UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
ANTIMICROBIALS DIVISION

Friday, July 15, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:

DP Barcode: D316776 **Reg. No. Or File Symbol:** 3008-OE

Manufacturing-use [ ] OR **End-use Product [X]**

TO: Adam Heyward, PM 34/ Lisa McKelvin
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FROM: Ian Blackwell, Biologist
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7/21/05

Product Formulation	
Active Ingredients:	**% by wt.:**
Copper carbonate	57.60%

1) BACKGROUND:

Osmose, Inc., is submitting an application for registration of ORD-X370. The product is end-use and is produced by an non-integrated system. The product will be used for treatment of wood to prevent fungal decay.

CTT/PSB contractor DynCorp/CSC conducted a primary review of this data. CTT conducted a brief secondary review of the submitted in formation for this review. The two submitted reports are assigned MRID Numbers 465331-01 and -02.

2) FINDINGS:

a) **Product Chemistry Data (MRID 465331-01)**

i) The certified limits provided on the Confidential Statements of Formula (CSFs) are correct and agree with the standard certified limits. The applicant has provided a certification statement for the certified limits used.
ii) The label ingredient statement, which lists the nominal concentration, is consistent with the CSF and conforms to recommendations of PR Notice 91-2, except that the applicant has not indicated the metallic copper equivalent resulting from the copper complex used as an active.
iii) The following Group A product chemistry data requirements for the end-use product are complete: 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), and 830.1750 (Certified Limits).
iv) The Group A product chemistry data requirement, 830.1800 (Enforcement Analytical Method) is incomplete. The applicant has not provided validation information with respect to precision and accuracy for the provided enforcement analytical method.
v) A Good Laboratory Practice (GLP) statement was provided with the submitted package stating this study does not contain laboratory work subject to the Environmental Protection Agency (EPA) GLP Standards per 40 CFR Part 160.
vi) Guideline test 830.1620 was not conducted for this product as it is not required for this product.

b) **Characterization and Product Chemistry Evaluation (MRID 465331-02)**

i) The following Group B product chemistry data requirements for the end-use product are complete: 830.6302 (Color), 830.6303 (Physical State), 830.6304 (Odor), 830.7000 (pH), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density). The applicant has addressed the color and odor of the product, even though this information is no longer required for end-use products.
ii) A statement of GLP compliance was included with the study package, stating that the study was conducted in accordance with 40 CFR Part 160, issued 17 August 1989.

105

3) **RECOMMENDATIONS:**

a) MRID Number 465331-01 is unacceptable. The problem with this study is on page 3 of 59. The report states that the study does not meet the requirements of 40 CFR, Part 160. PSB/AD cannot accept studies that do not comply with the GLP standards of the 40 CFR, Part 160.

b) The label ingredient statement, which lists the nominal concentration, is consistent with the CSF and conforms to recommendations of PR Notice 91-2, except that the applicant has not indicated the metallic copper equivalent resulting from the copper complex used as an active.

c) The Group A product chemistry data requirement, 830.1800 (Enforcement Analytical Method) is unacceptable. The applicant has not provided validation information with respect to precision and accuracy for the provided enforcement analytical method.

d) This submission is also unacceptable as the following studies are absent:

i) 830.6313. Stability to Normal and Elevated Temperatures, Metals and Metal Ions
ii) 830.6314. Oxidation/Reduction; chemical incompatibility
iii) 830.6315. Flammability/Flame Extension
iv) 830.6316. Explodability
v) 830.6317. Storage stability
vi) 830.6319. Miscibility
vii) 830.6320. Corrosion Characteristics
viii) 830.6321. Dielectric Breakdown Voltage
ix) 830.7200. Melting Point/Melting Range

e) A problem with the CSF is that, while the percent by weight of the metallic copper equivalent is listed, it does not list upper and lower certified limits for metallic copper equivalent. This needs to be corrected.

104

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

Non-integrated formulation system [X]

Are all TGAIs used registered? Yes [X] No [ ]

Integrated formulation system [ ]

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 (aqueous dispersion)*

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Group B:
Yes [X] No [ ]
Flammability not addressed in reviewed data packages.

4h. NCs and CLs are acceptable: Yes [X] No [ ]

4i. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
A. Copper carbonate	57.60	55.87	59.33

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]

107

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 [X] Not applicable [ ]

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 [ ]

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 [ ]

Stability and Corrosion studies not addressed in the reviewed study packages.

104

Product Chemistry (830 Series, Group A)

6a. Data Requirements	Acceptance of Information	MRID No.
830.1550[0] Product Identity and Composition	Acceptable	465331-01
830.1600 Description of Materials	Acceptable	465331-01
830.1620 Production Method[0]	Acceptable	465331-01 NA
830.1650 Formulation process[3]	Acceptable	465331-01
830.1670 Formation of impurities[4]	Acceptable	465331-01
830.1700 Preliminary Analysis[5]	Unacceptable	465331-01 NA
830.1750 Certified Limits[6]	n/a	465331-01
830.1800 Analytical Method[7] *Titrometric determination*	Acceptable	465331-01

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.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), etc.

Physical and Chemical Characteristics (Series 830, Group B)

6b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	Acceptable	light green (Ref. SOP ORD-11B/0).	465331-02
830.6303 Physical State	Acceptable	liquid (opaque aqueous dispersion (Ref. SOP ORD-11C/0).	465331-02
830.6304 Odor	Acceptable	latex paint-like odor (Ref. SOP ORD-11D/0).	465331-02
830.6313 Stability to Normal and Elevated Temperatures, Metals and Metal Ions	---	Not required	n/a
830.6314 Oxidation/Reduction; Chemical Incompatibility	Unacceptable	Not submitted	
830.6315 Flammability/Flame Extension	Unacceptable	Not submitted	
830.6316 Explodability	Unacceptable	Not submitted	
830.6317 Storage Stability	---	Not required at this point. (Currently being conducted.)	n/a
830.6319 Miscibility[2]	Unacceptable	Not submitted	
830.6320 Corrosion Characteristics	Unacceptable	Not submitted	
830.6321 Dielectric Breakdown Voltage	Unacceptable	Not submitted	
830.7000 pH[1]	Acceptable	9.21 for a 1% (w/w) solution with deionized water using a digital pH meter (Ref. SOP ORD-11K/0).	465331-02
830.7100 Viscosity	Acceptable	60.6625 mm^2/sec at 20°C and 27.1617 mm^2/sec at 40°C using Cannon-Fenske Routine, Size 200 viscometer. (Ref. SOP ORD-11L/0).	465331-02
830.7200 Melting Point/Melting Range	Acceptable	Not required	n/a
830.7300 Density/Relative Density/Bulk Density	Acceptable	1.7559 g/mL (14.63 lb/gal) at 25°C. (Ref. SOP ORD-11O/0).	465331-02

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.

[1] If product is dispersible with water
[2] If product is an emulsifiable liquid

110