

(1-4-2006)



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Nature² SPA**

DP Barcode: **D323850**
Manufacturing-use []

Reg. No. or File Symbol: **67712-RL**
End-use Product [**X**]

Active Ingredient Composition:

Metallic Silver*.....**0.92%**
***from silver nitrate**

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist *At 1/3/06*
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader *K.P. Hicks 1/4/06*
Product Science Branch
Antimicrobials Division (7510C)

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

BACKGROUND:

This re-submission in support of the new product registration, covering the subject pool disinfectant and algacide, was submitted by Scientific & Regulatory Consultants, Inc. on behalf of the registrant, Zodiac Pool Care, Inc. The agent, in this re-submission, is responding to the Agency letter dated

①

July 28, 2004 on behalf of Zodiac Pool Care.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter and transmittal document both dated August 29, 2005, pesticide application covering this re-submission dated 08/29/05, Agency letter dated July 28, 2004, revised Basic CSF (Pre-Reaction and Post-Reaction) dated 08/29/05, Certification with Respect to Citation of Data and Data Matrices (Agency & Public) all dated 08/29/05, review of MPS oxidizing equivalence dated 8/26/05, product label with diagrams and owner's manual dated 06/14/05 and Product Chemistry Data for Guideline Series 830 Group A under MRID # 466340-01 dated 08/29/05.

FINDINGS:

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient, metallic silver, given in the revised Basic CSF dated 08/29/05 agreed with the percentage declared on the label.
2. The upper and lower certified limits for both the active and inert ingredients are acceptable. The justification in support of utilizing wider certified limits for metallic silver are accepted.
3. All active and inert ingredients utilized are cleared for use in pesticide formulations.
4. The registrant has requested a delay, under OPPTS 830.1000 (e)(1)(vi)(C), covering the GLP preliminary five batch analysis for silver. The registrant has requested that this data requirement be delayed as a condition of registration until production runs of **Nature2 SPA** are made. This delay in data requirements is conditionally accepted.
The remaining Group A Product Chemistry Data requirements for this registration have been satisfied.

5. As discussed with the registrant's agent, the Basic CSF (Post-Reaction) should disclose the presence of [REDACTED] and its amount present in the silver media, which has a total weight and percentage of [REDACTED] in the formula. The full disclosure of the silver media composition in the CSF should be as follows: silver (0.92%), [REDACTED]

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6. The waiver request for Guideline Series 830 Group B data requirements are accepted . This decision is based on the Agency policy of not requiring such data requirements for silver-based water filters housed in cartridges. **Nature2 SPA** is substantially similar in product form to the exempted water filters.

7. All other comments noted in the prior review have been adequately addressed such as: silver nitrate has been identified as the source of the metallic silver and the use of a plastic in-line pool canister, to house this formulation has been noted in the CSF.

RECOMMENDATIONS:

This re-submission, in support of the new product registration of **Nature² SPA**, is accepted with comment.

Registrant is required to address items #4 and ~~#5~~ noted above in the Findings.

01/03/05 AT

BT
1/11/06