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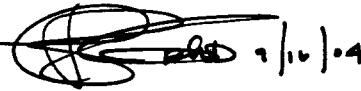
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460


OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 7, 2004

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 53735-RR, Pool Frog Mineral Reservoir
DP Barcode: 307224

From: Tajah L. Blackburn, Ph.D., Microbiologist  9/16/04
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Thru: Nancy Whyte, Acting Team Leader  9/16/04
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

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

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

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Silver (ionic, from 0.5% AgCl).....	0.37%
<u>Other Ingredient(s)</u>	99.63%
Total	100.00%

I BACKGROUND

The product, Pool Frog Mineral Reservoir (EPA Reg. No. 53735-RR), is a new product that uses silver chloride (AgCl) as its active ingredient. The applicant requested to register the product as a swimming pool water disinfectant for use in residential pools. Technology Sciences Group, on behalf of King Technology, Inc. (KTI), submitted the following responses to

the Agency's letter, dated March 9, 2004, to address several deficiencies highlighted in the initial submission. Per the submitted letter, the responses address comments in the efficacy review provided by Tajah Blackburn.

This data package contained a letter from the applicant's agent addressed to the Agency (dated July 14, 2004), proposed label, and Supplemental Deficiency Discussion and Response report.

II USE DIRECTIONS

The product is designed to be used for disinfecting water in residential swimming pools. Directions on the proposed label provided the following information regarding preparation and use of the product as a swimming pool water disinfectant: Before using the product for pool maintenance, balance the pH of the pool water to between 7.2 and 7.8, and total alkalinity between 60-120. Shock the pool with a chlorine shock per manufacturer's directions. For cartridge systems, use the product inside the Frog Cyclor. For skimmer systems, use the product inside the skimmer basket. [Use of the product in skimmer systems is limited to in-ground pools.] Use the product with 0.25- 1.0 ppm of an EPA-registered source of chlorine. Use on Pool Frog Mineral Reservoir for 6 months or for one season, whichever is shorter.

III SUBMITTED RESPONSES TO CITED DEFICIENCIES

- (1) **Agency Initial Comments:** When considering only water samples with free available chlorine in the concentration range of 0.23-1.0 ppm, the number of failing samples met the 15% criterion identified in DIS/TSS-12 when using both the laboratory-reported summary and the Agency generated "counts." However, the number of water samples evaluated did not meet the minimum number of 144 required in DIS/TSS-12. DIS/TSS-12 requires that a minimum of 144 samples be taken for bacteriological monitoring.

KTI's Response: KTI's Frog Mineral Reservoir In-Field Test collected 216 total samples for pool number one and 215 total samples for pool number two. This data was provided on pages 30 to 48 in Appendix U of the In-Field Test Report (MRID No. 461240-01).

KTI has acquired a certification dated April 20, 2004, from Ray Stocker, Study Director, stating that the duplicate samples are NOT true duplicates. The duplicate samples were two samples taken at opposite sides (one by the skimmer and one by the stairs) of the pool consecutively. Certification is enclosed in the document entitled, "Frog Mineral Reservoir Supplemental Deficiency Discussion and Response."

Agency's Final Comment: Pursuant to the submitted certifications from Ray Stocker, Study Director at Microbac Laboratories, Inc., it appears that the samples' numbers were incorrectly labeled as duplicates, when in actuality each sample was separate. Upon clarification, the sample number appears to exceed the minimum of 144 samples.

- (2) **Agency's Initial Comment:** Due to the conflict with sample collection number, additional bacteriological testing is needed to support the label-specified range of 0.25-1.0 ppm free available chlorine. Water samples for bacteriological analyses were not collected daily as specified.

KTI's Response: As indicated above, KTI's Frog Mineral Reservoir In-Field Test collected 216 total samples for pool number one and 215 total samples for pool number two. DIS/TSS-12 does not specify that the samples taken must be in a range consistent with labeling directions.

It is important to note that KTI is registering a silver product, not a specific chlorine product. In most instances, the level of antimicrobial agent (silver ion) was consistent with the labeling. Furthermore, KTI requested and was subsequently allowed to extend the study by one month to ensure collection of enough samples to meet DIS/TSS requirements.

In the original EUP protocol, KTI proposed that the in-field testing be conducted indoors where all chemical parameters, including chlorine concentration, could be closely monitored and controlled. This protocol was rejected by the Agency in the Memorandum from Michelle Wingfield to Marshall Swindell, dated March 22, 2002 because it was not "actual" use conditions.

During the two presubmission meetings with EPA on September 13, 2001, April 10, 2002 and during follow up conversations, it was clear the Agency wanted the field test to represent real-world residential swimming pools, in a worse-case scenario. Under normal usage, it is impossible to precisely control the levels of chlorine in a swimming pool due to the frequency of use, bather load, and the types and degree of organic contamination from the bathers as well as general weather conditions.

KTI's position in that the In-Field Efficacy Test of the Frog Mineral Formula conducted in Florida was truly a worse case scenario. Precise control was especially difficult in Southern Florida, due to intense, continual heavy rainfall and rapid solar degradation of environment in the United States to conduct this EUP Field Study during this period of time. More important, it is impossible to know the levels of chlorine at the time the sample is taken until after it has been properly analyzed.

