

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

January 4, 2007

DP BARCODE: # 333389

MRID : # 469466-01, # 469466-02, # 469466-03, # 469466-04

SUBJECT: Basic Copper Carbonate
(Name of Product)

REG. NO. OR FILE SYMBOL: 3008-OA

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use OR End-use Product

INGREDIENTS (PC Codes): 022901

CAS Number: 12069-69-1

TEST LAB: Eurofins Product Safety Laboratories & Huntingdon Life Sciences Ltd.

SUBMITTER: Osmose, Inc.

GUIDELINE: OPPTS Guidelines Series 830, Group A and B

COMMODITIES: N/A

REVIEWER: Alex Traska

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 1/4/07

COMMENT:

TO: Adam Heyward
PM Team # 34

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

BA 114107

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

Karen P. Hicks

THRU: Michele E. Wingfield, Chief
Product Science Branch
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APPLICANT:

Action code : A 55 new product; non-fast track; other uses

Due out date : 21 Apr 2007

Product Formulation

Active Ingredient(s): % by wt.

Copper carbonate96.8

Metallic Copper Equivalent: 55.6 %

BACKGROUND:

This application, in support of the new product registration of the subject manufacturing-use copper carbonate TGAI, was made by the registrant Osmosc, Inc.

The proposed new manufacturing-use product, **Basic Copper Carbonate**, is intended for the formulation wood preservative products. The registrant provided a Basic CSF covering the proposed product which is produced by a non-integrated formulation system.

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter and transmittal document dated September 28, 2006, proposed new Basic CSF dated September 21, 2006, Data Matrix (Agency Copy) dated 9/28/06, proposed new product label EPA dated 10/2/06 and product chemistry data covering OPPTS Test Guideline Series 830 Group A under MRID # 469466-01 dated September 28, 2006 and MRID # 469466-02 (Preliminary Analysis of Basic Copper Carbonate) dated September 26,

2006. The OPPTS Group B chemistry data was submitted under MRID # 469466-03 dated September 26, 2006 and MRID # 469466-04 (Vapor Pressure of Basic Copper Carbonate) dated September 15, 2006.

FINDINGS:

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient given in the proposed new Basic CSF dated September 21, 2006, agreed with the percentage declared on the product label.
2. The upper and lower certified limits for both the active and impurities were acceptable.
3. Both the Group A and Group B product chemistry data provided in support of this registration was acceptable and met all EPA and GLP requirements.
4. All other elements of this new product registration submission and the proposed new Basic CSF, dated September 21, 2006, are acceptable.
5. Correct ingredient declaration on product label to read Inert Ingredients:3.2%.

CONCLUSIONS:

This application, in support of the new product registration of, **Basic Copper Carbonate**, is accepted with comment.

Registrant must modify the label ingredient declaration as per item #5 of the Findings.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system
- Are all TGAs used registered? Yes No
- Integrated formulation system
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes No

- c. Physical state of product: powder
- d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes No
- e. The NCs and CLs are acceptable. Yes No
- | | | | |
|-------------------------|-----------|------------|------------|
| f. Active ingredient(s) | <u>NC</u> | <u>LCL</u> | <u>UCL</u> |
| Copper carbonate | 96.8% | 99.7% | 93.9% |
- g. For products produced by an integrated formulation system:
- Do all impurities of toxicological significance have a UCL?
Yes No Not applicable
 - Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes No Not applicable

II PRODUCT LABEL

- a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes No
- b. The formula contains one of the following:
- 10% or more of a petroleum distillate: Yes No
 - 1.0% or more of methyl alcohol: Yes No
 - sodium nitrite at any level: Yes No
 - a toxic List I inert at any level: Yes No
 - arsenic in any form: Yes No
- c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?
Yes No Not applicable
- d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes No Not applicable
- e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes No
- f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes No

Note: Storage stability study is not required for a TGA I.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	469466-01
830.1600 Description of Materials	A	469466-01
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	469466-01
830.1670 Formation of Impurities ⁴	A	469466-01
830.1700 Preliminary Analysis ⁵	A	469466-02
830.1750 Certified Limits ⁶	A	469466-01
830.1800 Analytical Method ⁷	A	469466-01
830.1900 Submittal of Samples		

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 CLs 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.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A		469466-03
830.6303 Physical State	A		"
830.6304 Odor	A		"
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	A		"
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	None of the product ingredients are strong oxidizing or reducing agents.	"
830.6315 Flammability/Flame Extension	A	The product does not contain any flammable materials and is [REDACTED]	"
830.6316 Explodability	A	The product does not have any explosive characteristics.	"
830.6317 Storage Stability	NA	Not Required for TGAI	
830.6319 Miscibility ¹	A	The product is not an emulsifiable concentrate. The product label does not recommend dilution of the product with oil.	"
830.6320 Corrosion Characteristics	NA	Not Required for TGAI	"
830.6321 Dielectric Breakdown Voltage	A	The product is not proposed for use around electrical equipment.	"
830.7000 pH ²	A	The pH of a 1% by weight dispersion of the product was determined to be 9.36.	"

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7050 UV/Visible Absorption	A	.	469466-03
830.7100 Viscosity	A	Not tested. Product is not a liquid.	"
830.7200 Melting Point/Melting Range	A	.	"
830.7220 Boiling Point/Boiling Range	A	Not tested. Product is not a liquid.	"
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was determined to be 1.474 g/ml (12.3 pounds/gallon) at 24°C.	"
830.7370 Dissociation Constants in Water	A	Not required. Product is inorganic.	"
830.7550/830.7560/830.7570 Partition Coefficient	NA	Not required. Product is inorganic.	"
830.7840/830.7860 Water Solubility	A	Not detected.	"
830.7950 Vapor Pressure	A	Vapor Pressure 5×10^{-5} Pa @ 25deg. C	"

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.

¹If product is an emulsifiable liquid

²If product is dispersible with water