

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

November 25, 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: September 8, 2003
Receipt Date: September 8, 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:

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	7510						
SURNAME	M. J. S.						
DATE	11-25						

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,

A handwritten signature in cursive script that reads "Wanda Mitchell".

for Robert S. Brennis

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.

Keep 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 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]



**ACCEPTED
with COMMENTS**

EPA Letter Dated:

NOV 25 2003

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

[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 (ClO_2) that is effective against: Minute Virus of Mice (MVM), Mouse Hepatitis Virus (MHV), 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 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 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 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.

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 AT 20°C 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.

(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.