TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 7-19-79 OUT 8-7-79

Reviewed by William E. Campbell, Jr. Date August 7, 1979

EPA Reg. No. or File Symbol

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Date Division Received

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

Data Accession No(s). 238825

Product Mgr. No. 32 Castillo

Product Name(s) Baquacil

Company Name(s) ICI Americas Inc.

Submission Purpose 2nd Quarterly Report

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 collected from the trial at the Lower Merion School pool are contained in this report.

201.0 Data Summary

201.1.1 Brief description of tests

A. OBJECTIVE AND CRITERIA FOR EVALUATION

It is the objective of this study to demonstrate, under typical field conditions, the efficacy of BAQUACIL as an antibacterial agent for use in recreational swimming pools. The relative effectiveness of the disinfectant will be evaluated by its capacity to control the numbers of selected, environmentally significant microorganisms: total bacteria, total coliform, fecal coliform, fecal streptococci, Staphylococcus aureus, and Pseudomonas aeruginosa.

B. INVESTIGATIONAL PERSONNEL

The consultant listed below was responsible for the execution of this study, according to the EPA protocol. He or his associates performed all experimental procedures and recorded all data regarding the study. Routine maintenance of the pool facility was performed by owner-operator staff.

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C. EXPERIMENTAL SITE

The facility used for testing in this study was:

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

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

| | |
|---|---|
| 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 DE |
| Flow Rate | 400 GPM |
| Turnover Time | 8 hours |
| Existing and Back-up Chemical Sanitizer | sodium hypochlorite |

D. METHODS

This trial was 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 prescribed or referenced below.

1. Sampling & Schedule - Samples for microbiological, routine chemistry, and sanitizer analyses were taken both in the morning and afternoon, generally on alternate days. Triplicate samples, designated A, B, and C were always taken from the same locations in the swimming pool, away from inlets. Subsurface specimens were collected in sterile, one liter bottles containing the appropriate neutralizer.

2. Pool Treatment with BAQUACIL - The pool was prepared for maintenance on BAQUACIL by the procedures described in Technical Bulletin. Target, working concentrations of BAQUACIL were 50 ppm (10 ppm a.i.).

3. Estimation of BAQUACIL Concentrations - Samples were taken from the pool for estimation of BAQUACIL concentration. Assay were performed by the consultant or his assistant. Additionally, a test kit was available for use at pool-side.

4. Clarification of Water with Hydrogen Peroxide - As BAQUACIL is not a chemical oxidant it was necessary to treat the pool with a shock dose of $H_2O_2$ to remove particulate material and oxidizable chemicals from pool water.

5. Bacteriological Analyses - Six categories of bacteria were enumerated by the techniques described in 201.2B of our review of the proposed experimental use program dated April 17, 1978.

   Within one-half hour of collection time, appropriate volumes of neutralized sample were filtered, and the membranes were placed onto solid media. Following incubation, bacterial colonies were counted, and the data were recorded on prepared forms.

6. Chemical Analyses - Pool water was characterized by chemical analysis once before treatment with BAQUACIL and once after conversion to BAQUACIL.

   Hardness, alkalinity, and pH were determined at each sampling using kits by Bausch & Lomb and Taylor.

7. Physical Characteristics - Physical characteristics of pool water, including temperature, color, and clarity were determined. Water clarity was evaluated by the procedure given in Suggested Ordinance and Regulations Governing Public Swimming Pools, section 24.4, APHA.

8. Pool Use and Bathing Load - Days and hours during which the pool facility is available for use are recorded. The number of persons using the pool were determined or estimated daily.

E. MATERIALS AND EQUIPMENT

Materials and equipment required for the analyses described in the "Methods" section are listed below.

1. Pool Treatment

(a) BAQUACIL - 20% solution of polyhexamethylene-biguanide hydrochloride, supplied in 6-gallon drums.

(b) Hydrogen Peroxide - E I DuPont technical grade, or equivalent, 50%, oxidation of particulate material.

(c) Sodium Thiosulfate Crystals - neutralization of chlorine at start-up.

(d) Hydrochloric acid, sodium bisulfate, sulfamic acid, sodium carbonate, sodium bicarbonate - commonly used chemicals for adjustment of pH.

(e) Aluminum Sulfate - commonly used as clarifying agent.

2. BAQUACIL Analysis

(a) BAQUACIL Test Kit, ICI Ltd., complete.

