

US EPA ARCHIVE DOCUMENT

FEE

DATE OUT: 15/NOVEMBER/ 2006

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**  
DP BARCODE No.: D332633 EPA File Symbol No.: 83232-R  
PRODUCT NAME: Q-104  
COMPANY: Quadrua, LLC.  
FOOD USE [ ] INTEGRATED FORMULATION [ ]  
PCC: 024401 Decision No. 365047 ACTION CODE: R31

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*SRW 11/20/06*

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*WKE 11/20/2006*

**INTRODUCTION:**

The Registrant has submitted product chemistry data to support the "Me-Too" registration of the proposed end-use product EPA File Symbol: 83232-R. The registrant has submitted the product chemistry data corresponding to Subgroup A under MRID No. 469109-01. The registrant is citing EPA's analytical method for quantitative determination of Cupric Ion in Copper Sulfate Formulations by Ion Chromatography (EPA Manual of Chemical Method for Pesticides and Devices, 2<sup>nd</sup> Edition, October 1, 1987). They have also Self-Certified product chemistry data for Subgroup B (PR Notice 98-1). The registrant has also submitted a CSF for the proposed formulation and a proposed product specific label both dated 2/14/2006. The applicant has claimed that the proposed formulation is substantially similar (Me-Too) to the registered product EPA Reg. No. 64962-1. The TRB has been requested to evaluate product chemistry data submitted and to determine proposed product's similarity with the cited products for registration of the proposed product.

**SUMMARY OF FINDINGS**

1. The proposed basic end use formulation is not substantially similar to the cited registered product EPA Reg. No. 64962-1. Therefore, bridging product chemistry data with the cited product for "me-too" registration of the subject product is not acceptable [FIFRA§3(c)3(i)(B)(I)]. However, the registrant has furnished all product chemistry data that is required for independently registering the subject formulation [FIFRA§3(c)(1)].
2. The source material of the single active ingredient in proposed basic formulation is Copper Sulfate Pentahydrate XXXXXXXXXX
3. The nominal concentrations of the active ingredients in the proposed and in the cited products are 19.8% and this matches with the label claim.
4. The certified limits of the active ingredient in the proposed product CSF differ from the standard certified limits set forth in 40CFR§158.175(b)(2).

**DP BARCODE No.:** D332633 **EPA File Symbol No.:** 83232-R **PRODUCT NAME:**  
Q-104

5. The CSF of proposed formulation (dated 2/14/2006) is filled out correctly & completely. The CSF for proposed formulation is in compliance with PR Notice 91-2. The inert ingredients present in the proposed formulation are cleared by the Agency for proposed use.

6. The data submitted corresponding to guidelines 830.1550 (product identity & composition), 830.1600 (materials used to produce the product), and 830.1650 (description of production process), 830.1670 (discussion of formation of impurities), satisfy the product chemistry data requirements of 40CFR§158.155, 158.160, 158.162, 158.165 and 158.167 respectively [MRID Nos. 469109-01].

7. The method proposed corresponding to guideline 830.1800 (enforcement analytical method) satisfy the requirements of 40CFR§158.180. The registrant is citing EPA's method for determination of Cupric Ion in Copper Sulfate Formulations by HPLC.

8. The data submitted corresponding to guideline 830 series subgroup B satisfy the data requirements of 40CFR §158.190. The registrant has Self-Certified the physical/chemical properties of the subject formulation [PR Notice 98-1].

#### **CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The proposed formulation (EPA File Symbol No. 83232-R, Q-104) is not substantially similar to the registered cited product (EPA Reg.No.64962-1) from the product chemistry point of view.
2. The proposed formulation (dated 2/14/2006) is acceptable for registration.

**DP BARCODE No.:** D332633 **EPA File Symbol No.:** 83232-R **PRODUCT NAME:**  
Q-104

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B

<u>Subgroup A</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830.1550. Chemical Identity (Same as Reg. Product. CSF)	A	469109-01
830.1600. Beginning Materials	A	469109-01
830.1650. Formulation Process	A	" " "
830.1670. Discussion of Impurities	A	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic CSF)	A	469109-01
830.1800. Enforcement Analytical Method	A	469109-01

DP BARCODE No.: D332633 EPA File Symbol No.: 83232-R PRODUCT NAME:  
Q-104

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Clear blue	Self-Cert
830.6303. Physical State	A	Liquid	..
830.6304. Odor	A	None	..
830.6314. Oxidation/Reduction Action	A	Reacts with metal having a higher oxidizing potential than copper.	
830.6315. Flammability (basic CSF 5/1/06)	A	Not flammable	Self-Cert
830.6316. Explodability	NA	Not explosive	"
830.6317. Storage stability	A		"
830.6319. Miscibility	NA		Self-Cert
830.6320. Corrosion Characteristics	A		Self-Cert
830.6321. Dielectric Breakdown Voltage	NA		"
830.7000. pH	A	Less than 1.0	"
830.7100. Viscosity	A	1.0 centistoke at 25 ° C	Self-Cert
830.7000. Density/Bulk Density	A	1.11 g/cm <sup>3</sup> at 20° C	Self-Cert

**Explanations:** A = 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.

**DP BARCODE No.:** D332633 **EPA File Symbol No.:** 83232-R **PRODUCT NAME:**  
Q-104

830.1800 (Enforcement analytical method): (Cited EPA's Method)

This cation chromatographic method was developed for a liquid copper sulfate formulation, which normally contains 6.3% cupric sulfate (anhydrous). Other formulations may be analyzed by this procedure with slight modifications. HPLC equipped with a Wescan Model 213A high sensitivity conductivity detector and Wescan Cation/HS column is used. The sample is dissolved in distilled water to give a final conc. of 0.128 mg/ml of Copper sulfate. The supernate is filtered through a 0.5  $\mu\text{m}$  filter. Amount injected is 100  $\mu\text{L}$  with a flow rate of 1.7 ml/min in ambient temp. keeping detector range at 100. Operating range should be adjusted to optimize resolution, response, and reproducibility. The percent cupric sulfate is calculated by a given formula described in the method.