2-11-80

TECHNICAL SUPPORT SECTION CHEMISTRY REVIEW-1

Disinfectants Branch

IN 1-31-80 OUT 2-11-80

Reviewed by William E. Campbell Jr. Date February 11, 1980

EPA Reg. No. or File Symbol

EPA Petition or EUP No. 10182-EUP-11

Date Division Received January 23, 1980

Type Product(s): I, (D), H, F, N, R, S Swimming Pool

Data Accession No(s). 241672 & 241673

Product Mgr. No. 32 Castillo

Product Name(s) Baquacil

Company Name(s) ICI Americas Inc.

Submission Purpose 4th Quarterly Report

Addendum - Efficacy

Chemical & Formulation Liquid Concentrate

Product weight 8.816 lbs./gal.

Active Ingredient(s):	%
poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene hydrochloride).	20%

200.0 Introduction

200.1 Use: For experimental use only for evaluation of the product as a swimming pool water disinfectant.

200.2 Background Information: An EUP was issued on December 4, 1978 to evaluate the product for the use indicated in 200.1 above. Efficacy data generated from trials at seven pools (two indoor and five outdoor) in two geographical areas (Pennsylvania and Tennessee) are contained in this report. A detailed report on the performance of the product in the Lower Merion Pool is contained in the efficacy review of the Second Quarterly Report dated August 7, 1979.

201.0 Data Summary

201.2 Brief description of tests

I. OBJECTIVE AND CRITERIA FOR EVALUATION

The objective of this study was to demonstrate, under typical use conditions, the efficacy of BAQUACIL as an antibacterial agent for use in recreational swimming pools in Pennsylvania and Tennessee as per the provisions of Experimental Use Permit No. 10182-EUP-11. The effectiveness of the sanitizer was evaluated by its capacity to control the numbers of three selected, environmentally significant microorganisms when a substantial bather load was present. The specified organisms and the maximum allowable counts, determined by membrane filter assay, are as follows:

Organism	Standard
Total Aerobic Count	200 CFU/ml
Total Coliform	2 CFU/dl
Fecal Streptococci	2 CFU/dl

As per the 1964 Suggested Ordinance and Regulations Covering Public Swimming Pools, paragraph 24.5, stipulated that at least 85% of the sample collected under prescribed bather load and other prescribed conditions shall meet the aforementioned bacterial indices.

Concerning pool loading it was suggested a minimum 25% of the maximum allowed bather load defined in the 1964 Suggested Ordinance, paragraph 12.2 as follows, be used to qualify samples:

a) one bather per 10 ft.^{2} pool water surface area in the non-swimmer area.

b) one bather per 24 ft.^{2} in the swimmer area.

c) 300 ft.^{2} area reserved for diving area.

Control of algae was also evaluated.

II. INVESTIGATIONAL PERSONNEL

The consultants listed below were responsible for the execution of this study, according to the EPA protocol, in Pennsylvania and Tennessee, respectively. They or their associates performed all experimental procedures and recorded all data regarding the study. Routine maintenance of the pool facility was performed by owner-operator staff.

(1) James A. Poupard M.S., S.M. (A.A.M.)
Microbiology Consultant
Penndel Laboratories, Inc.
666 Township Line Road
Havertown, PA 19083

(2) Raymond W. Beck, Ph. D.
Associate Chairman
Department of Microbiology
The University of Tennessee
Knoxville, TN 37916

III. Experimental Sites

The facilities used for testing in this study were:

(1) Sequoyah Square Apartments
3636 Taliluna Avenue
Knoxville, TN 37919

Sequoyah Square pool is an outdoor, in-ground pool with a diving board, serving approximately 180 tennants.

Construction	Concrete with paint
Total Volume	40,000 gallons
Dimensions	40' x 25' x 3-8'
Filter	60" x 40" high rate sand
Turnover Time	3-4 hours (Approx.)
Existing Chlorination System	Solid chlorine sticks with dissolution chamber attached to filter.

(2) Lower Merion School District Pool
301 Montgomery Avenue
Ardmore, PA 19003

Used for instruction, competition, and community recreational swimming, this indoor pool had an average daily bathing load of 400, seven days a week. The following is a description of the pool.

