab to dissolve and 15 minutes for the 6 gram tab" should be revised to read "Wait 10 minutes for the 1.5 gram tab and 15 minutes for the 6 gram tab to completely dissolve."

CONCURRENCES

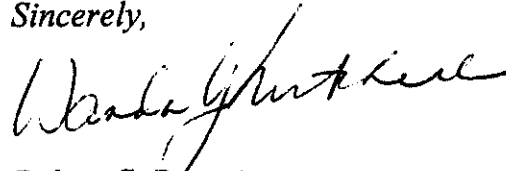
SYMBOL	7510c						
SURNAME	Mitchell						
DATE	12 24 03						

General Comments

A stamped copy of the labeling accepted with conditions, 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,



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

3 8 5

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 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%
Inert Ingredients.....	72.2%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for first aid and precautionary statements.

ACCEPTED
with COMMENTS
EPA Letter Dated:

EPA Reg. No. 70060-19
EPA Est. No. 70060-

Net Weight:

DEC 24 2003

(Expiration Date:)

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide,

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]

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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), Sialodacryoadenitis 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 the following gram negative and gram positive bacteria: *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* 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:

100 ppm Chlorine Dioxide (for control of 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 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 to dissolve and 15 minutes for the 6 gram tab. 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 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 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 to dissolve and 15 minutes for the 6 gram tab. 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, animal viruses and tuberculosis bacteria.

This product is not be used as a terminal steriant/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 precleaned 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.

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 S-10 Tab** to disinfect and kill tuberculosis bacteria, HIV-1 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. Preclean surfaces and then apply either a 100 ppm chlorine dioxide solution (for animal viruses) or 200 ppm chlorine dioxide solution (for disinfection, HIV-1 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.

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with COMMENTS
EPA Letter Dated:
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No. 70060-19

**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.

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EPA Letter Dated:**

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