UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
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SUBSTANCES

10/08/2008

DP BARCODE:	D355080
MRID:	474783-01
SUBJECT:	Coppercoat Copper Powder.
REG. NO. OR FILE SYMBOL:	85396-R
DOCUMENT TYPE:	Product Chemistry Review
Manufacturing-use [] OR	End-use Product [X]
INGREDIENTS (PC Codes)	(022501)
CAS Number:	(7440-50-8)
TEST LAB:	Ag-Chem Consulting LLC
SUBMITTER:	Coppercoat USA LLC
GUIDELINE:	830 Guidelines
COMMODITIES:	Formulation
REVIEWER:	Krishna K Deb
ORGANIZATION:	AD
APPROVER:	Karen P. Hicks
APPROVED DATE:	10/8/08
COMMENT:	

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10/08/2008

MEMORANDUM

85396-R
K Deb
10/03/2008

Subject: Chemistry Review for EPA Reg. No 39967-13
From: Krishna K Deb, Chemist
Product Science Branch, CT Team
Antimicrobial Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510P)

Thru: Miehele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510P)

To: **Marshall Swindell//Martha Terry**
Regulatory Management Branch (Rm. 33)
Antimicrobial Division (7510P)

Applicant Coppercoat USA

Action Code A532

Due date: 11/14/2008

Formulations from Label

Active Ingredient(s)

Copper Powder----------99.7%
INERT INGREDIENTS---------- 0.3%
Total----------100.0%

BACKGROUND:

On behalf of Coppercoat USA LLC, Ag-Chem Consulting is submitting an application for registration of a new TGAI, Coppercoat Copper Powder. This TGAI is one part of a three-component product. The three-component product consists of the TGAI, a resin, and a hardener, which when mixed forms an epoxy-based antifoulant intended for application to the hulls of freshwater and marine vessels. The data package included a Confidential Statement of Formula (CSF) for the basic formulation (dated June 20, 2008). This TGAI is produced by an integrated formulation system (i.e., the active ingredient that is not an EPA-registered product).

FINDINGS:

Group A Requirements – Coppercoat Copper Powder, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines (MRID 474783-01)

- Group A product chemistry data requirements applicable to TGAIs have been met, with the exception of OPPTS 830.1620 (Production Process), OPPTS 830.1700 (Preliminary Analysis), and OPPTS 830.1800 (Analytical Method). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.

Group B Requirements – Coppercoat Copper Powder, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines (MRID 474783-01)

- Group B product chemistry data requirements applicable to TGAIs have been met, with the exception of OPPTS 830.7200 (Melting Point/Melting Range), OPPTS 830.7300 (Density/Relative Density/Bulk Density), and OPPTS 830.7950 (Vapor Pressure). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.

- The study assigned MRID 474783-01 is missing Appendix 2 (which presumably was to include a Certificate of Analysis).

- A Good Laboratory Practice (GLP) statement was provided stating that the document assigned MRID 474783-01 meets the requirements of 40 CFR Part 160 with the following exceptions: (1) No inspections were conducted. (2) No audits were conducted on the raw data or the report. Although this GLP statement was provided, it appears that analytical data provided were not obtained from GLP-compliant testing of the TGAI.

Confidential Statement of Formula

- Certain information on the CSF could be improved, as noted in the "Recommendations" section of this report
- The CSF is acceptable.

Product Label

- Certain information on the product label could be improved, as noted in the "Recommendations" section of this report

- Certain information on the product label must be revised, as noted in the "Recommendations" section of this report.

RECOMMENDATIONS:

- To satisfy OPPTS 830.1620 (Production Process) requirements, the following information must be provided:

  - A description of the equipment used to produce the TGAI.

  - A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process.

  - A description of the procedures used to assure consistent composition of the TGAI (e.g., calibration of equipment, sampling regimens, analytical methods, and quality control measures). In particular, please identify any parameters that the TGAI is analyzed for prior to distribution (e.g., purity).

- Results from the analysis of five batches of the TGAI were provided. To satisfy OPPTS 830.1700 (Preliminary Analysis) requirements, the results for this preliminary analysis must be presented using the data reporting format requested under OPPTS 830.1700(c).

