

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



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

July 19, 2004

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Nature²® Spa.
DP Barcode: D303264
Reg. No. or File Symbol 67712-RL
TGAI/Manufacturing-use Product **OR** **End-use Product**
TO: Marshall Swindell / Tony Kish
PM Team 33
FROM: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobial Division (7510C)
THRU:: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)
THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)
APPLICANT: Zodiac Pool Care, Inc.
Action code: 188
Due date: 07/20/04

[Handwritten signature]
7/20/04

Product Formulation
Active Ingredient(s)

Silver

% by wt.

3.51

①

BACKGROUND:

The registrant is submitting a new registration data package for review. The registrant is using the MRID #455137-01 & 455140-01, and Silver RED as reference to request a waiver for acute toxicology and physical properties testing. The product to be used is **Nature²® Spa**. The integrated end-use product is a mineral sanitizer for spas that controls, kills, reduces, and destroys bacteria.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - Confidential Statement of Formula (CSF), dated 03/19/04, for the basic formulation.
 - A letter, dated 03/19/04. MRID # 462311-00.
 - The label, dated 03/22/04 (pin punch).
 - A Confidential Business Information, dated 03/19/04.
 - Product Chemistry Data Waiver Request, dated 03/22/04 (pin punch).
 - Study titled "Product Chemistry." MRID # 462311-01.
2. The CSF, dated 03/19/04, is the revised for the basic formulation.
3. The registrant is requesting a waiver for the 830 group B guidelines.
4. The CSF, dated 03/19/04, does not reflect the chemical reaction components (beginning material), and impurities.
5. The active ingredient(AI) does not show the purity of the source (Col. 10 of the CSF).
6. The CSF and the Label do not have the same nominal.
7. The nominal of the AI shows 3.51% on the label. Therefore, the total percentage by weight would not add up to 100% in the CSF.
8. The registrant justified a wider range because of the range of [REDACTED] of the AI source material supplier.
9. The registrant claims that the EPA REG # 67712-1 & 67712-5 are the same technology.
10. Prior to installation of the SPA filter, one needs to check the level of potassium peroxymonopersulfate (MPS). Otherwise, MPS needs to be added to the water.
11. The MRID #455137-01 (volume 2) pertains to EPA Reg # 67712-1, and the study title is "Toxicity Discussion." This product is not designed for drinking water.
12. The total percentage on the label for the AI & inert is 91.77%.
13. The product has an unregistered active ingredient source.

RECOMMENDATIONS:

1. The registrant should reflect a pre-reaction and a post-reaction CSF.
2. The registrant should consider using 99% of AI to calculate percentage by weight, and the certified limits. Since this represents the minimum concentration that the AI might be exposed to, the lower limit should fall within EPA standard limits.
3. The registrant must update column 13a of the CSF in order to match with the nominal of the AI on the label. A reminder that the total weight and the percentage by weight should be 100.
4. The registrant must include the purity in column 10 of the CSF which will be included to calculate the nominal of the AI.
5. The registrant cannot use the silver RED as reference to waive the 830 Group B Physical/Chemical Properties Test Guidelines. The silver RED maximum concentration allowance is 1.71% of silver, and is designed for drinking water. This product has a concentration of 3.51% of silver, and is not designed for drinking water.
6. The composition of the cartridge material should be listed on the CSF. This cartridge is a part of the product for which registration is being sought, and although the cartridge material is not a part of the pesticide formulation, it is a carrier and the Agency must approve its use as a part of a delivery system for pesticides.
7. The registrant cannot use the MRID #455137-01 & 455140-01 for physical/chemical properties test guidelines, because these documents refer to **toxicity**.
8. The registrant must correct the total percentage on the label for the AI to be 100% and not 91.77%.
9. The registrant should reflect the pre-reaction and post-reaction in the CSF. This product is an integrated system.
10. The registrant should submit the five-batch preliminary analysis of the quantity of the active ingredient (AI), and a certificate of analysis from the supplier of the AI.

