

US EPA ARCHIVE DOCUMENT

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

Tuesday, September 1, 2009

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 72083-4
Product Name: Halopure Water Purifier Insert
DP Barcode: D368169

CODE: (575) Follow-up Data to Conditional registration

DATE DUE: September 09, 2009

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
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Earl Goad 9/1/2009

THRU: Karen Hicks, Team Leader
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Karen Hicks

TO: Emily Mitchell PM#32/Tom Luminello
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Halosource, Inc

PRODUCT FORMULATION FROM LABEL:

<u>PC Codes</u>	<u>Active Ingredient(s):</u>	<u>% by wt.</u>
008701	Bromine	18
	<u>Other Ingredient(s):</u>	82
	Total:	100.0

BACKGROUND:

Halosource, Inc has an submitted a Storage Stability and Corrosion Characteristics study (MRID # 478172-01) to satisfy the Product Chemistry Data Requirements for their conditionally registered product. EPA Reg #: 72083-4 (Halopure Water Purifier Insert) is an end use, replacement cartridge used in a water purification device.

FINDINGS:

1. A storage stability and corrosion characteristic study was performed to address Product Chemistry guidelines OPPTS 830.6317 and 830.6320. This study was to determine how well the Halopure Water Purifier Insert retains its concentration of active ingredient and evaluate the corrosive effects on the container materials when stored up to the period of time.
2. Study Information:
 - a. Study MRID#: 478172-01
 - b. Testing Laboratory: Eurofins | Product Safety Laboratories
 - c. Author: William D. Gravelle, M.S..
 - d. Date Completed: July 23, 2009
 - e. Quality Assurance: Statement of compliance with (40CFR §160.12) was included.
 - f. Test material: Halopure Purifier Insert ; lot #: 07-HPBR-0514
 - g. Physical Form: Solid, opaque-colored bead, composed of cross linked polystyrene.
 - h. Storage Container: plastic purifier inserts sealed in Mylar-like material.
 - i. Storage Temperature Range: 20-27 °C
 - j. No Protocol deviations reported or found.
3. Declared certified limits of actives in product test material.

Polystyrene bead impregnated with bromine 16 ± 0.8

4. Analytic Method: Titration (consistent with enforcement analytical method, for the active ingredient).

5. Results:

- a. Storage Stability: Change in % Active Ingredient under storage conditions.

Test Substance	Initial	3-Month	6-Month	9-Month	12-Month	1 Year Average
Halopure Water Purifier Insert	%Bromine Mean± SD					
	16.8±0.25	16.5±0.11	16.4±0.24	15.6±0.06	15.6±0.06	16.18

Under the conditions of storage the concentrations of the active ingredients were found to remain within the acceptable EPA Standard Certified Limits.

- b. Corrosion Characteristics:

Storage Container Weight Changes

Storage Time	0-3 Month	0-6 Month	0-9 Month	0-12 Month
% Difference	0.10	0.24	0.17	0.27*

* n=5, mean=0.268, SD=0.06, range 0.19-0.33

Under the storage conditions, at each time interval, the material of the container showed no signs of cracking, variation, fogging or discoloration. The percent weight change of the container ranged from 0.10 to 0.33%.

CONCLUSIONS:

PSB/CTT finds the submission to be fully acceptable in meeting the storage stability and corrosion characteristics data requirements for the registration of this product.