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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 2, 2000

MEMORANDUM:

Subject: Efficacy Review for EPA Reg. No.: 67712-R/-E/-G/-U/-L/-A/-T/-I/-O/-N/-RR/-RE/-RG/-RU, "Nature $^{2®}$G45-VC40"
DP Barcode: D263152
Case No: 068051

From: Emily Mitchell, M.S., Team Leader Emily Mitchell 10/5/00
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Through: Michele E. Wingfield, Chief
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Applicant: Zodiac Pool Care, Inc.
3420 Northwest 53rd Street
Fort Lauderdale, FL 33309

Formulation From Label:

Active Ingredient(s)	% by wt.
Silver	2.96%
Copper sulfate pentahydrate*	6.39%
Inert Ingredient(s)	90.65%
Total	100.00%

*Copper (Cu) as metallic 1.62%

The above active ingredients will change slightly according to the Reg. No.

I. Background:

The registrant, Zodiac, has submitted a registration for "Nature$^{2®}$ G45-VC40", designed for residential pools as a disinfectant and algaecide. This registration is for 14 new products, EPA Reg Nos. 67712-R/-E/-G/-U/-L/-A/-T/-I/-O/-N/-RR/-RE/-RG/-RU. The Nature$^{2®}$ technology is based on the dissolution of silver and copper ions into pool water. Disinfection and algaecidal effectiveness is based on the maintenance of 0.01 - 0.06 ppm silver and 0.02 - 0.1 ppm copper ions in the circulating water accompanied by 0.5 ppm chlorine. The current product relies on a combination of alumina spheres coated with either metallic silver or copper sulfate contained in a cartridge appropriately sized for the pool volume.

II. Use Directions:

According to the draft labeling submitted by the applicant, Zodiac intends to market this silver and copper sulfate product for use by consumers of pools and spas in residential settings. Specific claims include: natural mineral purifier for pools, kills 99.9999% of organisms in 30 seconds, in the presence of soil, disinfectants pool water, kills/controls/reduces/destroys bacteria and algae, germicidal pool treatment, sanitizes swimming pool, controls pathogenic bacteria, prevents cloudy water, improves appearance of pool water and inhibits growth of undesirable algae and bacteria. The directions state that the user should clean debris and algae out of the pool and equipment before starting up a new cartridge. The consumer should also make sure the pool water is chemically balanced before installing purifier cartridge. Install the cartridge after the pool water has been balanced. Superoxidize the pool water with chlorine (one pound of granular chlorine or one gallon of liquid chlorine per 10,000 gallons) to burn off contaminants and activate cartridge. Run the circulating pump either: (a) 24 hours a day for 4 days, maintaining 1-2 ppm chlorine throughout, or (b) 6 hours a day for 14 days, maintaining 1-2 ppm chlorine throughout. Let chlorine dissipate to 0.5 ppm once start up period is completed. Once the 4-day or 14-day start up period is done, allow the free available chlorine residual to drop to 0.5 ppm (by reducing the amount of chlorine you add then: (1) run pump and filter at least 6 hours every day, (2) balance pH and total alkalinity once a week, (3) check chlorine residual; add chlorine to maintain at least 0.5 ppm free chlorine twice a week, and (4) if water is hazy, superoxidize with 1 pound chlorine granules, or 1 gallon liquid chlorine per 10,000 gallons as needed. After heavy use or rainstorms, superoxidation is recommended.

III. Agency Standards for Proposed Claims:

The Agency Standard for antimicrobial products that bear claims for swimming pool disinfection, were designed to consider numerous factors: 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. Therefore, a two-phased study (presumptive laboratory testing and confirmatory field testing) is required.

A. Laboratory test requirements - Presumptive efficacy of swimming pool water disinfectants may be substantiated with data derived from the A.O.A.C. Method for Water Disinfectants for Swimming Pools or with slight modifications (e.g., pH) thereof, against both *Escherichia coli* and *Streptococcus faecalis*.

