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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 22, 2002

MEMORANDUM

SUBJECT: Review of Data to Support an Experimental Use Permit for Frog Mineral Reservoir
EPA File Symbol: 53735-EUP-R
DP Barcode: D277230

FROM: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

TO: Marshall Swindell PM-33/Tony Kish
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: King Technology
530 11th Avenue, South
Hopkins, MN 55343

Formulation

Active Ingredient	Percent
Silver Chloride	0.5%

I Background

King Technology is applying for an Experimental Use Permit (EUP) to conduct swimming pool field studies on their product Frog Mineral Reservoir. The product is designed to be used with chlorine to eliminate bacteria, prevent algae and help maintain a neutral pH in swimming pools. The product would allow the chlorine residual to be reduced from 0.6 ppm to 0.4 ppm available chlorine, yet maintain its effectiveness as a swimming pool disinfectant. The product is installed in the recirculation system of the pool whereby the water flowing through the system passes through a bed of granular calcium carbonate coated with silver chloride. Hydrated silver ions are then released into the recirculating water. The hydrated silver ions

have a low level of biocidal effectiveness and while this is not sufficient alone to maintain the disinfectant level in a swimming pool, it does allow a reduction in the amount of available chlorine needed to properly disinfect the pool.

An experimental use permit (EUP) for swimming pool products is needed to confirm the findings from presumptive efficacy testing conducted in the laboratory studies. The testing under the EUP employs actual field conditions and requires the product to be tested in outdoor swimming pools for an entire swimming season (4 - 12 months).

Included with this EUP are the following: a proposed protocol for conducting the field studies; a rationale for the proposed indoor pool testing and bather load; the presumptive laboratory efficacy test, MRID # 454488-02; the Confidential Statement of Formula; and a proposed label. The laboratory study was conducted by MicroBiotest, Inc, a commercial testing facility located in Sterling, Virginia. The author of the study is Donna B. Suchmann.

II USE DIRECTIONS

For Experimental Use Only
The Frog Mineral Reservoir is part of a complete pool care system when used correctly with 0.4-1.0 ppm chlorine levels will eliminate bacteria, prevent algae and help maintain a neutral pH in swimming pools.

This product should only be used in the Frog Cycler. Check the Frog Mineral Reservoir (FMR) label to make sure you have the correct FMR for you Frog Cycler. Use only the factory recommended FMR. Use of any other product could result in damage to pool equipment or surface, unsafe pool conditions, fire or explosion. Do not use this product for more than 6 months.

III AGENCY STANDARDS

Numerous factors influence the concentrations necessary for disinfection of swimming pool water in practical applications: numbers of swimmers in the pool; frequency of use; frequency with which water is changed; general weather conditions; and types and degree of organic contamination of the water by the swimmers themselves (e.g., suntan lotions and oils) and by various debris. Therefore, a two-phased study (presumptive laboratory testing and confirmatory field testing) is required.

(1) Laboratory test requirements: Presumptive efficacy of swimming pool water disinfectants may be substantiated with data derived from the AOAC Method for Water Disinfectants for Swimming Pools or with slight modifications (e.g., pH) thereof, against both *Escherichia coli* (ATCC 11229 and *Enterococcus faecium* (ATCC 6569).

(2) Performance standard for laboratory test. The lowest concentration of the test germicide providing results equivalent to those of the sodium hypochlorite control is the lowest concentration of the product that can be considered effective.

(3) Field test requirements. In addition to the laboratory test requirements referred to above, confirmatory efficacy data shall be derived from in-use tests under an Experimental Use Permit in at least two swimming pools. The tests must be conducted for an entire swimming season (4 to 12 months).

(4) Performance standard for field test.

The product, when used as recommended in swimming pool water, should demonstrate that not more than 15% of the samples collected shall fail to meet the following bacterial indices.

(i) The standard plate count at 35° shall not exceed 200 colonies per 1.0 ml.

(ii) The most probable number of coliform bacteria shall be less than 2.2 organisms per 100.0 milliliter. When the membrane filter test is used there shall be no more than 1.0 coliform organisms per 50 ml.

(iii) The most probable number of entercoccal organisms shall be less than 2.2 organisms per 100.0 milliliter. When the membrane filter test is used there shall be no more than 1.0 enterococcal organisms per 50 ml.

IV SUMMARY OF THE SUBMITTED STUDY

MRID # 454488-02 AOAC Official Method Disinfectants for Swimming Pools (Presumptive Efficacy Test). Study completion date, June 11, 2001

1 mL of the test microorganism was added to 199 mL of the test substance. The test substance consisted of a range of silver ions (0 ppb - 34 ppb) and an available chlorine residual of 0.4 ppm or 0.6 ppm. Inoculated flasks were tested at 20 - 23°C. At intervals of 0.5, 1, 2, 3, 4, 5, and 10 minutes post-inoculation, 1 mL samples were withdrawn from the flasks and transferred to neutralizer blanks containing 9 ml of phosphate buffer dilution water with 0.1% sodium thiosulfate. Solutions were shaken thoroughly, ten-fold serial dilutions were prepared and plated on the appropriate agar medium. In addition, five tryptic soy broth subculture tubes were inoculated with 1 mL aliquots for each *E. coli* neutralizer tube and five fluid thioglycollate broth subculture tubes were inoculated with 1 mL aliquots from each *E. faecium* neutralizer tube. All dilution plates and subculture tubes were incubated for 48 ± 2 hr at 37 ± 2°C. Initial counts for *E. coli* were: 1.1×10^6 cfu/mL, and for *E. faecium*, the initial counts were 1.0×10^6 cfu/mL. Both met the criterion count of $>9.9 \times 10^5$ cfu/mL. Sodium hypochlorite control solutions were used to demonstrate that appropriate levels of chlorine both before the test and after microbial challenge were met.

