



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 2, 2002

**MEMORANDUM**

**Subject:** Efficacy Review for EPA File Symbol 70060-EE / Aseptrol SE  
DP Barcode: D278165  
Case No.: 070737

**From:** Ian Blackwell, Biologist  
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**To:** Robert Brennis, PM 32 / Wanda Mitchell  
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**Through:** Emily Mitchell, Team Leader  
Efficacy Evaluation Team  
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**Applicant:** Engelhard Corp.

**Formulation From Label:**

<u>Active Ingredient(s)</u>	<u>% by wt</u>
Sodium chlorite	6.4
Sodium Dichloroisocyanurate dihydrate	1.0
<u>Inert Ingredient(s)</u>	<u>92.6</u>
Total	100.0

- I **BACKGROUND:** The Engelhard Corporation has submitted a water purifier test using cysts. The study was conducted by MicroBioTest, Inc. The MRID Number is 455014-01.

PSB/AD recently conducted a review of 70060-EE (D276350) that was completed on 10/31/2001. That submission also included a water purifier test on cysts. However, that study was completed on 5/1/01, subsequent to the completion of the study included in this submission (completed 2/16/00). It is also noted that although this study was submitted in support of Aseptrol-SE Water Purifier tablets, it was conducted using Aseptrol WBT60F2.5.

## II Use Directions

Aseptrol-SE Water Purifier Tablets are only for the emergency disinfection of drinking water. Aseptrol-SE tablets are for use by campers, hikers, militaries, emergency organizations and anyone who needs to drink water of questionable microbiological quality.

For control of bacteria, viruses and cysts: Aseptrol-SE Water Purifier Tablets kill bacteria, viruses and cysts in non-turbid waters. To Use: Remove the 250 mg Aseptrol-SE Water Purifier Tablet from its foil envelope and quickly insert the tablet into ½ liter (or ½ quart) of contaminated water. Allow to react for 30 minutes, in an area away from sunlight, in order to generate a use-solution of 4 ppm chlorine dioxide. The treated water is now ready for drinking.

## III Agency Standards for Proposed Claims

Water purifiers are designed to decontaminate water. The intention is to remove, kill or inactivate all types of disease-causing microorganisms from water to yield water that is safe for drinking. Typical water contaminating microbes include bacteria, viruses and protozoan cysts.

According to the Guide Standard and Protocol for Testing Microbiological Water Purifiers (4/86), microbiological reduction requirements for a water purifier test for cysts must include an influent challenge of at least  $10^6$  cysts/liter and produce a reduction of 99.9% (3 log). The test is to be conducted using *Giardia muris*, *Cryptosporidium parvum* may also be tested.

## IV Comments on the Submitted Efficacy Studies

- 1 MRID Number 455014-01: "EPA Water Purifier Challenge Using Cysts" by Donna B. Suchmann. MicroBioTest, Inc. Lab Project Number 414-107. Study

Completion Date 2/16/2000.

This study was conducted to assess the ability of Aseptrol WBT60F2.5 Water Purifier Tablets to kill or eliminate cysts in contaminated or inoculated water. Cysts for the test species *Cryptosporidium parvum* and *Giardia muris* were used.

This assay used two types of test water as per the April, 1986, EPA document "Guide Standard and Protocol for Testing Microbiological Water Purifiers":

- A. Type 1 is normal, "non-stressed", non-challenge water:
- Free of chlorine or other disinfectant residuals
  - pH is 6.5 - 8.5
  - Total Organic Carbon (TOC) 0.1-5.0 mg/L
  - Turbidity 0.1-5 NTU
  - Temperature 20°C
  - Total Dissolved Solids (TDS) 50-500 mg/L.
- B. Type 2 is for the stressed, challenge phase of the study:
- Free of chlorine or other disinfectant residual
  - pH  $9.0 \pm 0.2$  °C.
  - TOC not less than 10 mg/L
  - Turbidity not less than 30 NTU
  - Temperature  $4^{\circ}\text{C} \pm 1^{\circ}\text{C}$
  - TDS  $1,500 \text{ mg/L} \pm 150 \text{ mg/L}$

Four sterilized 1-liter flasks were used to hold 298.5 mL of the EPA test water under test. The flasks were spiked with both types of (oo)cysts, mixed by swirling and 1.0 mL samples were withdrawn to function as the control.

At the end of the testing/incubation period, the intestines were harvested, ground and stained with the Merifluor system. The slides were then observed for the presence of cysts from *Giardia muris* and *Cryptosporidium parvum*.

## V Results

From Table 1 of MRID Number 455014-01 (Test Water #1)

Treatment	Total Pups Treated (oral gavage)	No. of mice positive/total number surviving
Aseptrol WTS-F2, Lot 18604-12-2	10	0/9
Aseptrol WBT60F2.5, Lot 18604-18-1	10	0/9
Aseptrol WBT60F2.5, Lot 18604-24-1	10	0/9
Initial Positive Control, EPA Water #1 spiked with both cysts	10	8/8
Negative Control - EPA Water #1 spiked with both cysts - heat inactivated	10	0/9
<i>C. parvum</i> oocysts - positive control	10	9/9
<i>G. muris</i> cysts - positive control	10	10/10
Uninoculated control	10	0/9

From Table 2 of MRID 455014-01: (Test Water #2)

Treatment	Total Pups Treated (oral gavage)	No. of mice positive/total number surviving
Aseptrol WTS-F2, Lot 18604-12-2	10	6/6
Aseptrol WBT60F2.5, Lot 18604-18-1	10	7/7
Aseptrol WBT60F2.5, Lot 18604-24-1	10	5/5
Initial Positive Control, EPA Water #1 spiked with both cysts	10	7/7
Negative Control - EPA Water #1 spiked with both cysts - heat inactivated	10	0/6
<i>C. parvum</i> oocysts - positive control	10	9/9
<i>G. muris</i> cysts - positive control	10	8/8
Uninoculated control	10	0/6

## VI Conclusions

Under the conditions of this assay, Aseptrol WBT60F2.5 was an effective disinfectant of EPA test water type #1 inoculated/contaminated with *Giardia muris* and *Cryptosporidium parvum*. This same assay found Aseptrol WBT60F2.5 to be **ineffective** as a disinfectant of EPA Test Water type #2 contaminated with *Giardia muris* and *Cryptosporidium parvum*. This report did not include the influent challenges used in this study.

## VII Recommendations

This study was not conducted using Aseptrol SE Tablets, but used Aseptrol WBT60F2.5-4g. **At this time, the request to add labeling stating that Aseptrol SE is effective against water contaminated with cysts or oocysts is not supported.**