Construction	Concrete, tiled
Total Volume	204,000 gallons
Diving Well	42' x 27' x 12'
Swimming Pool	42' x 75' x 3.5-5.5'
Filter	42" x 48" element; diatomacious earth
Flow Rate	400 gpm
Turnover Time	8 hours
Existing and Back-up Chemical Sanitizer	sodium hypochlorite

(3) Phoenixville Area YMCA
East Pothouse Road
Phoenixville, PA 19460

This pool is chiefly used for recreational lap swimming an d competition. By the nature of use, the maximum loading at any given time is approximately 40-50 swimmers.

Construction	Concrete, painted
Total Volume	147,000 gallons
Dimensions	81' x 45' x 3.5-5.5'
Filter	4.5 x 5' high rate sand
Turnover Time	4.5-5 hours (approx.)
Existing Chemical System	Timed liquid sodium hypochlorite

(4) Surburban Swimming Club
3615 Gradyville Road
Newtown Square, PA 19073

Suburban Swimming Club is an indoor community facility with diving board and an average daily bathing load of 200-300 persons.

Construction	Steel, painted
Total Volume	165,000 gallons
Dimensions	75' x 42' x 3-2'
Filter	30-48" elements; diatomacious earth
Turnover Time	9 hours
Existing Chlorination System	Timed liquid sodium hyporchlorite

(5,6) Meadows Condominium Pools
Gleeson Road
Knoxville, TN 37919

Meadows I pool is an outdoor, in-ground recreational swimming pool with a diving board. Residents of approximately 200 units have access to this pool.

Construction	Concrete with granite finish
Total Volume	47,000 gallons
Dimensions	40' x 30' x 3-7'
Filter	60" x 40" high rate sand
Turnover Time	3-4 hours (Approx.)
Existing Chlorination System	Calcium hypochlorite (HTH) added by hand

Meadows II is an outdoor, in-ground pool with a diving board. It is used exclusively for recreational swimming. Residents of approximately 200 units have access to this pool.

Construction	Concrete with granite finish
Total Volume	32,400 gallons
Dimensions	40' x 20' x 3-7.5'
Filter	2 x 30" fiberglass; high rate sand
Turnover Time	5-6 hours (Approx.)
Existing Chlorination System	Solid chlorine sticks and dissolution compartment attached to filter

(7) Kingston Square Apartment Pool
6315 Kingston Pike
Knoxville, TN 37916

Kingston square pool is an outdoor, in-ground pool with a diving board, used exclusively for recreational purposes by tennants of 180 apartment units.

Construction	Concrete with paint
Total Volume	38,600 gallons
Dimensions	45" x 29" x 3-8" (elongated octagon)
Filter	30" fiberglass; high rate sand
Turnover Time	6 hours (Approx.)
Existing Chlorination System	Solid Chlorine sticks and dissolution compartment attached to filter.

IV. Methods and Materials

Trials were conducted in accordance with the prevailing state and local regulations pertaining to physical, chemical and microbiological standards for swimming pools. Experimental procedures and materials used are described in the efficacy review of August 7, 1979.

Materials and equipment required for analyses described in the "Methods" section are also listed in the efficacy review of August 7, 1979.

V. Neutralizer for the Active Ingredient

EXPERIMENTAL

Three identical test series were prepared in sterile sealed serum bottles. Each series contained a blank consisting of phosphate buffered dilution water (PBDW), a 0.7% lecithin/2% Tween 20 neutralizer control in PBDW, a 50 ppm BAQUACIL control (Mix No. 5889) in PBDW, and a 50 ppm BAQUACIL plus lecithin neutralizer sample. All of the samples were placed in a water bath at 20°C and allowed to come to temperature. The BAQUACIL was added to the BAQUACIL/neutralizer test samples from a 1% stock solution via needle and syringe 15 seconds before inoculation with the test organisms.

The bacterial suspensions were prepared by washing off 48 hours lawns of Escherichia coli, ATCC 11229; Staphylococcus aureus, ATTCC 6538; and Streptococcus faecalis, ATCC 1054, with 5 mls of sterile PBDW. The organism level for each suspension was adjusted to approximately 10^4 Colony Forming Units/ml (CFU/ml) using standard curves and a Klett-Summerson photometer. These three standard suspensions provided the inoculum for each series.

The volume of each test sample was 99 mls. All of the samples were inoculated with 1 ml of standardized suspensions. This dilution of the suspension yielded bacterial numbers of approximately 10^2 in the test samples.