CONCLUSION:

The CSF, dated 03/19/04, for the basic formulation is not acceptable. The CSF and the label do not have the same nominal. The waiver is not acceptable for the following:

- 830.6303 Physical state
- 830.6317 Storage stability
- 830.6320 Corrosion characteristics

The registrant must comply with the requirements, recommendations and concerns listed above. The label does not comply with non of the PR Notice 83-3 & 84-1. The storage and disposal should be grouped together. The label does not mention the storage procedure.

(3)

PRODUCT CHEMISTRY REVIEW

11. CONFIDENTIAL STATEMENT OF FORMULA

11a. Type of formulation and source registration

- Non-integrated formulation system
- Are all TGAI used registered? Yes No NA

- Integrated formulation system

- if "ME-TOO", specify EPA Reg. # of existing product:

11b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes No NA

11c. Physical state of product: Solid.

11d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes No

Data has not been submitted to the reviewer.

11h. NCs and CLs are: acceptable Not acceptable

11i. Active ingredient (s)

A. Silver

NC	UCL	LCL
1.05%	1.10%	0.998%

11j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes No Not applicable

- All impurities of $\geq 0.1\%$ in the product have been identified?

Yes No Not applicable

12. PRODUCT LABEL

12a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes No

12b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes No
- 1.0% or more of methyl alcohol: Yes No
- Sodium nitrite at any level: Yes No
- a toxic List 1 inert at any level: Yes No
- arsenic in any form: Yes No

12c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes No Not applicable

12d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?

Yes [] No [] Not applicable [X]

12e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses?

PR Notice 84-1 Yes [] No [X] Not applicable []
PR Notice 83-3 Yes [] No [X] Not applicable []

12f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?

Yes [] No [] Pending [X]

13a.

PRODUCT CHEMISTRY (Series 830 Part A)

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix) ¹	U	462311-01
830.1600 Description of Materials	U	462311-01
830.1620 Manufacturing Process ²	U	462311-01
830.1650 Formulation Method ³	NA	
830.1670 Discussion of Impurities ⁴	U	462311-01
830.1700 Analysis ⁵	A	462311-01
830.1750 Certified Limits ⁶	A	462311-01
830.1800 Analytical Method for AIs ⁷	A	462311-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required, G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

5

Physical and Chemical Characteristics (Series 830, Part B)

13b. Physical/Chemical Properties*

	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	N		
830.6303 Physical State	N		
830.6304 Odor	N		
830.6313 Stability to normal & elevated temp., metals, & metal ions	NA		
830.6314 Oxidation/Reduction: chemical incompatibility.	N		
830.6315 Flammability/Flash Pt	NA		
830.6316 Explodability	NA		
830.6317 Storage stability	N		
830.6319 Miscibility	NA		
830.6320 Corrosion characteristics	N		
830.6321 Dielectric breakdown voltage	NA		
830.7000 pH	NA		
830.7050 UV/Visible absorption	NA		
830.7100 Viscosity	NA		
830.7200 Melting point/melting range	NA		
830.7220 Boiling point/ boiling range	NA		
830.7300 Density/sp. gravity	NA		
830.7370 Dissociation constants in water	NA		
830.7520 Particle size, fiber length, & diameter distribution	NA		
830.7550 Partition coefficient(n-octanol/water), shake flask method	NA		
830.7560 Partition coefficient(n-octanol/water), generator column method	NA		
830.7570 Partition coefficient(n-octanol/water),	NA		
830.7840 Water solubility: Column elution method; shake flask method	NA		
830.7860 Water solubility, generator column method	NA		
830.7950 Vapor pressure	NA		

planation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required
 data gap; U=requires upgrading; W=waived; E=EPA estimate.
 Registrant must perform one year study.
 Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc;
 unless otherwise indicated, the property should be at 25°C.

LC