B. 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.

C. Field test requirements - Confirmatory efficacy data should be derived from in use tests under an Experimental Use Permit in at least two swimming pools. The test must be conducted for an entire swimming season (4 to 12 months). Reports must include the following information concerning the test pools: the design of the pool, the recirculation and filter system, and water capacity, the daily bather load, the amount and identification of all chemicals added daily to the swimming pool water, the range of chemical characteristics of the swimming pool water, the physical characteristics of the swimming pool water, meterological data, water samples for bacteriological analysis should be taken on opposite sides of the pool in the shallow area and as remote as possible from the inlets (a minimum of 144 samples should be collected during the test period), the concentration of the antimicrobial agent in the swimming pool water monitored daily at the same time-intervals and that the bacteriological assay samples should be obtained and the method that the product user will employ for monitoring the level of antimicrobial agent contained in the pool water.

D. 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.

IV. Summary of the Submitted Protocol:

The Nature$^{2®}$ technology is based on the dissolution of silver and copper ions into pool water. Algaecide and disinfection effectiveness is based on the maintenance of 0.01 - 0.06 ppm silver and 0.02 - 0.1 ppm copper ions in the circulating water accompanied by 0.5 ppm chlorine. The current product relies on a combination of alumina spheres coated with either metallic silver or copper sulfate contained in a cartridge appropriately sized for the volume of the pool. The source of the ions changed throughout the development of the product. The submitted studies were conducted with alternate sources of silver and copper ions. The ANSI/NSF-50 Disinfection Efficacy Study was conducted on a test cartridge prepared with alumina spheres coated with metallic silver and alumina spheres coated with copper sulfate. The 1994 Field Study was conducted using test cartridges with metallic silver coated alumina spheres and metallic copper foil. The 1998 Field Study was performed with test cartridges containing a combination of alumina spheres coated with either metallic silver or copper sulfate. The efficacy of the product was due to the level of available silver and copper ions.

To evaluate the effectiveness of the Nature$^{2®}$ System for pools, an ANSI/NSF-50 Disinfection Efficacy study was performed using a 4,800 gallon swimming pool (15' diameter, 4' depth). The study was conducted by filling the pool with municipal tap water followed by treatment of the water with 5.25% sodium hypochlorite. The Nature$^{2®}$ System was installed and the study was initiated when the chlorine level had dissipated. The water hardness was adjusted to 180 ppm, the alkalinity to 150 ppm, the water temperature was 21°C, and the silver and copper levels were measured at 0.04 ppm and 0.07 ppm. Baby oil (22 mg/L) and urea (9.0 mg/L) were added to the pool to serve as an organic soil load and to simulate body oils and skin care products. Circulation was performed manually to accomplish thorough mixing.

An independent laboratory performed the sampling and inoculation of the pool to achieve 2.0×10^6 cfu *Enterococcus faecium* and 2.0×10^6 cfu *Pseudomonas aeruginosa*/100 mL pool water. Microbial samples (200 mL each) were aseptically collected immediately after addition of the soil load and test organisms and at two minute intervals for 30 minutes. Immediately upon collection of samples, appropriate neutralizers were added to the sample to quench antimicrobial activity. At the start of the test, chlorine was added to the pool to achieve a 0.4 ppm level in the initial 10 minutes of the test. At the ten minute mark, the chlorine addition was stopped for the remaining 30 minutes of the test. The chlorine was measured at the 30 minute time interval and found to have fallen to 0.25 ppm.

The sample demonstrated a 6.3 $\log_{10}$ reduction of *Pseudomonas aeruginosa* and *Enterococcus faecium*. Although, four of the other contact times demonstrated a recovery of <6 cfu/100mL, the product, Nature$^{2®}$ exceeded the ANSI/NSF-50 requirement for a 3 $\log_{10}$ reduction at 30 minutes.

1994 Florida Field Study

The study incorporated 10 in ground, outdoor residential pools, located in central Florida, to demonstrate the effectiveness of the product, Nature$^{2®}$ as a swimming pool disinfectant under field conditions. The study included 5 months (June to November) of swimming season, three models of the test cartridge appropriate for pools sized 7,000 to 13,000 gallons. An independent laboratory collected samples weekly and performed measurements for silver, copper and chlorine concentrations, pH, water hardness, and bacteriologic monitoring. The study was not performed according to EPA GLP Standards. The microbial recovery where the level of chlorination fell below 0.4 ppm, 21 water samples of 146 demonstrated non-coliform bacteria and no samples remain with coliforms detected.