Agency's Final Comment: Due to the confusion posed by the mislabeling of individual samples as duplicates, additional samples were requested to support the label specified range of 0.25-1.0 ppm free available chlorine. Since the product's efficacy depends on the presence of chlorine at a range of 0.25-1.0 ppm, chlorine levels should be monitored, as representative of consumer usage. **KTI believes that "it is impossible to precisely control the levels of chlorine in a swimming pool due to frequency of**

use, bather load, weather conditions, and organic contaminants.” Per the proposed label, a chlorine range of is 0.25- 1.0 ppm is required with the active ingredient; therefore, precise control of chlorine levels is imperative to determine efficacy. Since monitoring chlorine levels appear to be problematic from the industry's viewpoint, can this be an indicator of future consumer problems maintaining and/or monitoring chlorine levels? Furthermore, the variables of use pattern, bather load, types and degree of organic contamination, and weather conditions are obvious insults in a typical outdoor pool setting that cannot be controlled, but their potential influence can mitigate efficacy.

- (3) **Agency's Initial Comments:** The laboratory report indicated that data collected on several dates were rejected, however the report identified only the date, the pool affects, and the reason, but the rejected data was not included in the submitted study.

KTI's Response: The enclosed KTI's supplemental efficacy report has been included in the current submission.

Agency's Final Comments: The requested rejected data was submitted, thereby satisfying the deficiency.

- (4) **Agency's Initial Comments:** Protocol deviations were observed that were not included in the laboratory report, for an example, "daily" sample collection was defined as "at least five times per week," but samples were not typically collected on holidays, including the 4-day Thanksgiving weekend, thereby shortening the actual collection of bacteriological data to as little as three days per week. Furthermore, physical water characteristics were not determined daily, i.e., days included in the weekend and holidays.

KTI's Response: The study protocol as approved by EPA under the Experimental Use Permit states that sampling of pool water will occur on average of five times per week. The study altered this provision of the approved protocol.

Agency's Final Comments: According to DIS/TSS-12, swimming pool water is monitored daily at the same-time interval. Furthermore, due the submission of revised calculation of sample number, and referenced modifications exclusive to the Experimental Use Permit, no additional information is needed to satisfy this deficiency.

- (5) **Agency's Initial Comments:** Daily information about the number of hours of sunlight for the outdoor pool was not reported.

KTI's Response: The protocol as approved by the EPA did not specify that sunlight data would be collected. However, KTI's supplemental efficacy report (enclosed) provides sunlight information, obtained from the U.S. Naval Observatory database.

Agency's Final Comments: According to DIS/TSS-12, efficacy reports must include meteorological data including air temperature, rainfall and number of hours of sunlight (determined daily) for outdoor pools. The submitted supplemental efficacy report included the hours of sunlight. Therefore, no additional information is needed to satisfy the deficiency.

- (6) **Agency's Initial Comments:** The distance between sampling points was not identified.

KTI's Response: Neither DIS/TSS-12 nor the study protocol approved by EPA required this information. However, KTI's supplemental efficacy report (enclosed) provided this information.

Agency's Final Comments: As outlined in DIS/TSS-12, water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remotely as possible from the inlets, preferably at the midpoints between inlets. A minimum of 144 samples should be collected during the test period. Samples should be taken just below the surface of the water and preferably at such times when the number of persons using the pool during the preceding hour has been at least equal to 50% of the maximum bather load of the pool and the number of persons in the pool water at the time the samples are collected is at least equal to 25% of the maximum bather load of the pool. KTI has submitted the necessary information in the current data package.

- (7) **Agency's Initial Comments:** The field study did not demonstrate the individual effectiveness of the two agents (i.e., Ag⁺ in the product versus free chlorine from any of several EPA-registered products). Therefore the field study data has not thoroughly demonstrated the effectiveness of the product, Pool Frog Mineral Reservoir.

KTI's Response: The field study was designed to show the effectiveness of the Frog Mineral Reservoir when used as part of a combination pool treatment system consisting of the Frog Mineral Reservoir and low levels (<1.00 ppm) of chlorine from any EPA-registered source. The effectiveness of any EPA-registered chlorine product was demonstrated as a condition of the registration. The Frog Mineral Reservoir contributes to the disinfection of swimming pools, in combination with at least 0.25 ppm of chlorine, does maintain acceptable efficacious levels.

Agency's Final Comments: Upon clarification of the sample number and deficiency issues, efficacy has been demonstrated with the Pool Frog Mineral Reservoir in combination with at least 0.25 ppm of chlorine.

- (8) **Agency's Initial Comments:** No times, methods or sites of the chemical additions were documented. However, the dates in which chemicals were added to the pool and the description of such treatments were provided.

KTI's Response: As shown in KTI's supplemental efficacy report (enclosed), all chemical additions were made by broadcasting the chemicals over the surface of the pool, following common industry methodology. Chemical additions in each pool occurred between 9 and 10 A.M. and between 3 and 4 P.M., if applicable, on most days.