The level of bacteria was monitored, using aeseptic technique, at 0 hrs. for the blanks only in each series and for all samples at 1,2,3, and 4 hours post inoculation by dilution plate counts using Tryptone Glucose Extract Agar. These plates were enumerated after 48 hours incubation at 30°C. Three replicate platings were made for each sample.

Baquacil

During the experimental testing of the product, approximately 650 samples were collected for microbiological analysis. Tables 3 and 4 provide an analysis of the performance of the product in pools with 10 or more bathers present during pool sampling.

Table 3 describes the performance of BAQUACIL versus each of the three required indicator organisms, as well as staphylococci. In Recommended Regulations Concerning Operation and Maintenance of Public Swimming Pools, 1978 Revision, prepared by The Public Health Joint Committee on Swimming Pools and Bathing Places (APHA), the proposed standard for staphylococci is 50 CFU/dl. An interpretation of the data, according to the standing and proposed standards, clearly shows that BAQUACIL is efficacious with respect to control of individual species or categories of bacteria. Passing rates for samples from all pools average 98.8% for total aerobic count, 89.7% for total coliforms, 97.7% for fecal streptococci and 98.8% for staphylococci.

BAQUACIL exhibited at least 85% control in four of the five pools and on a cumulative average passed the 85% specification (Table 4). Even when the $\geq$ 10 bather load qualified samples were evaluated against a quadruple jeopardy microbiological criterion (i.e. the three EPA specified organism + the proposed staphylococci standards), BAQUACIL again surpassed the 85% passing sample specification in four of the five pools, and the BAQUACIL pools overall passed the 85% specification.

Analysis was performed on data representing samples taken when the number of bathers was 25% of the maximum allowable bather load, calculated for the individual pools according to the details previously given. The results of this analysis (Table 5 and 6) show that essentially all five pools under BAQUACIL treatment and heavy bather loads met the 85% passing sample specification and on overall cumulative average have a greater than 90% passing score. The three out of 39 failures (Table 9) occurred when the product concentration was below 10 ppm (i.e. less than 1/3 of the recommended minimum level). Experience indicates the preferred product concentration range to be 30-50 ppm.

Neutralizer

Three series of samples were prepared to be tested against Escherichia coli, ATCC 11229; Staphylococcus aureus, ATCC 6538; and Streptococcus faecalis, ATCC10541. Each test series contained a blank, a lecithin/TWEEN 20 neutralizer control, a BAQUACIL control and a BAQUACIL + neutralizer (lecithin/Tween 20) sample. After inoculation with the test bacteria, each sample was monitored at designated time intervals for viable bacteria. After one hour, the BAQUACIL control in each series contained no viable bacteria. At the end of the four hour test period, the remaining samples showed no significant difference in the bacterial numbers in the blank versus those of the lecithin/Tween 20 neutralizer and the BAQUACIL + neutralizer for any of the test organisms. This demonstrates that the Lecithin/TWEEN 20 combination gave effective neutralization of BAQUACIL and did not have an adverse impact on bacterial numbers. The figures in Table 7 represent the average value of replicate plating results.

EXHIBIT I

SUMMARY OF EUP POOL TRIALS

Pool	Period on Chlorine (total days)	BAQUACIL Testing Conversion Date	BAQUACIL Testing Duration (days)	Comments
Kingston Square Knoxville, TN	23	June 13, 1979	42	• excellent performance • terminated because of filter blockage due to inadequate backwashing
Meadows I Knoxville, TN	23	June 13, 1979	94	• near perfect operation • one algae problem easily solved according to instructions
Meadows II Knoxville, TN	18	June 13, 1979	94	• near perfect operation • one algae problem easily solved according to instructions
Lower Merion Ardmore, PA	38	March 8, 1979	16	• inadvertently contaminated with anionic detergent--test terminated because of inconvenience
Phoenixville YMCA Phoenixville, PA	2	June 10, 1979	74	• water maintained in good to excellent conditions • filter support collapsed during last week of testing
Sequoyah Square Knoxville, TN	10	July 12, 1979	30	• water excellent at all times • same management as Kingston Square returned to chlorine because of perceived threat to filter system
Suburban Swimming Club Newtown Square, PA	16	May 29, 1979	78	• deteriorated filter and inadequate maintenance on a continuing basis resulted in excess particulates in water including DE from filter coat
Cumulative	130		428	

