EEE BRANCH REVIEW

DATE:	IN	OUT	IN	OUT	IN 9/3/75	OUT 9/16/75
	FISH & WILDLIFE		ENVIRONMENTAL CHEMISTRY		EFFICACY	

FILE OR REG. NO. 35966-E

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED 8/29/75

DATE OF SUBMISSION 8/25/75

DATE SUBMISSION ACCEPTED

TYPE PRODUCT(S): I,(D) H, F, N, R, S Bacteriostatic Water Filter

PRODUCT MGR. NO. 33

PRODUCT NAME(S) Waterco A-S 5 Model

COMPANY NAME Waterco Industries, Inc.

SUBMISSION PURPOSE Resubmission with data

CHEMICAL & FORMULATION Silver 0.175%

200.0 Introduction

200.1 Use

Bacteriostatic Water Unit

201.0 Data Summary

201.1 Abstract of Test Reports

Chemical and bacteriological reports were provided. The chemical report indicated that ten units were challenged with 2500 gallons of tap water. Except for one 10-hour non-use period after passage of 500 gallons of water through the units, the flow of water passed through the units during the 2500-gallon lifetime was continuous. The silver concentration in the effluent was determined at periodic intervals during the lifetime of the units. The bacteriological report indicated that six units, three product test units and three control units with activated carbon and no silver, were each challenged to a 100 ml aqueous suspension of Escherichia coli at a concentration of 560 micro-organisms per ml after the units were conditioned. Passage of 2250 gallons of tap water, representing 90% of a unit's life, constituted the conditioning procedure for each unit. The bacterial challenged dosage remained within each unit 24 hours before it was decanted from the unit and assayed.

201.1.1 Brief Description of Tests

Chemical determinations for silver were made by the Atomic Absorption Method. Bacteriological assays were made by plate counts using TGE agar after each 100 ml sample had been neutralized with 500 ppm sodium thioglycollate and 730 ppm sodium thiosulfate.

201.1.2 Data Summaries

The chemical data provided for the 10 units are summarized below:

Sampling Time	ppb Ag
Initial ("o" gallonage)	0-4
500 gal. challenge	2-16
After 10-hr. non-use period	3-8
1500 gal. challenge	0-2
2500 gal. challenge	0-3

Flow rate = 2 gal./min.; temp. = 29°C; pH tap water = 7.5; pH treated effluent = 6.5

The bacteriological data provided are indicated below:

Unit No.	Ag Present	Ag Conc. (ppb)	Bacterial Count
1	No	0	4510
2	No	0	3920
3	No	0	3817
4	Yes	2	0
5	Yes	2	30
6	Yes	2	9

Initial Inoculum = 560 E. coli/ml.

202.0 Recommendations

202.1 Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.

202.2.2 Data not appropriate: Data derived from tests designed to demonstrate effectiveness of the product for water entrapped within the unit during a 24-hour non-use or stagnation period are not appropriate to support the claim "water sanitizer" which is synonymous with "water purifier." Data developed in accordance with Part VII B of the "Interim Standards For Water Purifiers", June 13, 1975 must be provided to support the claim "water sanitizer."

202.2.3 Lesser claims data will support: The data provided will support a claim for bacteriostatic activity within the unit. A claim "Inhibits bacterial growth within the unit is also acceptable."

An evaluation of these data for effectiveness in reducing the bacterial population within the unit during a 24-hour non-use or stagnation period is prohibited by lack of control data such as (1) a determination of the concentration of E. coli in the challenge suspension after 24 hours to verify that the bacteria did not "die-off" naturally outside the unit; and (2) a determination of the bacterial recovery and silver concentration that can be expected in the effluent immediately after a challenge with the E. coli suspension to substantiate the bacterial reduction after treatment within the unit.

203.0 Labeling

The claims on the product label must be revised to correspond with the data provided.

The review of this application can not be completed until the circular referenced on the product label is submitted. Any other collateral literature intended to be used in conjunction with this product should also be submitted for review.

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9/16/75
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