

(11-27-02)

DATA EVALUATION RECORD

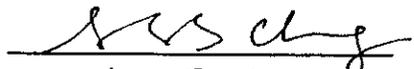
SILVER CHLORIDE (SPA FROG MINERAL FORMULA)

STUDY TYPES: **Product Identity and Composition (OPPTS 830.1550)**
Description of Beginning Materials (OPPTS 830.1600)
Description of Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 45742001 and 45742002

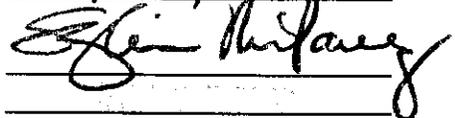
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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobials Division

November 27, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Spa Frog Mineral Formula
DP Barcode: D286389
Reg. No. or File Symbol 53735-EUP-E

TGAI/Manufacturing-use Product [] OR End-use Product [x]

TO: (Team leader/Regulator)
PM Team (#)

FROM: (Reviewer), Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Chief
Product Science Branch
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Product Formulation

Active Ingredients % by wt.

Silver chloride (silver ion): 0.5% (0.37%)

- I. **BACKGROUND:** In a letter dated 8/19/2002, it is stated that the applicant is submitting "an application for an experimental use permit to conduct field-testing in spas of their Spa Frog product, which contains silver ions as the active ingredient." It is to be used only in Minnesota. The Spa Frog can be used with any EPA registered source of bromine to disinfect spas. The Spa Frog is the actual item of commerce and Spa Frog Mineral Formula (EPA Reg. No. 53735-EUP-E) is the active component of Spa Frog (MRID 45742001). The DER is evaluating Spa Frog Mineral Formula.

II. FINDINGS:

1. The upper and lower certified limits of the active ingredient silver chloride ($\pm 20\%$) and silver ion (+22% and -19%) are outside the OPPTS 830.1750 recommended range ($\pm 10\%$). The upper and lower certified limits of the inert [REDACTED] are outside the recommended range of $\pm 5\%$. Explanations were given for the expanded limits. However, the limits are not entirely consistent with the preliminary analysis, in which 2 of 5 batches had a mean AgCl concentration below the lower limit of 0.4% w/w. Also there was up to 25% relative standard deviation for the three replicates of each batch. The registrant claims that these are "laboratory" and not "production" lots and the AgCl concentration is expected to stabilize when the product is manufactured on a large scale.
2. The product names on the label (Spa Frog) and on CSF (Spa Frog Mineral Formula) are not consistent. The study (MRID 45742001) lists the product name as Spa Frog Mineral Formula (Packaged in the Spa Frog). The active ingredient AgCL listed on the CSF should be AgCl.
3. The one-year storage stability study is in progress.
4. The study (MRID 45742001) includes an MSDS for [REDACTED] which is not pertinent for this product. *Review*

III. RECOMMENDATIONS:

1. The registrant needs to change the certified limits of the product to reflect the preliminary analysis and re-examine the limits after large-scale production is instituted to see that they are still accurate.
2. The applicant needs to be consistent in presenting the product name. The applicant needs to correct AgCL to AgCl on the CSF.
3. The applicant needs to submit results of the one-year storage stability study upon its completion.

IV. PRODUCT CHEMISTRY REVIEW:

1. CONFIDENTIAL STATEMENT OF FORMULA (CSF):

- 1a. Type of manufacturing process and source active ingredient registration
 - Non-integrated formulation system (i.e., all TGAI in product are registered) []
 - Integrated production system [x]
 - if "ME-TOO," specify EPA Reg. # of existing product: _____

TABLE 1. Product Identity, Composition, and Certified Limits

PRODUCT NAME: Spa Frog Mineral Formula EPA Reg. #: 53735-EUP-E							
Ingredient name (% purity)	CAS Reg. #	PC Code	EPA Reg. #	Ingredient concentration in product, % w/w			Purpose in formulation
				Nominal	Upper limit	Lower limit	
Silver chloride	7783-90-6	072506		0.5%	0.6%	0.4%	Active
Silver ion				0.37% pure a.i.	0.45% pure a.i.	0.30% pure a.i.	