V RESULTS

The average colony forming unit per mL at each time point was reported as $<1.0 \times 10^1$, for the silver ion concentrations from 0 ppb - 34 ppb at both 0.4 and 0.6 ppm

available chlorine. All subculture tubes were negative for growth. Test results using *E. coli* and 0 ppm available chlorine in solutions with 6 ppb - 34 ppb silver ions, demonstrated a >3.0 x 10^4 average cfu/mL recovery on agar plates and growth in all the subculture tubes. The sodium hypochlorite control met the test acceptance criteria against *E. coli* and *E. faecium*, with complete kill in 0.5 minutes.

VI COMMENTS ON THE SUBMITTED DATA

MRID # 454488-02

The submitted presumptive laboratory study demonstrates the ability of reduced levels of available chlorine (0.4 ppm) to kill the challenge microorganisms, *Escherichia coli* (ATCC 11229) and *Enterococcus faecium* (ATCC 6569) within a 0.5 minute contact time. This level of effectiveness was achieved even in the absence of silver ions. The test results presented in the study were for levels of silver ions from 0 ppb - 34 ppb in the presence of the reduced chlorine levels (0.4 ppm). All the subculture tubes were negative for growth. Therefore, the results of the test indicate that silver ions do not contribute to the killing ability of 0.4 ppm available chlorine in water.

VII BRIEF DESCRIPTION OF PROPOSED EUP

The stated objective of the EUP is as follows: "The proposed study is intended to substantiate the disinfectant effectiveness of a combination product consisting of chlorine plus a proprietary silver release system, both intended for use in swimming pools. The amount of free available chlorine (FAC) that will be maintained in the water within each pool during the study will be between 0.4 and 1 ppm."

King Technology, Inc. is proposing the use of two above ground pools at their facility in Hopkins, Minnesota, which will be fitted with the Frog Mineral Reservoir and used in this study. The applicant also proposes a bather load of one person in each pool for a period of 15 minutes per day for 5 days a week. The pools have the following specifications: approximately 3000 gallons, turn-over rate of 2 hours, and 100 sq. ft. cartridge filter. Water in each pool will be circulated at least 8 hours daily. Human bathers will use each pool at least 5 days per week. A minimum of 144 samples will be collected during the six-month test period and undergo microbiological examination. A subset of this number will undergo physical and chemical analysis.

Water samples will be taken at opposite sides of each swimming pool in the shallow area, away from the inlets, over the six-month test period. Microbiological examination of the samples will be based on the membrane filter methods described in Standard Methods for the Examination of Water and Waste Water, 17th Edition, 1987, for heterotrophic bacteria, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, and fecal coliform bacteria.

Additional parameters to be measured on a daily basis: free chlorine, silver ions, pH, air temperature, pool water temperature, clarity/turbidity, bather load, and bacterial load. On a monthly basis the iron, copper, alkalinity, nitrogen ammonia, calcium hardness and chloride levels will be measured.

VIII COMMENTS ON EUP PROTOCOL

In the EUP application, King Technology, Inc. proposes the use of two 3000 gallon indoor above ground pools. The company's rationale for this use is because they are unable to test the product for the full six-month period in outdoor pools in Minnesota nor they were unable to identify a contract testing laboratory willing or capable of performing a six-month test in any location. The company also states that the Frog Mineral Reservoir "is not impacted by environmental conditions typically associated with outdoor pools. Silver ions are relatively insensitive to fluctuations in ultraviolet light, temperature, rainfall, and organic material entering through environmental exposure." The Agency is unable to accept this rationale for use of indoor pools. The field testing of swimming pool products is to confirm the effectiveness of the product as a disinfectant under actual use conditions. All possible environmental conditions (ultraviolet light, rain, organic material, water temperature) which will have some impact on the chemistry used to maintain a disinfectant level in swimming pools must be evaluated under actual conditions not simulated conditions. This would not be accomplished with the proposed indoor swimming pool. Although the silver ions may not be affected by these environmental changes, the reduced chlorine residuals certainly would, and again, must be evaluated under actual use conditions. Therefore, the use of indoor pools for this EUP is not acceptable.

The proposal for a bather load of one person in each pool for a period of 15 minutes per day for 5 days a week, is also not acceptable. Again, this does not adequately challenge the disinfectant's use under actual field conditions.

IX CONCLUSIONS

The Product Science Branch recommends that the proposed Experimental Use Permit for the product, Frog Mineral Reservoir be denied for the following reasons:

a. The presumptive efficacy data shows no evidence that the use of the products contributes to disinfection at reduced chlorine levels. The 0.4 ppm available chlorine was comparable to the chlorine control in killing the target microorganisms even in the absence of additional silver ions.

b. The proposed use of 3000 gallon indoor pools is not acceptable for testing the efficacy of the product under actual field conditions. The product would be used in outdoor pools and must be evaluated under that use.

c. The proposed use of one bather for 15 minutes per day for 5 days a week is also not reflective of actual use conditions and is unacceptable.