

(1/9/89)

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - 1

Antimicrobial Program Branch

IN 11-15-88 OUT 12-27-88

Reviewed By Emily A. Mitchell ^{WEC} 1/9/89 Date 12-27-88
Emily H. Mitchell

EPA Reg. No. or File Symbol 57425-1

EPA Petition or EUP No. None

Date Division Received 11-17-88

Type Product(s) Water Disinfectant

Data Accession No.(s) 408756-01

Product Mgr. No. PM 32 (Kempter)

Product Name(s) CHLOR-FLOC Emergency Drinking Water Tablets

Company Name(s) Control Chemical

Submission Purpose Resubmission with Efficacy Data and Proposed Label

Chemical & Formulation Tablets to be dissolved in water

<u>Active Ingredient(s):</u>	<u>%</u>
Sodium dichloro-s-Triazinetrione	2.5%

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200.0 Introduction

200.1 Uses:

Clarification and disinfection of drinking water from polluted sources.

200.2 Background Information:

The submission received 11-17-88, is a resubmission with efficacy data and proposed label.

201.0 Data Summary (Accession No. 408756-01)

201.1 Brief Description of Tests:

The following references were provided:

1. Test of CHLOR-FLOC Against *Giardia muris* cysts: Cold Water Temperatures, Research Institute For Diseases In A Tropical Environment Of The South African Research Council (MRC) (dated 10-24-88).

201.2 Test Summaries:

a. Cysticidal Tests (Effects of Chlorination)

1. Method: Chlorination effects of Chlorofloc
2. Modification: A modification of the methods of Rice and Schaefer (1984) and Bingham and Meyer (1979) was used to induce excystment.
3. Samples:
Giardia muris cysts obtained from Prof E.A. Meyer of the Department of Microbiology and Immunology, The Oregon Health Sciences University, Portland, Oregon, USA. They are maintained in inbred BALB/c mice according to the method described by Roberts-Thomson et al (1976).

Giardia muris cysts were harvested from stool of BLAB/c mice using 1M sucrose as described by Roberts-Thomson et al (1976). Cysts were kept in tap-water at 4°C until used. Cyst numbers were adjusted using a haemocytometer.

4. Dilution: Undiluted

5. Exposure: 7 & 15 minutes at 15°C
 7 & 15 minutes at 10°C
 15 minutes at 5°C

6. Incubation: 20 mins. at 37°C in solution A
 1 hour at 37°C in solution B

Examined microscopically at a magnification of 400X to determine whether excystation had occurred.

7. Test Organism: Giardia lamblia

8. Test Results: Levels of excystment

5°C for 15 minutes	Untreated Control	Chlorfloc Control	Chlorfloc Test	
			<u>Tablets/liter</u> <u>One</u>	<u>Two</u>
Excysted trophozoites viable and non-viable	93.05	84.79	23.12	Nil
Non-excysted intact cysts	6.95	15.21	76.88	100%

10°C for 7 & 15 minutes	Untreated Control	Chlorfloc Control	Chlorfloc Test	
			<u>7 min</u>	<u>15 min</u>
Excysted trophozoites viable and non-viable	97.3	79.6	37.25	Nil
Non-excysted intact cysts	2.7	20.4	62.75	100%

15°C for 7 & 15 minutes	Untreated Control	Chlorfloc Control	Chlorfloc Test	
			<u>7 min</u>	<u>15 min</u>
Excysted trophozoites viable and non-viable	95.4	81.4	9.43	Nil
Non-excysted intact cysts	4.6	18.6	90.57	100%

25°C for 7 minutes	Untreated Control	Chlorfloc Control	Chlorfloc Test
Excysted trophozoites viable and non-viable	92.2	84.7	0
Non-excysted intact cysts	7.8	15.3	100

9. Conclusions: Results show satisfactory performance of the product against Giardia lamblia by chlorination of cysts from contaminated water at temperatures reflecting:

- 5°C 100% kill obtained using 2 tablets for 15 mins.
- 10°C 100% kill obtained using 1 tablet for 15 mins.
- 15°C 100% kill obtained using 1 tablet for 15 mins.
- 25°C 100% kill obtained using 1 tablet for 15 mins.

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Company Name Control Chemical

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202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted cysticidal data are acceptable to support effectiveness of the product as a water disinfectant against Giardia lamblia when tested in simulated turbid hard water by effects of chlorination at cold water temperatures (assuming it to be 5-25°C).

203.0 Labeling

- a. Under "USE DIRECTIONS" label should reflect the same results as in the summary.

Change	22°C	1 tablet	1 min. to
	25°C	1 tablet	7 mins.

Change	15°C	1 tablet	11 mins. to
	15°C	1 tablet	15 mins.

Change	10°C	1 tablet	11 mins. to
	10°C	1 tablet	15 mins.

Change	5°C	2 tablets	11 mins. to
	5°C	2 tablets	15 mins.