INERT INGREDIENT INFORMATION IS NOT INCLUDED

- 1b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [] No [] NA [x]
- 1c. The chemical identity, composition (including that for the TGAI), density, pH, and flammability on the CSF are consistent with guidelines in OPPTS Series 830, Part A and OPPTS 830.7300, 830.7000, and 830.6315 respectively: Yes [x] No []
- 1d. Nominal Concentrations and Certified Limits for active ingredients are:
Acceptable [] Not acceptable [x]
- 1e. Nominal Concentrations and Certified Limits for inert ingredients are:
Acceptable [x] Not acceptable [] Not applicable []
- 1f. For products produced by an integrated formulation system:
 - All impurities of toxicological significance have an Upper Certified Limit?
Yes [] No [] Not applicable [x]
 - All impurities of $\geq 0.1\%$ in the product have been identified?
Yes [] No [] Not applicable [x]

2. PRODUCT LABEL:

- 2a. The active ingredients statement (chemical IDs and Nominal Concentrations) on the label is consistent with the CSF? Yes [x] No []
- 2b. The product contains one of the following:
 - 10% or more of a petroleum distillate: Yes [] No [x]
 - 1.0% 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]
- 2c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [x]

- 2d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label? Yes [] No [] Not applicable [x]
- 2e. 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 []
- 2f. Does the product require an expiration date at which time the Nominal Concentration falls below the Lower Certified Limit (based on the one year storage stability data or other information)? Yes [] No []*
- *Note: Unknown, the one-year stability study is in progress.

3. OPPTS SERIES §830 GUIDELINES:

TABLE 2. Product Chemistry Series 830, Part A

OPPTS Guideline	Acceptance of Information*	MRID No. and other Source
830.1550 Chemical ID ¹	U ^a	45742001, CSF, Label
830.1600 Description of Materials	A	45742001
830.1620 Production Process ²	A	45742001
830.1650 Formulation Process ³	NA	
830.1670 Discussion of Impurities ⁴	A	45742001
830.1700 Preliminary Analysis ⁵	A	45742001
830.1750 Certified Limits ⁶	U ^b	45742001, CSF
830.1800 Analytical Method for AIs	A	45742001

*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 Table 1 of Product Chemistry Review for additional information.

²For MP or EP products manufactured by an integrated production system.

³For products manufactured by a non-integrated system (i.e., using a registered TGA1 or MP).

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

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

⁶If different from standard Certified Limits recommended in 40 CFR 158.175, discussed under "Findings" of the Product Chemistry Review.

^a See FINDINGS No. 2.

^b See FINDINGS No. 1.

TABLE 3. Product Chemistry Series 830, Part B

Physical/Chemical Properties	Acceptance of data*	Value or qualitative description	MRID No. and other source
830.6302 Color	NR	Not required for EP.	
830.6303 Physical State	A	Granular solid	45742002
830.6304 Odor	NR	Not required for EP.	
830.6313 Stability	NR	Not required for EP.	
830.6314 Oxidation/Reduction	A	Product is inert to oxidation or reduction.	45742002
830.6315 Flammability/Flash Pt	A	Not flammable	45742002
830.6316 Explodability	A	Product has no potential to act as an explosive.	45742002
830.6317 Storage Stability	U	Product is expected to be stable for decades; one-year storage study at room temperature is in progress.	45742002
830.6319 Miscibility	A	Product is not miscible with any common polar or "apolar" solvent.	45742002
830.6320 Corrosion Characteristics	A	Product is non-corrosive.	45742002
830.6321 Dielectric Breakdown Voltage	A	Product is not used around electrical equipment.	45742002
830.7000 pH	A	8.8-9.0 (1% suspension in deionized water)	45742002
830.7050 UV/Visible Absorption	NR	Not required for EP.	
830.7100 Viscosity	NA	Product is a solid.	45742002
830.7200 Melting Point	NR	Not required for EP.	
830.7220 Boiling Point	NR	Not required for EP.	
830.7300 Density/Sp. Gravity	A	Bulk density: 1.369 g/mL; 1.3-1.4 g/mL	45742002; CSF
830.7370 Dissociation Constant	NR	Not required for EP.	
830.7550-7570 Partition Coefficient	NR	Not required for EP.	
830.7840-7860 Water Solubility	NR	Not required for EP.	
830.7950 Vapor Pressure	NR	Not required for EP.	

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