

US EPA ARCHIVE DOCUMENT

(1-15-03)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

January 8, 2003

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
SPA FROG Mineral Formulation**

DP Barcode: 286389 **Reg. No. Or File Symbol: 53735-EUP-E**
Experimental Use [X] **OR** **End-use Product []**

TO: Marshall Swindell/Tony Kish
PM Team No. 33

FROM: Nancy Whyte, Chemist *NGW*
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THRU: Karen P. Hicks, CT Team Leader
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1/15/03

THRU: Michele E. Wingfield, Chief
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Product Formulation

Active Ingredient(s)	% by wt.
Silver chloride	0.5%
Available silver	0.37%

BACKGROUND:

The registrant has submitted for Agency review and approval the chemical formula for coated particles that will be used in the *Spa Frog* filtration device for water treatment in hot tubs and spas when combined with the use of bromine. An application for an experimental use of the device in field testing only in Minnestora accompanied the product chemistry data submitted in three documents (MRID Nos.457420-01 and -02). The primary review of the product chemistry data was conducted by Oak Ridge National Laboratories.

~~NEXT INGREDIENT INFORMATION IS NOT INCLUDED~~

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

FINDINGS:

1. The silver content of the particles is obtained from [REDACTED] to produce coated particle which are then placed in a water filtration device for use in spas and hot tubs.
2. A pre-reaction Confidential Statement of Formula showing the materials used in the production of silver chloride to create silver ions was included with the Confidential Statement of Formula for the coated [REDACTED]
3. The certified limits of the silver chloride as well as those of the silver ions are wider than the Agency standards listed in 40 CFR, Part 158.175. A detailed description of the production process and an explanation of the need for wider certified limits was included in the data package. Due to the variability of the size of [REDACTED] and the production process itself, a wider variation of limits is needed to accommodate the coating of the particles to assure an amount of silver that would achieve disinfection.
4. All the product chemistry data required by 830 Series Guidelines were addressed. See summary of data attached below. The study for storage stability (830.6317) and corrosion characteristics (830.6320) is underway and will be reported to the Agency when complete at the end of the one-year testing period.
5. The nominal concentration of the active ingredient listed in Box 13B of the Confidential Statement of Formula agrees with that in the label ingredient claims statement, conforming to the recommendations of PR Notice 91-2. The amount of available silver was listed on the Confidential Statement of Formula but not listed just below the label ingredient claims statement. It has been added in the appropriate place by the reviewer

RECOMMENDATIONS:

1. The request for wider certified limits of the active ingredient is approved.
2. The Confidential Statements of Formula for both the pre-and post reaction production of the coated particles, dated January 3 and January 7, 2003, respectively, are acceptable.
3. The amount of available silver should be added to the area of the label ingredient claims statement (as required for metals) prior to the printing of the final approved label before distribution of the product for use.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

• Non-integrated formulation system

• Are all TGAI used registered? Yes No

• Integrated formulation system

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

4b. Clearance of inerts for non-food or food use:

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

4c. Physical state of product: Granular

4d. 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

4e. NCs and CLs are acceptable: Not acceptable

4f. Active ingredient (s)

	NC	UCL	LCL
A. Silver chloride	0.5%	0.6%	0.4%
Available silver	0.37%	0.45%	0.30%

4g. For products produced by an integrated formulation system:

• All impurities of toxicological significance have a UCL?
Yes No Not applicable [A]

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

Yes No Not applicable

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No []

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [] No [X]
- 4.0% or more of methyl alcohol: Yes [] No [X]
- Sodium nitrite at any level: Yes [] No [X]
- a toxic List 1 inert at any level: Yes [] No [X]
- arsenic in any form: Yes [] No [X]

5c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [] No [] Not applicable [X]

5e. 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? Yes [X] No []

5f. 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 [X] Storage stability study pending

PRODUCT CHEMISTRY (Series 830 Part A)

	Acceptance of Information	MRID No.
830.1550 Chemical ID (See Appendix) ¹	A	457420-01
830.1600 Description of Materials	A	457420-01
830.1620 Manufacturing Process ²	A	457420-01
830.1650 Formulation Method ³	A	457420-01
830.1670 Discussion of Impurities ⁴	A	457158-01
830.1700 Analysis ⁵	A	457420-01
830.1750 Certified Limits ⁶	A	457420-01
830.1800 Analytical Method for AIs ⁷	A Atomic absorption spectrometry	457420-01

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),

Physical and Chemical Characteristics (Series 830, Part B)

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	NR		
830.6303 Physical State	A	Granular solid	457420-02
830.6304 Odor	NR		
830.6314 Oxidation/Reduction	A	Non- reactive	457420-02
830.6315 Flammability/Flash Pt	A	Not flammable	“
830.6316 Explodability	A	Not explosive	“
830.6317 Storage Stability	A	Pending completion at end of one year	:
830.6320 Corrosion Character.	A	Pending	“
830.7000 pH	A	8.8-9.0 1% aqueous	“
830.7100 Viscosity	NA	Not a liquid	
830.7300 Density/sp. gravity	A	1.369 gm/ml	457420-02

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

* 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.