(b) Colorimetric Determination - Spectrophotometer assay procedure.

3. Microbiological Analyses

Material and equipment, or equivalent, as described in the references cited in 201.1.1 D-5 above.

201.1.2 Data summaries

A. Chlorine

The NaOCl-treated water of LMP was monitored over a period of 38 days to obtain a base of data to which the BAQUACIL system could be compared. During this time samples were

taken on twelve different days, twelve in the morning to represent light loading or a resting period and nine in the afternoon immediately following routine use of the pool. Table I summarizes information gathered on the chlorinated pool water.

Six categories of bacteria were enumerated according to the Millipore technique. Sample volumes filtered were 100ml per triplicate sample, except when dilutions or split samples were necessary because of expected large numbers of organisms, and the numbers appearing in Table I are averages of the triplicates.

B. BAQUACIL

Lower Merion pool was converted to BAQUACIL treatment on March 8, 1979. Free and combined chlorine were neutralized by the addition of 2.5 kg (5.5 lbs) sodium thiosulfate, and when no free or combined chlorine could be detected in the water (DPD method) the pool was charged with 10.05 gallons of BAQUACIL.

Within half-an-hour a slight haze had developed; although the main drain as well as one-inch tiles at the 12 foot depth could be seen at all times. The filtration system completely removed the particulate material, so that by 8:00 AM on March 10th the water was perfectly clear.

Monitoring of the pool water continued, according to protocol, as with the chlorinated system, covering a period of 16 days. A summary of data collected during this time is presented in Table 2.

201.1.3 Discussion of results

A. Chlorine

Few coliforms, fecal coliforms, or fecal streptococci were recovered. On one occasion (2/28/79 PM) the number of fecal streptococci exceeded (6 CFU/100 ml) the specified standard of 1 CFU/50 ml. The total aerobic count averaged 182 (SD=327) CFU/ml in AM samples increasing to 476 (SD=549) CFU/ml in PM samples. Clearly, a portion of this population of bacteria were staphylococci which numbered 28 (SD=39)

CFU/100 ml in AM samples and a greatly increased 6714 (SD5067) CFU/100 ml in PM samples. By calculation staphylococci accounts for 0.15% of the morning total aerobic count and 14.11% of the afternoon total count.

> Forty-three percent of all total aerobic counts exceeded the standard of 200 CFU/ml.

The chlorine level in the pool averaged 0.63 ppm (SD=0.098) (DPD). At six of 21 observations the concentration was <0.7 ppm the target level of the automated (Enviroscan) chlorine control system. It is difficult to correlate the numbers of bacteria recovered at any given time with the corresponding concentrations, although there is a definite pattern of drastic increase in bacterial numbers with increased bathing load.

Daily bathing loads were generally on the order of 400 persons. The numbers of bathers in the pool at the time of sampling and during the preceeding hour were recorded. The bathing load averaged 12.8 (SD=18) at sampling and 17.3 (SD=10.4) for the preceeding hour.

B. Baquacil

All bacterial counts were within the standards specified in 202.5 of the review previously cited. No coliforms, fecal coliforms, fecal streptococci, or Pseudomonas aeruginosa were detected. The total aerobic count averaged <1.0 (SD=0) CFU/100ml in the AM samples and increased to <5.5 (SD=8.09) CFU/100ml in the PM samples, compared to the standard of 200 CFU/ml. Staphylococcus counts were greater than 100 CFU/100ml only 25% of the time. The other 75% of the samples contained an average of 6.8 (SD=9.15) CFU/100ml. One of the higher (TNTC) counts (March 16th, PM) is questionable because the corresponding total count is 1.0 CFU/ml or 100 CFU/100ml.

Following the initial charge of 10.05 gallons of BAQUACIL a total of 6.5 gallons was added at four separate times as replenishment. On March 23 the BAQUACIL concentration was assayed at 29 ppm, equivalent to approximately 6 gallons of BAQUACIL in the water, assuming 5 ppm per gallon in the



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204,000 gallon pool. Therefore, about 10.5 gallons were consumed over the sixteen-day period.

The average concentration of BAQUACIL was 33.1 (SD=6.17)ppm. Except for one occasion when the level dropped to 21 ppm and the total count was found to be 19 CFU/ml and the Staphylococci were more numerous, bacterial counts did not seem to correlate with any recorded changes in BAQUACIL level.

