

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 21, 2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
Frog Mineral Reservoir

DP Barcode: 277232

Experimental Use Permit [X] OR

Reg. No. Or File Symbol: 53735-EUP-R
End-use Product []

TO: Marshall Swindell/Tony Kish
PM Team 33

FROM: Nancy Whyte, Chemist *NW*
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THRU: Karen P. Hicks, CT Team Leader
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THRU: Michele E. Wingfield, Chief
Product Science Branch
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[Handwritten signature]
10/25/01

Product Formulation
Active Ingredient(s)

% by wt.

Sodium chloride

0.5%

BACKGROUND:

This is a request for an experimental-use permit to perform field testing for a device which is used in connection with chlorine to treat swimming pools. The product consists of a sealed reservoir containing silver chloride (active ingredient) [redacted] and an inert [redacted] carrier [redacted]. Submitted to support product chemistry data requirements were three documents, MRID Nos. 454454329-01, -01c, and 454485-01.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

FINDINGS:

1. The pesticide component of this device is produced by [REDACTED] While this process was clearly described in MRID No. 485488-01, page 29, no pre-reaction Confidential Statement of Formula was submitted to show the ingredients used to produce the pesticide prior to its incorporation with the inert ingredients contained in the reservoir.
2. All the upper and lower certified limits listed on the final Confidential Statement of Formula are wider than the standards set forth by the Agency in 40 CFR, Part 158.178. There was no discussion of the need for wider limits in the description of 830.1750--Certified Limits on page 40 of MRID No. 4545485-01.
3. All ingredients in the formulation have been approved for use in pesticides.
4. Data submitted to support product chemistry data requirements of 830 Series, Part B are complete. The nature of the product is such that some physical and chemical characteristics do not apply to this product. Part A Guidelines, with the exception of 830.1750 are also complete.
5. The ingredient claims statement on the experimental use label is in agreement with the nominal concentration of the active ingredient listed on the Confidential Statement of Formula and conforms to PR Notice 91-2.

RECOMMENDATIONS:

1. The registrant must submit a pre-reaction Confidential Statement of Formula which shows the reaction of [REDACTED]
2. The certified upper and lower limits of the ingredients listed on the Confidential Statement of Formula must be corrected to be in compliance with the Agency standards, or the registrant must submit data to support the use of wider limits. If no justification for wider limits is submitted, a revised Confidential Statement of Formula with corrected certified limits must be sent to the Agency for review and approval.
3. Product chemistry data submitted are acceptable with the exception of those discrepancies noted above. A summary of the data is attached below.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

PRODUCT CHEMISTRY REVIEW

4. **CONFIDENTIAL STATEMENT OF FORMULA**

4a. Type of formulation and source registration

- Non-integrated formulation system
 - Are all TGAIs used registered? Yes [] No []
- Integrated formulation system [X]
- 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[X]

4c. Physical state of product: Solid

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B

Yes [X] No []

4h. NCs and CLs are acceptable: Yes [] No [X] Not acceptable []

4i. Active ingredient (s)	NC	UCL	LCL
A. Silver chloride	0.5%	0.6%	0.4%

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

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

- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes [] No [] Not applicable [X]

5. PRODUCT LABEL Experimental-use label only at this time

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]
- 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]

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]

4.

PRODUCT CHEMISTRY (830 Series, Part B)

Guideline	Acceptance of Information	MRID No.
830.1550 ¹ Product Identity	A	454488-01
830.1600 Description of Materials	A	454485-01
830.1620 Production Method ²	A	454488-01
830.1650 Formulation process ³	U	454485-01
830.1670 Formation of impurities ⁴	A	454488-01
830.1700 Preliminary Analysis ⁵	A	454488-01
830.1750 Certified Limits ⁶	U	454488-01
830.1800 Analytical Method ⁷	A Atomic absorb.	454488-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; 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 CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6303 Physical state	A	Solid	454329-01
830.6303 Odor	NR		
830.7200 Melting point	NR		
830.7220 Density/Relative density/bulk density	A	1.374 gm/mL	454329-01
830.7000 pH ¹	A	6.7-6.8	454329-01
830.6314 Oxidation/Reduction	A	Components are inert	454329-01
830.6315 Flammability	A	Components do not support combustion	454329-01
830.6317 Storage stability	A	Pending study	454329-01
830.7100 Viscosity	NR		
830.6319 Miscibility ²	NA		
830.6320 Corrosion Character.	A	No corrosion expected	454329-01
830.6321 Dielectric breakdown	NR		454329-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; 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.

¹ If product is dispersible with water

² If product is an emusifiable liquid