Agency's Final Comment: The submitted information to addresses the cited deficiency.

- (9) **Agency's Initial Comments:** To demonstrate synergism, one must first demonstrate the efficacy of each agent (product) alone and then demonstrate that the combined effect exceeds the efficacy that would result from a simple additive effect.

KTI's Response: KTI does not seek to claim silver and chlorine to have a synergistic effect. The study was not to prove claims that silver increases the effectiveness of chlorine. Instead the study was to prove that the Frog Mineral Reservoir is efficacious and meets DIS/TSS-12 requirements when used with chlorine levels as low as 0.25 ppm.

Agency's Final Comments: It appears that the cited deficiency is due to the lack of clarification. KTI's response is sufficient.

IV LABELING ISSUES

Agency's Comment: Change the active ingredient to "silver chloride" from "silver" (ionic form silver chloride).

Revised Labeling: KTI has proposed to meet with the Agency for further discussion concerning this matter.

Agency's Comment: The product must clearly state on the front panel that it must always be used in conjunction with the King chlorine-containing "Bac-Pac," or other compatible EPA registered chlorine pool product.

Revised Labeling: The advised statement has been added to the front panel of the Frog Mineral Reservoir label.

Agency's Comment: The marketing claim states that the product will "seek and destroy" bacteria. Information included in the data package did not indicate that silver chloride or silver ions will actively "seek" out bacteria. The applicant must delete this claim from the proposed label.

Revised Labeling: The claim, "Charged Minerals Seek and Destroy Bacteria" and all similar claims have been deleted and replaced with "The Frog System destroys bacteria, reducing chlorine use up to 50% to 80%* when compared to EPA recommendations of 1.0 to 3.0 ppm for standard chlorine treated pools.

Agency's Comment: Delete "purifier" globally. This term is reserved for water purifiers which have separate efficacy requirements.

Revised Labeling: The claim "purifier" has been deleted on the Frog Mineral Pool Reservoir labeling and replaced with "Patented Mineral Pool Sanitizer."

Agency's Comment: Delete the statements, "Cuts chlorine use by 50-80%. No data was provided to support this claim.

Revised Labeling: This claim is supported by the submitted efficacy data (MRID No. 461240-01) that showed disinfection of pools using silver and chlorine at 0.25 ppm to 1.0 ppm. This amount is 50 to 80% lower than the EPA recommended chlorine levels of 1.0 to 3.0 ppm. KTI proposes to add a qualification statement to this claim to read, "Cuts chlorine use by 50 to 80%* when compared to EPA recommendation of 1.0 to 3.0 for standard chlorine treated pools.

Agency's Comment: The 0.25 ppm and 50% less chlorine claim are not acceptable pending resolution of efficacy issues and possible further claim qualifications/restrictions.

KTI's Comment: KTI is proposing that the 0.25 ppm and 50% less chlorine claims compared to other mineral systems remain on the Frog Mineral Formula labeling pending resolution of efficacy issues addressed in this response.

Agency's Comment: Change "60-120" to "60-120 ppm," regarding alkalinity.

Revised Labeling: The label has been changed to read, 60-120 ppm regarding alkalinity.

Agency's Comment: The following sentence, which refers to alternate sources of chlorine, is not acceptable, "Maintain recommended chlorine levels in the pool following label directions for use." First it contradicts the claims of using less chlorine because it requires use of recommended chlorine levels. Second, it needs to be expanded to show that using less of an EPA registered chlorine product to achieve a reduction, yet still be in harmony with the efficacy data.

Revised Labeling: The Frog Mineral Reservoir label has been changed to "Maintain recommended chlorine levels of at least 0.25 in the pool."

Agency's Comment: All skimmer applications are not acceptable. No data for this variation was provided so it is not acceptable and all related labeling is not acceptable.

KTI's Comment: The skimmer application is simply a variation in the Frog Mineral Formula delivery mechanism. In both applications, pool water constantly flows through the container holding the Frog Mineral Formula. Comparable levels of silver ions are released into the water in both cases.

The same Frog Mineral Formula is used in both types of applications. Furthermore, the recommended levels of chlorine are the same for both delivery methods. The variation in the two methods of delivery will not influence the efficacy of the product.

Final Agency's Comment: KTI has indicated that the skimmer application is a variation

of the Frog Mineral delivery mechanism. However, product variability/comparison was not disclosed. In the absence of data related to the use of the Frog Mineral Formula delivery mechanism, proper comparison is needed by submission of comparative data and/or comparative product analysis.

V CONCLUSIONS

1. Submission of the requested information to address the cited deficiencies renders the efficacy data acceptable for the product Frog Mineral Reservoir as a swimming pool disinfectant with free available chlorine, in the label-specified range of 0.25-1.0 ppm. However, proper monitoring of chlorine levels are imperative for product efficacy and final acceptance.

VI RECOMMENDATIONS

1. Several of the labeling deficiencies have been addressed, and are now acceptable. However, the following deficiency needs to be addressed, since it is still pending Agency discussion:

_– Change the active ingredients to “silver chloride” from “silver” (ionic from silver chloride).