

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
**Antimicrobials Division**

March 19, 2002

**SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Cutrine - Ultra**

**DP Barcode: D281525**  
**Manufacturing-use [ ] OR**

**Reg. No. Or File Symbol: 8959-LG**  
**End-use Product [X]**

**TO:** Adam Heyward PM,34 / Laverne Dobbins, Team Reviewer  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**FROM:** Robert A. Turpin, Chemist *R.A.T.*  
Product Science Branch, CT Team  
Antimicrobials Division (7510C)

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

*K.P.H. 3/20/02*

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

**Product Formulation**

Active Ingredient(s)	% by wt.
Copper .....	9.70%

**BACKGROUND:** The applicant has resubmitted a Confidential Statement of Formula and draft label in support of its application for registration of Cutrine - Ultra. The resubmission is in response to a letter from the Agency, dated February 21, 2002, informing the applicant of several deficiencies in its earlier submission. The Product Science Branch has performed the review.

**FINDINGS:**

1. The Confidential Statement of Formula , as corrected, is acceptable.
2. The draft label has been correctly changed to be in conformity with the Confidential Statement of Formula. The draft label is acceptable.
3. The Group B Physical and Chemical Characteristics are acceptable to the Agency.

**RECOMMENDATIONS:**

- All product chemistry submitted is acceptable to the Agency.

**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: Liquid

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 [X] No [ ] Not acceptable [ ]

4i. Active ingredient (s)	NC	LCL	UCL
Copper .....	9.7%	9.22%	10.19%

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

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

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]

2.

**PRODUCT CHEMISTRY (830 Series, Part B)**

Guideline	Acceptance of Information	MRID No.
830.1550 <sup>1</sup> Product Identity		
830.1600 Description of Materials		
830.1620 Production Method <sup>2</sup>		
830.1650 Formulation process <sup>3</sup>		
830.1670 Formation of impurities <sup>4</sup>		
830.1700 Preliminary Analysis <sup>5</sup>		
830.1750 Certified Limits <sup>6</sup>		
830.1800 Analytical Method <sup>7</sup>		

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

<sup>1</sup>See Confidential Appendix A for additional information

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

<sup>3</sup>For products from a TGAI or MP.

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

<sup>5</sup>Five batch analysis required for products produced by an integrated formulation system.

<sup>6</sup>If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate 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.
830.6302 Color	A	Dark blue	---
830.6303 Physical state	A	Liquid	455332-04
830.6303 Odor	A	Amine like	---
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	A	1.2322	455332-04
830.7000 pH <sup>1</sup>	A	10.23	455332-04
830.6314 Oxidation/Reduction	A	The product is not an oxidizing agent but is a slight reducing agent	455332-04
830.6315 Flammability	NA		
830.6317 Storage stability	A	No change in copper concentration in one year storage	
830.7100 Viscosity	A	396 mPa*s	455332-04
830.6319 Miscibility <sup>2</sup>	NA		
830.6320 Corrosion Character.	A	Not corrosive to plastic storage container	---
830.6321 Dielectric breakdown	NA	NA	

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.

<sup>1</sup> If product is dispersible with water

<sup>2</sup> If product is an emulsifiable liquid