UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

April 11, 2008

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 72083-U, HaloPure Water Purifier Insert, DP Barcode: 349257

From: Tajah L. Blackburn, Ph.D., Microbiologist
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Antimicrobials Division (7510P)

4/30/08

Thru: Michele Wingfield, Chief
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To: Emily Mitchell PM 32/ Tom Luminello
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Applicant: HaloSource
1631 220th St. SE
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Formulations from Label

Active Ingredient(s)	% by wt.
Bromine*	18%
Other Ingredients	86%
Total	100%

*Available as Br+

I BACKGROUND

The product, HaloPure Water Purifier Insert, is a new product. The registrant requests to register the product as a purification system for drinking water. Efficacy testing was conducted at BioVir Laboratories, Inc., located at 685 Stone Road, Unit 6, in Benicia, CA 94510. The data package included a letter from the registrant (dated December 6, 2007), proposed label, proposed instruction manual, EPA Form 8570-4, Statement of No Data Confidentiality, and one efficacy study (MRID No. 473281-01).

II USE DIRECTIONS

Per the product label, HaloPure Water Purifier is a drinking water purification system designed to disinfectant surface water, well and ground water, and tap water. The system utilizes HaloPure BR, a contact microbiocide to kill bacteria and viruses. Directions on the proposed labeling and instruction manual provided the following instructions for using the system:

Product Setup:

1. Assemble your ceramic filter system per the system's provided instructions. Otherwise follow Steps 2 through 4.
2. Rinse both top and bottom stainless steel containers with clean water to remove any oil and dirt from shipping.
3. Install outlet tap: place a gasket on both the inside and outside of the clean water container and tighten nut onto tap.
4. Insert the ceramic prefilter candle(s) with the rubber gasket in center hole inside the unfiltered water container and screw on wing nut underneath on bottom of unfiltered water container. The wing nut must screwed in by hand. Do not cover.
5. Assemble the Purifier Insert.
    a. Attach the post treatment basin to the purifier chamber using the supplied screws
    b. Place the lid on top of the chamber
    c. Remove the upper portion of the ceramic filter and place the HaloPure Purifier belt in between the upper and lower sections.
6. Place the assembled system on a level surface.
7. Prior to first use, flush 7-10 liters of clean water through the system to remove any dust or dirt from the system. Discard treated water.

Using the System

1. Operate as you would normally do with your ceramic filtration system.
2. Ensure that the lower reservoir spigot is closed when not dispensing water.
3. Fill the upper reservoir with water.
4. Allow the water to flow through the ceramic filters.
5. The water will be treated by HaloPure Purifier Insert and collected into the bottom reservoir.
6. Dispense water from the spigot as needed.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Guide Standard and Protocol for Testing Microbiological Purifiers

As set forth in EPA Enforcement Strategy and as supported by a Federal Trade Commission (FTC) decision (FTC v. Sibco Products Co., Inc., *et al.* November 22, 1965), a unit, in order to be called a microbiological water purifier, must remove, kill or inactivate all types of disease-causing microorganisms from the water, including bacteria, viruses, and protozoan cysts so as to render the processed water safe for drinking. In order to make the claim of "microbiological water purifier," units must be tested and demonstrated to meet the microbiological reduction requirements of Table 1 according to the test procedures described in the Challenge Test Water/Halogen Disinfection (specific for the type of unit involved).

Table 1. Microbiological Reduction Requirements

Organism	Influent Challenge*	Min. Required Reduction	
		Log	%
Klebsiella terrigena (ATCC-33257)	10^7/100 ml	6	99.9999
Poliovirus[1] (ATCC VR-59)	1 x 10^7/L	4	99.99**
Rotavirus (Wa or SA-11) (ATCC VR-899/VR-2018)	1 x 10^7/L	4	99.99**
Giardia muris or *Giardia lamblia****	10^6/L	3	99.9

* The influent challenges may constitute greater concentrations than would be anticipated in source waters, but these are necessary to properly test, analyze and quantitatively determine the indicated log reductions.

** Virus types are to be mixed in roughly equal 1 x 10^7/L concentrations and a joint 4 log reduction will be acceptable.

*** It should be noted that new data and information with respect to cysts may in the future necessitate a review of the organism choice and of the challenge and reduction requirements.

Challenged Test Water/Halogen Disinfectant

This water is intended for the stressed challenge phase of testing where units involve halogen disinfectants, and shall have the following specific characteristics:

(a) Free chlorine or other disinfectant residual;
(b) pH 9.0 ± 0.2;
(c) Total Organic Carbon (TOC) not less than 10 mg/L;
(d) Turbidity not less than 30 NTU;
(e) Temperature 4°C ± 1° C;
(f) Total Dissolved Solids (TDS) 1,500 mg/L ± 150 mg/L

IV SYNOPSIS OF SUBMITED EFFICACY STUDY

1. MRID No. 473281-01, HaloPure Water Purifier Insert Product Performance Study: Product Microbial Disinfection Study for HaloSource HaloPure Purifier Belt Purifier System, conducted by Richard Danielson, PhD. Study completion date—September 26, 2006. Project Identification No Included.

