UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

January 3, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Cutrine - Ultra

DP Barcode: D279122 **Reg. No. Or File Symbol: 8959-LG**
Manufacturing-use [ ] OR **End-use Product [X]**

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

FROM: Robert Turpin, Chemist R. T.
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THRU: Karen P. Hicks, CT Team Leader
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THRU: Michele E. Wingfield, Chief
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Product Formulation

Active Ingredient(s)	**% by wt.**
Copper	9.7

BACKGROUND: The applicant has submitted an application for registration of its product, Cutrine – Ultra. In support of the application the applicant has submitted a Confidential Statement of Formula (CSF), Data Matrix Forms, a proposed Product Label, and studies of Product Identity and Composition,

Beginning Materials, Production Process and Formulation of Impurities (MRID #455332-01); Analysis and Certification of Product Ingredients and Analytical Method to Verify Certified Limits (MRID #455332-02); Preliminary Analysis (MRID #455332-03); and, Physical and Chemical Characteristics (MRID #455332-04). The primary review has been performed by the Product Science Branch.

FINDINGS:

1. The lower certified limit of the active ingredient, copper, is less than the Agency standard as required in 40 CFR 158.175. For ingredients having a concentration greater than 1% but less than 50%, the certified limits are +/- 5%.

2. On the label, the percentage of inert ingredients is stated incorrectly. The correct percent is 90.3%.

3. MRID #455332-01: Product Identity and Composition – Statement of Formula, the lower certified limit is less than the Agency standard of 5% less than the nominal concentration.

4. MRID #455332.01: The Description of Beginning Materials (830.1600), Manufacturing Process (830.1650), Discussion of Formation of Impurities (830.1670) are disclosed in satisfaction of the guidelines of series 830.

5. MRID #455332-02: The Certification of Ingredient Levels states a lower limit of 9.0%, which is less than the Agency default value of 9.22%. Explanation is provided indicating the lower limit is based on manufacturing experience. No further discussion is provided to explain the circumstances preventing the achievement of the higher lower limit.

6. MRID #455332-03: The Preliminary Analysis study described the analytical method of determining the concentration of copper in five batches. It is noted that the test substance was identified as having a copper content of 9.0% as supplied by Laporte Water Technologies & Biochem. Two replicate analyses were performed on each of five lots. The recorded concentrations ranged from a low of 9.63% to 9.86%.

7. MRID #455332-04: The Physical and Chemical Characteristics (40 CFR 158.190) Group B are disclosed.

RECOMMENDATIONS:

1. The CSF is acceptable with comment. The applicant is required to submit to the Agency justification for the lower certified limit of the active ingredient being below the standard or to raise the lower certified limit (LCL) of the active ingredient to that of the standard, i.e., 9.22%.

2. The draft label is acceptable with comment. The label misstates the inert content. The applicant is required to correct the percentage of the inert to reflect a content of 90.3% given the content of active ingredient to be 9.7%.

3. MRID #455332-01, Product Identity and Composition, is acceptable with comment. The applicant is required to bring into compliance with the standard, the statement of the lower certified limit of the active ingredient or to submit to the Agency justification of the lowered concentration. A statement of justification will be reviewed in light of MRID #455332-03, Preliminary Analysis, the results of said study indicating concentrations well within the standard limits established in 40 CFR 158.175.

4. MRID #455332-02, as above, the applicant is required to bring into compliance with the standard, the statement of the lower certified limit. The study is acceptable upon receipt by the Agency of the correction or justification for maintaining the lowered limit.

5. MRID #455332-03 is acceptable.

6. MRID #455332-04, Group B Physical and Chemical Characteristics, is acceptable.

7. The applicant is required to submit data to complete the Physical and Chemical Characteristics profile, i.e., color (830.6302), odor (830.6303), storage stability (830.6317), corrosion (830.6320), and, dielectric breakdown (830.6321).

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 ⅓ 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 [X] No [ ] NA[ ]

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
A. Copper	9.7%	9.0%	10.19%

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

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]

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

Guideline	Acceptance of Information	MRID No.
830.1550[1] Product Identity	U	455332-01
830.1600 Description of Materials	A	455332-01
830.1620 Production Method[2]	A	455332-01
830.1650 Formulation process[3]	NA	
830.1670 Formation of impurities[4]	A	455332-01
830.1700 Preliminary Analysis[5]	A	455332-03
830.1750 Certified Limits[6]	U	455332-02
830.1800 Analytical Method[7]	A	455332-02

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

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[1]See Confidential Appendix A for additional information

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

[3]For products from a TGAI or MP.

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

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

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

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

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	G		
830.6303 Physical state	A	Liquid @ 24° C	455332-04
830.6303 Odor	G		
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	A	1.2322	455332-04
830.7000 pH[1]	A	10.23	455332-04
830.6314 Oxidation/Reduction	A	Not an oxidizer/slightly reducing agent	455332-04
830.6315 Flammability	NA		
830.6317 Storage stability	G		
830.7100 Viscosity	A	396.0 mPa.s	455332-04
830.6319 Miscibility[2]	NA		
830.6320 Corrosion Character.	G		
830.6321 Dielectric breakdown	G		

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 ^{0}C.

[1] If product is dispersible with water.

[2] If product is an emulsifiable liquid.