Table 1

PERFORMANCE OF CHLORINE VS. INDIVIDUAL CATEGORIES OF BACTERIA WHEN BATHER LOAD AT SAMPLING ≥ 3 AND FREE CHLORINE ≤ 0.4 ppm and 7.2 ≤ pH ≤ 7.8

Pool	Total Samples	Samples Within Specification							
		Total Aerobic Bacteria		Total Coliforms		Fecal Staphylococci		Staphylococci	
		Number	%	Number	%	Number	%	Number	%
Kingston Square	6	3	50.0	6	100.0	6	100.0	6	100.0
Meadows I	3	3	100.0	3	100.0	3	100.0	3	100.0
Meadows II	3	0	0	3	100.0	2	66.7	3	100.0
Lower Merion	none qualified -- bathing load < 3								
Phoenixville YMCA	none qualified -- bathing load < 3								
Sequoyah Square	9	9	100.0	8	88.9	5	55.6	7	77.8
Cumulative	21	15	71.4	20	95.2	16	76.2	19	90.5

Table 2

PERFORMANCE OF CHLORINE VS. COMBINED TOTAL AEROBIC BACTERIA, TOTAL COLIFORMS AND FECAL STREPTOCOCCI TRIPLE JEOPARDY CRITERION WHEN BATHER LOAD AT SAMPLING ≥ 3 AND FREE CHLORINE ≥ 0.4 ppm and $7.2 \leq$ pH ≤ 7.8

Pool	Samples Within Specifications		Samples Outside Specifications	
	Number	%	Number	%
Kingston Square	3	50.0	3	50.0
Meadows I	3	100.0	0	0
Meadows II	0	0	3	100.0
Lower Merion	none qualified -- bathing loads < 3			
Phoenixville YMCA	none qualified -- bathing loads < 3			
Sequoyah Square	5	55.6	4	44.4
Cumulative	11	52.4	10	47.6

Table 3

PERFORMANCE OF BAQUACIL VS. INDIVIDUAL CATEGORIES OF BACTERIA WHEN BATHER LOAD AT SAMPLING ≥ 10

Pool	Total Samples	Samples Within Specification: Total Aerobic Bacteria Number	%	Total Coliforms Number	%	Fecal Streptococci Number	%	Staphylococci Number	%
Kingston Square	12	12	100.0	11	91.7	12	100.0	12	100.0
Meadows I	9	9	100.0	9	100.0	9	100.0	9	100.0
Meadows II		none qualified -- bathing loads <10							
Lower Merion	12	12	100.0	12	100.0	12	100.0	11	91.7
Phoenixville YMCA	51	50	98.0	43	84.3	49	96.1	51	100.0
Sequoyah Square	3	3	100.0	3	100.0	3	100.0	3	100.0
Cumulative	87	86	98.8	78	89.7	85	97.7	86	98.8

Table 4

PERFORMANCE OF BAQUACIL VS. COMBINED TOTAL AEROBIC BACTERIA, TOTAL COLIFORMS AND FECAL STREPTOCOCCI TRIPLE JEOPARDY CRITERION WHEN BATHER LOAD AT SAMPLING ≥ 10

Pool	Samples Within Specifications		Samples Outside Specifications	
	Number	%	Number	%
Kingston Square	11	91.7	1	8.3
Meadows I	9	100.0	0	0
Meadows II	none qualified -- bathing loads <10			
Lower Merion	12	100.0	0	0
Phoenixville YMCA	40	78.4	11	21.6
Sequoyah Square	3	100.0	0	0
Cumulative	75	86.2	12	13.8

Table 5

PERFORMANCE OF BAQUACIL VS. INDIVIDUAL CATEGORIES OF BACTERIA AT SPECIFIED MINIMUM BATHER LOADS AT SAMPLING

Pool/Minumum Load	Total Samples	Sample Within Specification: Total Aerobic Bacteria Number	%	Total Coliforms Number	%	Fecal Streptococci Number	%	Staphylococci Number	%
Kingston Square/11	9	9	100	9	100	9	100	9	100
Meadows I/13	3	3	100	3	100	3	100	3	100
Lower Merion/21	6	6	100	6	100	6	100	5	83.3
Phoenixville YMCA/21	18	18	100	15	83.3	18	100	18	100
Sequoyah Square/9	3	3	100	3	100	3	100	3	100
Cumulative	39	39	100	36	92.3	39	100	38	97.4