The HaloPure Purifier belt Purifier system is gravity fed treatment system. Water passes sequentially through a ceramic filter, a carbon filter and finally through a purifier cartridge which supplies a disinfectant to the water stream. The water is collected in a reservoir and is accessed by an outlet spout. Four systems were supplied by the manufacturer to efficacy evaluation. The system purifies about 30 L per day with a 300 L capacity. The challenge water was dechlorinated Benicia tap water was fed into holding tanks where general test water #1 and challenge test water #2 were made to the specifications set forth in the protocol. The challenge organisms were Poliovirus Vaccine Strain 1 (LSa, ATCC #VR-59) propagated in BGMK cell lines, Rotavirus SA-11 (ATCC# 33257) propagated in BGMK cell lines, and Klebsiella terrigena (ATCC# 33257). Thirty (30) L of Test water #1 was added to the upper reservoir daily. At times 0, 25% and 50% capacity (<10 L, 75 L and 150 L, respectively) of Test water #1 was spiked with challenge organisms and processed. The two day stagnation time was observed and samples collected. At times 60%, 75%, and 100% (180 L, 225 L, and 300 L, respectively), the systems were challenged with Test Water #2 and challenge organisms, followed by another two day stagnation period observed between 75% and 100%. Since the use pattern is at least 20 L per day with 4 total days of stagnation this system was challenged over a 15-day period (@ 30 L/day). Controls included those for positive and negative controls, biochemical identification of target organism in at least 20% of the effluent samples, and viral titer control.

Protocol Deviations

1. The original EPA Protocol (circa 1987) suggests the use of a variety of African Green Monkey cell line known as MA-104 for the assay of the polio-/rota-virus. The polio- and virus- viruses used in this study were propagated and assayed using a BioVir cell line of the African Green Monkey variety (BV-BGMK). The BV-BGMK cell line is ten times more sensitive and produces more viruses (for spikes) than the suggested MA-104 cell line (data available, but not shown) and therefore was used for this study.\

2. Additional unexpected protocol deviations were considered insignificant and thus not impacting study conduct.

Protocol Notes

1. BioVir Laboratories, Quality Control Report states that the water quality parameters for both Test Water #1 and Test Water #2 were met (letter dated October 6, 2006).

V RESULTS

Results of Bacteriological Challenge with HaloPure Purifier Belt Purification System

Challenge Point (%)	Influent cfu/100 ml	Unit 1 cfu/100 ml	Log reduction	Unit 2 cfu/100 ml	Log reduction	Unit 3 cfu/100 ml	Log reduction
0	2.20E +08	<1	>8.34	<1	>8.34	<1	>8.34
25	1.70E+08	<1	>8.23	<1	>8.23	<1	>8.23
50	2.10E +08	<1	>8.32	<1	>8.32	<1	>8.32
1st 48 hr		<1				<1	
60	1.00E +08	<1	>8.00	<1	>8.00	<1	>8.00
75	8.80E +07	<1	>7.92	<1	>7.92	<1	>7.92
2nd 48 hrs							
100	1.50E+08	<1	>8.18	<1	>8.18	<1	>8.18

Results of Polio- and Rota- Virus Challenge with HaloPure Purifier Belt Purification System

Challenge Point (%)	Influent pfu/100 ml	Unit 1 pfu/100 ml	Log reduction	Unit 2 pfu/100 ml	Log reduction	Unit 3 pfu/100 ml	Log reduction
0	2.20E +07	<100	>5.34	<100	>5.34	<100	>5.34
25	1.50E+08	<100	>6.18	<100	>6.18	<100	>6.18
50	1.90E +07	<100	>5.28	<100	>5.28	<100	>5.28
1st 48 hr							
60	4.50E+07	<100	>5.65	<100	>5.65	<100	>5.65
75	5.60E +07	<100	>5.75	<100	>5.75	<100	>5.75
2nd 48 hrs							
100	3.90E+07	<100	>5.59	<100	>5.59	<100	>5.59

Results of Bromine Measurements of HaloPure Purifier Belt Purification System Effluent

Challenge Point (%)	Unit 1 mg/L	Unit 2 mg/L	Unit 3 mg/L
0	1.16	1.36	0.79
25	0.83	0.76	1.16
50	0.69	0.59	0.88
1st 48 hr	0.10	0.04	0.17
60	0.46	0.18	0.23
75	0.11	0.10	0.11
2nd 48 hrs	0.09	0.09	0.05
100	0.05	0.07	0.04

VI CONCLUSIONS

1. The Guide Standard and Protocol for Testing Microbiological Water Purifiers set a performance standard for *Klebsiella terrigena* (6 log reduction) Poliovirus and Rotavirus (4 log reduction), and Giardia cysts (3 log reduction). Furthermore, the Guide Standard states that "to qualify microbiological water purifier must treat or remove all types of challenge organisms to meet specified standard." The efficacy data submitted

demonstrated acceptable log reductions for *K. terrigena*, Poliovirus and Rotavirus. Efficacy was not submitted for Giardia cysts. The label states that "Ceramic pre-filters remove 99.99% of cysts"; however data was not submitted. Furthermore, it is unclear if the ceramic pre-filters are packaged with HaloPure Purifier system. In the absence of efficacy data against Giardia cysts, claims as a water purification system are unacceptable.

2. According to the EPA Registration Eligibility document, Bromine is registered for use in water filters to purify drinking water aboard US Naval ships and offshore oil well platforms. From the submitted label, the intended use site of this product is not stated.

Note: An additional label for HaloPure BR was included in the data package. Clarification regarding this submission is requested.

VII RECOMMENDATIONS

1. In the absence of acceptable efficacy data against Giardia cysts, water purification claims are unacceptable. The performance standard in its entirety must be satisfied, as set forth in the Guide Standard and Protocol for Testing Microbiological Water Purifiers (1987).

2. According to the documents submitted, there is are two proposed label and an instruction manual. Significant information in the instruction manual should be included on the product label (i.e. directions, etc). Consider merging the two documents to address the deficiencies.

3. The Agency requests submission of data (or references) regarding the use of the BV-BGMK cells for propagation of viruses, to support protocol modification.