1998 Australia Field Study

The study incorporated 13 in ground, outdoor residential pools, located in New South Wales, Australia, to demonstrate the effectiveness of the product, Nature$^{2®}$ as a swimming pool disinfectant under field conditions. The study compared two models of the test cartridge appropriate for pools sized 9,200 to 15,800 gallons. A double crossover design was utilized to allow comparison of the results with standard pool chlorination. An independent laboratory collected water samples from each field site

and performed measurements for silver, copper and chlorine concentrations, pH, turbidity, and bacteriologic monitoring for total bacteria, fecal coliform and *Pseudomonas aeruginosa*. Upon statistical analysis, no statistical difference was found with respect to the pool disinfection between the Nature$^{2®}$ System and traditional chlorination. Of 25 water samples, 3 demonstrated recovery of bacteria above the 200 cfu/mL non-coliform criteria, 1 water sample demonstrated recovery of *Pseudomonas aeruginosa* and no water samples demonstrated recovery of fecal coliform bacteria. The few recoveries exceeding EPA bacterial levels were eliminated when the water samples were corrected for improper pool maintenance. The study was not performed according to EPA GLP Standards.

V. Comments On The Proposed Protocol:

The data thus far submitted to the Agency by the applicant as evidence of their silver and copper sulfate cartridge's efficacy suggest that the product is efficacious under certain selected test conditions. The test method (ANSI/NSF-50 Method) proposed by the applicant, retains the basic requirements of DIS/TSS-12 (A.O.A.C. Official Method 965.13-Disinfectants for Swimming Pools) while at the same time accommodating what they feel are distinguishing characteristics of the silver-copper sulfate cartridge. However, additional changes should be made to the protocol design or proposed submitted label.

VI. Conclusions and Recommendations:

While the test protocol provides a basically sound scientific approach to the evaluation of the applicant's product, Nature $^{2®}$ G45-VC40, there are specific details that require additional refinement. They are as follows:

- Future studies should be discussed with the Agency prior to their initiation and should be conducted in compliance with Good Laboratory Practice Standards (40 CFR Part 160).

- Zodiac Pool Care, Inc. must state on label that a registered chlorine product must be used in conjunction with the "Nature $^{2®}$ G45-VC40". **The applicant's product is ineffective without the use of a registered chlorine product.**

- Additional confirmatory studies should be conducted with the organism *Escherichia coli.*

Additional Labeling Comments:

A final review of the proposed label will be conducted once the product has been registered and the following changes have been made.

1. The name, Nature$^{2®}$ is potentially misleading. The registrant should insert Brand after the name or delink it from the product's name.

2. Label must state that "Nature $^{2®}$G45-VC40" cartridge be used with a registered chlorine pool product.

3. Label must clarify that cartridge must be discarded after 6 months use or 1 pool season.

4. The statement "Natural Mineral Purifiers" must be deleted. The product is not a purifier and the term natural is misleading. Chlorine must be used with this product for effectiveness.

5. The site for spas must be deleted unless directions for spa use is expanded and separated from swimming pool directions for use.

6. The statements "Patented mineral process controls bacteria", "Patented mineral process assists in killing bacteria and algae", "Kills bacteria", "Controls/kills/reduces/destroys bacteria", "Specially formulated to control pathogenic bacteria", and "Inhibits the growth of [undesirable] bacteria", must be deleted or revised. Claims must be qualified. The term bacteria is too broad. This product will not control or kill all bacteria. The product assist in controlling bacteria when used with a registered chlorine product.

7. Terms such as "It works", "Improves water", "It feels great!", and "Its easy!" must be deleted from the label.

8. The statement "Germicidal pool treatment" must be deleted.

9. Revise the statements "Kills 99.9999% of organisms in 30 seconds" and "Kills 99.9999% of organisms in 30 seconds in the presence of soil" to include the name of the organisms and an additional statement including the use of a registered chlorine.

10. Revise statement "Kills Gram negative/gram positive/pathogenic bacteria/disease-causing bacteria/fecal bacteria" to include the nomenclature of the pathogenic bacteria.

11. Delete the statement "A trace of silver (an excellent sanitizer) keeps pool sanitized and crystal-clear." Silver is not a water sanitizer.

12. Delete the statement "A trace of copper inhibits algae growth."