Shortly after the conversion to BAQUACIL treatment a generalized, adverse effect upon swimmers eyes was observed. Approximately half of the swimmers were noticeably affected. Within 15 minutes after entering the water they experienced a stinging sensation and redness in the white area of the eye. The effect was transient and was described by several bathers to be no worse than any they had experienced with chlorine.

It is generally accepted that swimmer comfort is optimum when total alkalinity is above 80 ppm, pH is near 7.5, and the water is free from irritants such as chloramines and particulates not removed by filtration. Therefore, in an effort to alleviate the eye irritation problem. Attention was directed to these parameters of pool water chemistry.

Total alkalinity was raised from 40-60 ppm to 100-120 ppm by the addition of sodium bicarbonate. Hydrogen peroxide was added to the pool (35 ppm $H_2O_2$) to oxidize particulate matter and irritants compounds such as chloramines. Lastly, the pH was carefully maintained at 7.5 $\pm$ 0.1. These adjustments were accomplished on March 16 and 17.

Complete elimination of the eye irritation problem, as well as enhanced clarity, resulted from the measures described above.

The average bathing load at sampling was 7.69 (SD=9.67) and 18.6 (SD=17.1) the preceeding hour.

For the purpose of computing user loading, the total pool area (3105 sq. ft.) was designated as the "swimming

area."1/ On the basis of 24 sq. ft. per swimmer the maximum bather load for the pool would be 131 swimmers.2/

For the sampling period covered by the report (3/8/79-3/23/79) a total of 16 samples in triplicates, were collected. Of this number, 15 (93.75%) were collected when the bathing load was <25% of maximum at sampling and <50% of maximum the preceeding hour.

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1/ Suggested Ordinance and Regulations Covering Public Swimming Pool, (1964) APHA, New York. Par. 12.1

2/ Ibid. Par. 12.2

TABLE 1

BACTERIA RECOVERED FROM WATER TREATED WITH SODIUM HYPOCHLORITE

| | | Total Count** | Total Coli-form* | Fecal Coli-form* | Fecal Strep.* | Staph.* | Ps.aeru-ginosa * | Chlorine (ppm) | Bathing Load at sam-pling | Bathing Load preceeding hour |
|---|---|---|---|---|---|---|---|---|---|---|
| 1/29/79 | AM | 11 | 0 | 0 | 0 | 55 | 0 | 0.7 | 19 | 22 |
| | PM | 159 | 0 | 0 | - | 11,398 | 0 | 0.7 | 35 | -- |
| 1/31/79 | AM | 2 | 0 | 0 | 0 | 10 | 0 | 0.7 | 2 | 18 |
| | PM | 222 | 2 | 0 | - | 6,843 | 0 | 0.7 | 40 | 23 |
| 2/2/79 | AM | 373 | 0 | 0 | 0 | 1 | 0 | 0.7 | 0 | 22 |
| | PM | 363 | 2 | 0 | - | 12,500 | 0 | 0.3 | 65 | -- |
| 2/5/79 | AM | 18 | 0 | 0 | 0 | 2 | 0 | 0.5 | 0 | 14 |
| | PM | 103 | 1 | 0 | 0 | 7,100 | 0 | 0.5 | 12 | -- |
| 2/8/79 | AM | 964 | 0 | 0 | 0 | 14 | 0 | 0.7 | 1 | 25 |
| | PM | 932 | 0 | 0 | 2 | 18 | 0 | 0.7 | 9 | 22 |
| 2/9/79 | AM | 705 | 0 | 0 | 0 | 24 | 0 | 0.7 | 2 | 40 |
| | PM | 437 | 0 | 0 | 1 | 3,700 | 0 | 0.3 | 0 | 12 |
| 2/12/79 | AM | 7 | 0 | 0 | 0 | 8 | 0 | 0.7 | 2 | 14 |
| | PM | 225 | 0 | 0 | 1 | 13,833 | 0 | 0.2 | 0 | 9 |
| 2/14/79 | AM | 2 | 0 | 0 | 1 | 139 | 0 | 0.7 | 0 | 0 |
| | PM | | | | | | | | | |
| 2/26/79 | AM | 3 | 0 | 0 | 1 | 11 | 0 | 0.8 | 26 | 20 |
| | PM | | | | | | | | | |
| 2/28/79 | AM | 3 | 0 | 0 | 0 | 13 | 0 | 1.0 | 26 | 20 |
| | PM | 1767 | 0 | 0 | 6 | 281 | 0 | 0.9 | 0 | 26 |
| 3/2/79 | AM | 66 | 0 | 0 | 0 | 4 | 0 | 0.7 | 0 | 0 |
| | PM | | | | | | | | | |
| 3/7/79 | AM | 24 | 0 | 0 | 1 | 52 | 0 | 0.7 | 30 | 25 |
| | PM | 77 | 0 | 0 | 0 | 4754 | 0 | 0.4 | 0 | 0 |