Table 6

PERFORMANCE OF BAQUACIL VS. COMBINED TOTAL AEROBIC BACTERIA, TOTAL COLIFORMS AND FECAL STREPTOCOCCI TRIPLE JEOPARDY CRITERION AT SPECIFIED MINIMUM BATHER LOADS AT SAMPLING

Pool/Minumum Load	Samples Within Specifications		Samples Outside Specifications	
	Number	%	Number	%
Kingston Square/11	9	100	0	0
Meadows I/13	3	100	0	0
Lower Merion/21	6	100	0	0
Phoenixville YMCA/21	15	83.3	3	16.7
Sequoyah Square/9	3	100	0	0
Cumulative	36	92.3	3	7.7

TABLE 7

BAQUACIL NEUTRALIZER EFFICACY

Sample	Organism	0	1	2	3	4
Blank	E.C.	1.2×10^2	9.7×10^1	7.0×10^1	9.0×10^1	9.7×10^1
Blank	S.A.	6.0×10^2	5.6×10^2	3.2×10^2	3.6×10^2	4.8×10^2
Blank	S.F.	2.4×10^2	1.8×10^2	1.7×10^2	1.5×10^2	2.3×10^2
Control 0.7% lecithin 2.0% Tween 80	E.S.	--	9.3×10^1	1.0×10^2	1.3×10^2	1.0×10^2
	S.A.	--	8.1×10^2	8.3×10^2	8.3×10^2	8.3×10^2
	S.F.	--	2.5×10^2	2.1×10^2	2.5×10^2	2.2×10^2
Control 50 ppm BAQUACIL	E.C.	--	<10	<10	<10	<10
	S.A.	--	<10	<10	<10	<10
	S.F.	--	<10	<10	<10	<10
BAQUACIL @ 50 ppm + 0.7% lecithin/ 2.0% Tween 20	E.C.	--	7.6×10^1	1.2×10^2	1.4×10^2	9.0×10^1
	S.A.	--	8.1×10^2	8.4×10^2	7.6×10^2	8.3×10^2
	S.F.	--	1.8×10^2	2.5×10^2	2.2×10^2	2.1×10^2

Organism Key: EC = Escherichia coli, ATCC 11229
SA = Staphylococcus aureus, ATCC 6538
SF = Streptococcus faecalis, ATCC 10541

The above figures represent survivors given in Colony Forming Units/ml (CFU/ml)

TECHNICAL SUPPORT SECTION CHEMISTRY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 10182-EUP-11

Date Division Received January 23, 1980

Product Manager No. 32 Castillo

Product Name(s) Baquacil

Company Name(s) ICI Americas Inc.

202.0 Conclusions and Recommendations

202.1 Claims Related to Human Health

202.1.1 Efficacy supported by the data: The efficacy data generated under the EUP together with the data submitted in support of the application for the EUP are considered adequate to support efficacy of the product as a swimming pool water disinfectant at a product concentration of 30-50 ppm.

202.2 Claims Not Related to Human Health

Pursuant to Section 3(c)(5) of the FIFRA, as amended by the Federal Pesticide Act of 1978, and under the provisions of 40 CFR 162.18-2, claims for control of microorganisms not directly related to human health do not require supporting efficacy data. On this basis, algicidal claims for the product do not require supporting efficacy data. Therefore, the algicidal and algistatic data contained in the submitted report are not summarized in this review.

203.0 Comments to be Resolved Prior to Registration

203.1 Additional Data

Test Kit

The effectiveness of the product as a swimming pool water disinfectant is dependent on maintaining the desired concentration in the pool water. Since under normal use conditions the test kit will be used to determine product concentration in the water, the precision and accuracy of the test kit must be provided.

203.2 Labeling

A. Effective Dosage Range

Based on data generated under the EUP, the lowest acceptable level of product in the pool water, before a top-up dose is required must be specified.

B. Compatibility

Since the recommendations for using most algicides and oxidizing agents in swimming pools are based on the campatibility of the chemicals with chlorine, appropriate precautionary wording against using commonly recommended algicides and/or oxidizing agents known to be incompatible with this product must be provided in labeling.

C. The meaning of compatibility shall also include consideration for the comfort of the pool user. Therefore, the parameters of alkalinity and/or hardness of pool water chemistry necessary for optimum bather comfort must be addressed in labeling.