

US EPA ARCHIVE DOCUMENT

DATE OUT: 21 June 2000

SUBJECT: EP [ ] MP [x] PRODUCT CHEMISTRY REVIEW  
DP BARCODE No.: D263588  
REG./File Symbol No.: 73020-R  
PRODUCT NAME: Copper Sulfate Pentahydrate Manuf.  
COMPANY: Emron Corp.

TO: PM #22, Cynthia Giles-Parker/Janet Whitehurst  
Fungicide Branch  
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist  
Technical Review Branch  
Registration Division (7505C)

**INTRODUCTION:**

The registrant, Emron Corporation, is submitting a "Me Too" application for the registration of the new end-use product, Copper Sulfate Pentahydrate Manufacturing Use. The active ingredient in this product is Copper Sulfate Pentahydrate at 99% a.i. and is intended for use as a manufacturing use product and for non pesticidal industrial use. In addition, the registrant states that the proposed product is substantially similar to E.P.A. Reg. No. 35896-20. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 29 Dec 1999, a draft label, and product chemistry data contained in MRID#s 450268-01 and -02. The Technical Review Branch (TRB) has been asked to review this submission.

**SUMMARY OF FINDINGS:**

TRB has reviewed this submission and reports the following findings:

- There are no inert ingredients in this product.
- The proposed product and the referenced product have the same active ingredient.
- The proposed product lists several related impurities; however, no nominal concentration or upper certified limit was provided.
- The nominal concentration listed on the draft label and the CSF are the same.

- The draft label contains the appropriate storage and disposal statements.
- The certified limits as proposed on the CSF are acceptable.

**CONCLUSIONS:**

TRB has reviewed this submission and concludes the following:

- The CSF dated 29 Dec 1999 is not acceptable because the related impurities listed on the CSF do not have a nominal concentration or the upper certified limit listed on the CSF.
- This submission meets the data requirements as specified in 40 CFR 158.167, 158.175, and 158.180 with respect to discussion of formation impurities, certified limits, and enforcement analytical method. The data requirements with respect to product identity and composition (158.155), description of materials used to produce the product (158.160), description of production process (158.162), and preliminary analysis (158.170) are outstanding.
- This submission also satisfies the data requirement as specified in 40 CFR 158.190 with respect to physical and chemical characteristics.

1. DP BARCODE No.: D263588    2. REG./File Symbol No.: 73020-R
3. Registration     4. Reregistration , Rereg Case No. \_\_\_\_\_
5. Product Name: Copper Sulfate Pentahydrate Manufacturing Use
6. Pesticide Type:                      Fungicide                       Herbicide   
 Insecticide                       Rodenticide                       Antimicrobial   
 Plant Growth Regulator     Others: \_\_\_\_\_
7. Uses:                      Food     Non food use
8. Type of Submission: New     Resubmission     Amendment   
 "ME-TOO"                       Alternate Formulation                       Repack   
 Experimental Use Permit     Other (Specify) \_\_\_\_\_
9. If "Me-TOO" Registration, this product is  is not   
 similar or substantially similar to EPA's Reg. No.: 35820-20,  
 If not, comment in Confidential Appendix A on the differences  
 between the registered and the new source where significant.

**CONFIDENTIAL STATEMENT OF FORMULA, DATED (29 Dec 1999) :**

10. Type of formulation and the sources of active ingredients:
- a. Non-integrated formulation system.....[ ]
- b. Are all technical grade active ingredients used  
 registered?                      yes     no
- c. Integrated formulation system.....[x]
11. Composition: The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:
- | Active ingredient(s)        | NC | % by weight |     |
|-----------------------------|----|-------------|-----|
|                             |    | UCL         | LCL |
| Copper Sulfate Pentahydrate | 99 | 100         | 96  |
12. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

yes [x] no [ ]

- 13. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

yes [x] no [ ]

- 14. Clearance of intentionally added ingredients in the formulation for the intended use:

a. Formulation intended for food use under 40CFR§180.1001:

yes [ ] no [x] Some are cleared, others are not [ ]

Cleared under list: c [ ] d [ ] e [ ]

b. Formulation intended for non-food use:

yes [x] no [ ] Some are cleared, others are not [ ]

- 15. For products produced by an integrated formulation system: All impurities of toxicological significance have an UCL:

yes [ ] no [x] not applicable [ ]

All other impurities 0.1% associated with the active ingredient in the product are reported at their nominal concentrations:

yes [ ] no [x] not applicable [ ]

PRODUCT LABEL, EPA RECEIVED (draft) :

- 16. The active ingredients statement (chemical identities, nominal concentrations) is consistent with the CSF yes [x] no [ ]

- 17. The formulation contains one of the following:

10% or more of a petroleum distillate: yes [ ] no [x]
1% 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 [x] no [ ]

- 18. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?

yes [ ] no [x] not applicable [ ]

19. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

yes [ ]                      no [ ]                      not applicable [x]

20. 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 [ ]

**PRODUCT CHEMISTRY DATA (GROUP A)**

<u>21. Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830-1550 Chemical Identity	Y	csf 29 Dec 1999
830-1600 Description of Materials	N	

Product	Used to Produce the		
830-1620	Description of Production Process	N	
830-1650	Description of Formulation Process	NA	
830-1670	Discussion of Impurities	Y	450268-01
830-1700	Preliminary Analysis	N	
830-1750	Certified Limits	Y	csf 29 Dec 1999
830-1800	Enforcement Analytical Method	Y	450268-01

**PRODUCT CHEMISTRY DATA (GROUP B)**

<u>24. Physical/Chemical Properties</u>	<u>Data Required Fulfilled</u>	<u>Value or Qualitative Description</u>	<u>MRID No.</u>
830-6302 Color	N		
830-6303 Physical State	Y	crystalline solid	450268-02
830-6304 Odor	N		

830-6314 Oxidation/Reduction:Chemical Incompatibility	Y	test substance is not an oxidizing or reducing agent	450268-02
830-6315 Flammability/Flame Extension	NA		
830-6316 Explodability	NA		
830-6317 Storage Stability of Product	I	12 month study in progress	
830-6319 Miscibility	NA		
830-6320 Corrosion Characteristics	I	study in progress	
830-6321 Dielectric Breakdown Constant	NA		
830-7000 pH	Y	4.65 @ 25°C	450268-02
830-7100 Viscosity	NA		
830-7300 Density	Y	1.42 g/ml @ 24°C	450268-02

**Explanations:** Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

CONFIDENTIAL APPENDIX

Note to the PM:

The CSF for EPA Reg. No. 35896-20, Copper Sulfate Pentahydrate, needs to be revised because the nominal concentration is the same as the lower certified limit. PR-Notice 91-2 discontinued the practice of listing the lower certified limit as the nominal



concentration.