* CFU/100ml ** CFU/1ml

TABLE 2

BACTERIA RECOVERED FROM WATER TREATED WITH BAQUACIL SANITIZER

| | | Total Count*** | Total Coli-form* | Fecal Coli-form* | Fecal Strep.* | Staph.* | Ps.aeru-ginosa* | BAQUACIL (ppm) | Bathing Load at sam-pling | Bathing Load preceeding hour |
|---|---|---|---|---|---|---|---|---|---|---|
| 3/8/79 | AM | | | | | | | | | |
| | PM | < 1 | 0 | 0 | 0 | 31 | 0 | 44 | 8 | 0 |
| 3/10/79 | AM | < 1 | 0 | 0 | 0 | 14 | 0 | 38 | 8 | 65 |
| | PM | < 1 | 0 | 0 | 0 | 13 | 0 | 37 | 13 | 15 |
| 3/12/79 | AM | < 1 | 0 | 0 | 0 | 2 | 0 | 34 | 9 | 25 |
| | PM | 19 | 0 | 0 | 0 | >575 | 0 | 21 | 23 | 21 |
| 3/14/79 | AM | < 1 | 0 | 0 | 0 | 1 | 0 | 42 | 0 | 15 |
| | PM | < 1 | 0 | 0 | 0 | 1 | 0 | 35 | 3 | 14 |
| 3/15/79 | AM | < 1 | 0 | 0 | 0 | 11 | 0 | 39 | 3 | 23 |
| | PM | 20 | 0 | 0 | 0 | 902 | 0 | 35 | 0 | 0 |
| 3/16/79 | AM | < 1 | 0 | 0 | 0 | 4 | 0 | 29 | 0 | 10 |
| | PM | < 1 | 0 | 0 | 0 | >600** | 0 | 30 | 0 | 0 |
| 3/19/79 | AM | | | | | | | | | |
| | PM | 0 | 0 | 0 | 0 | 0 | 0 | 33 | 12 | 45 |
| 3/21/79 | AM | < 1 | 0 | 0 | 0 | 3 | 0 | 24 | 35 | 25 |
| | PM | 6 | 0 | 0 | 0 | 157 | 0 | 30 | 7 | 9 |
| 3/23/79 | AM | < 1 | 0 | 0 | 0 | 0 | 0 | 30 | 0 | 25 |
| | PM | < 1 | 0 | 0 | 0 | 2 | 0 | 29 | 2 | 6 |

3/13/79 - 4 gallons BAQUACIL added
3/19/79 - 0.5 gallons BAQUACIL added
3/21/79 - 1.0 gallons BAQUACIL added
3/22/79 - 1.0 gallons BAQUACIL added

* CFU/100ml
** TNTC
*** CFU/1ml

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

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

Date Division Received July 16, 1979

Product Manager No. 32 Castillo

Product Name Baquacil

Company Name ICI Americas Inc.

202.0 Conclusions and Recommendations

202.1 Experimental Use Program

While we realize that all samples cannot be collected when the number of persons using the pool during the preceeding hour has been equal to at least 50% of the maximum bathing load of the pool and the number of persons in the pool water at the time samples are collected is equal to at least 25% of the maximum bathing load, an effort should be made to include more samples collected under high bather loading conditions. For the submitted report, 15 or 93.75% of the samples were not collected under the conditions indicated. (Considering the total pool area, 3150 sq. ft., as swimming area and allowing 24 sq. ft./ swimmer).

203.0 Comments to be Resolved Prior to Registration

203.1 Additional Data

A. Neutralizer

Data must be submitted to show that the neutralizer employed inactivates the active ingredient and does not possess antimicrobial activity per se.

B. 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

compatibility 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.