



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 28, 2001

MEMORANDUM:

Subject: Product Efficacy Review for EPA Reg. No.: 71326-E / Viral Stop
DP Barcode: D271724
Case No: 069804

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Applicant: Cascade Designs, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
sodium hypochlorite	3.5
<u>Other Ingredient(s):</u>	<u>96.5</u>
Total:	100%

BACKGROUND: Cascade Designs, Inc., has submitted a product efficacy study to support the registration of their product "SweetWater Guardian C". The MRID Number is 452466-03. The study was conducted by BioVir Laboratories, Inc.

This study was conducted to evaluate the SweetWater Guardian C system as a microbiological water purifier. This product consists of a water microfilter along with a treatment of a sodium hypochlorite solution. This product is intended to be a portable system to be used by climbers, hikers, campers, people in foreign countries, etc. The pump and microfilter were a part of EPA Reg. No. 71326-1 (which has been cancelled). That product contained an iodinated resin as an active ingredient. The iodinated resin of 71326-1 has been replaced by a sodium hypochlorite treatment in 71326-E.

This submission contains a unique protocol that is based upon the Agency Guide Standard for Microbiological Water Purifiers, with changes based on the proposed product's intended use pattern. Challenge microorganisms are placed into suspension in various test waters made with various water quality constituents. The various suspensions are run through the test water purifiers. The effluent is then cultured to determine the ability of the purifier to remove or inactivate bacteria, viruses and protozoan cysts.

Summary of the Submitted Data:

The data was generated using a modified version of the Guide Standard and Protocol for testing Microbiological Water Purifiers. The test was conducted using *Klebsiella terrigena* (ATCC #33257), Poliovirus 1 (ATCC #VR-59), *Giardia muris* (Robert Dobson strain), *Cryptosporidium parvum* Moon Harley Strain. The microorganisms were challenged in the following test waters:

5.1 Test Water #1 (General Test Water)

- 5.1.1 Chlorine Free Potable Water
- 5.1.2 pH 6.5-8.5
- 5.1.3 TOC, 0.1 to 5.0 mg/L
- 5.1.4 Turbidity, 0.1 to 5 NTU
- 5.1.5 Temperature, 20°C ± 5°C
- 5.1.6 TDS, 50-500 mg/L

5.2 Test Water #2 (Challenge Test Water/ Halogen Disinfection)

- 5.2.1 Chlorine Free Potable Water
- 5.2.2 pH 9.0
 - 5.2.2.1 pH adjusted with chlorine free potable water
- 5.2.3 TOC, ≥ 10 mg/L
 - 5.2.3.1 Adjusted with humic acid (Aldrich, Lot# 05924KN)
- 5.2.4 Turbidity, ≥ 30 NTU
 - 5.2.4.1 Adjusted with Test Dust, Nominal 0-5 m (Powder Technologies, Inc. Lot #4782J)
- 5.2.5 Temperature, 4 °C ± 1°C
- 5.2.6 TDS, 1,500 ± 150 mg/L
 - 5.2.6.1 Adjusted with Sea Salts (Sigma Chemical, Lot #84H0444)

Test Procedure in brief:

1. The test microfilters were primed/flushed with 10 liters of general water prior to testing.
2. The filter units were challenged with bacteria, virus or protozoa at 0, 25, and 50 gallons of water run-through after an initial stagnation period. At 60, 75 and 100 gallons after a second stagnation period, the filters were rechallenged with bacteria, virus or protozoa as called for.
3. After samples of the contaminated water were collected from the filtration units, one liter of water was treated with 4 drops of Sodium Hypochlorite Solution (1.6%).

Results:

(Table 6 copied from MRID Number 452466-03)

Organism	US EPA Minimum Required Reduction	Reduction Achieved by the Guardian Microfilter
<i>Klebsiella terrigena</i>	6	7.5
Poliovirus 1 & Rotavirus SA-11	4	4
<i>Cryptosporidium parvum</i>	3	3.8
<i>Giardia muris</i>	3	4

RECOMMENDATIONS: PSB findings are:

MRID Number 452466-03: "SweetWater Guardian C (Guardian Microfilter and Treatment with Sodium Hypochlorite Solution). Report of Purifier Status Based on USEPA Guide Standard and Protocol for Testing Microbiological Water Purifiers" by Richard E. Danielson, Ph.D. BioVir Laboratories, Inc. Lab ID # Project 000354. Study Completion Date 9/19/2000.

This study has demonstrated the ability of the SweetWater Guardian C system to function as a microbiological water purifier, removing and/or inactivating bacteria, viruses and cysts. The log of the reduction of *Klebsiella terrigena*, Poliovirus1, Rotavirus SA-11, *Cryptosporidium parvum* and *Giardia muris* met or exceeded EPA standards in each case.

LABELING:

The product label should include a statement explaining the actual function of the product, such as "Removes and/or inactivates bacteria, viruses and cysts from contaminated water."