- An electrodeposition procedure was provided for determining the percentage of copper in a sample. To satisfy OPPTS 830.1800 (Analytical Method) requirements, this discussion must be re-written, formatted, and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, and Calculations.

- To satisfy OPPTS 830.7200 (Melting Point/Melting Range) requirements, a copy of a GLP-compliant laboratory study characterizing the melting point of the TGAI must be provided.

- To satisfy OPPTS 830.7300 (Density/Relative Density/Bulk Density) requirements, a copy of the GLP-compliant laboratory study characterizing the density of the TGAI must be provided.

- To satisfy OPPTS 830.7950 (Vapor Pressure) requirements, a copy of a GLP-compliant laboratory study characterizing the vapor pressure of the TGAI must be provided.

- The following revisions to the CSF are recommended:

  - Under Item #4, record an EPA-assigned registration number (e.g., 85396-XXX).

  - Under Item #7, record the density of the TGAI obtained from the requested GLP-compliant laboratory study.

- The following revisions must be made to the product label:

  - Because the copper powder is not 100% pure, the "Ingredient Statement" on the product label must be revised to read:

Copper Powder	99.7%
Other Ingredients	0.3%
Total	100.0%

  - Under the "Environmental Hazards" section of the product label, change "National Pollution Discharge" to read "National Pollutant Discharge."

  - Under the "Environmental Hazards" section of the product label, add a "Physical and Chemical Hazards" section similar to that provided on the product label for Copper Powder 1921 (EPA Reg. No. 60061-111) and also include the following statement from the product label for Perma-Hull Ultimate (EPA Reg. No. 68679-1): "Avoid strong alkalies, chlorides, bromides, and mineral acids."

- The following revisions to the product label are recommended:

  - Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from its container.

  - Under the "Surface Preparation" section of the product label, change "must be must be cleaned" to read "must be cleaned."

  - Under the "Surface Preparation" section of the product label, change "contaminates" to read "contaminants."

  - Under the "Application" section of the product label, change "by bush" to read "by brush."

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [ ]
- Are all TGAIs used registered? Yes [ ] No [X]
- Integrated formulation system [X]
- 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 [ ]

Note: This product is not intended for food use.

c. Physical state of product: *Solid*

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 [ ]

Note: Physical and chemical property data were not developed under GLP standards.

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Copper powder source	100.0	97.0	103.0
Copper powder	99.7	96.7	102.7

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [ ] No [X]

Note: Because the copper powder is not 100% pure, the "Ingredient Statement" on the product label must be revised to read: Copper Powder 99.7%; Other Ingredients 0.3%; Total 100.0%.

b. The formula 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]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

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 [X] 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 studies are not required for TGAIs.

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

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	474783-01 and CSF
830.1600 Description of Materials	A	474783-01
830.1620 Production Process[2]	A.	474783-01
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	474783-01

Data Requirements	Acceptance of Information	MRID No.
830.1700 Preliminary Analysis[5]	U – Results from the analysis of five batches of the TGAI were provided. The results for this preliminary analysis must be presented using the data reporting format requested under OPPTS 830.1700(c).	474783-01
830.1750 Certified Limits[6]	A – Standard certified limits were proposed. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	474783-01
830.1800 Analytical Method[7]	U – An electrodeposition procedure was provided for determining the percentage of copper in a sample. This discussion must be re-written, formatted, and presented as a stand-alone methodology, so that the method can be followed by any analyst. The methodology might include sections such as Summary, Scope, Equipment (i.e., Apparatus, Reagents), Analytical Procedure, and Calculations.	474783-01
830.1900 Submittal of Samples	A – Samples will be provided, if requested.	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); 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), 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	The TGAI has a salmon color.	474783-01
830.6303 Physical State	A	The TGAI is a solid at room temperature.	474783-01
830.6304 Odor	A	The TGAI is odorless.	474783-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	A	The TGAI is stable and not corrosive.	474783-01
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	Based on known chemistry, inorganic copper will not oxidize metals. Note: The product label for Perma-Hull Ultimate includes the following statement: Avoid strong alkalies, chlorides, bromides, and mineral acids.	474783-01
830.6315 Flammability/ Flame Extension	A	The TGAI is a solid.	
830.6316 Explodability	NA	The TGAI is not explosive. *[Not required for a TGAI.]*	474783-01
830.6317 Storage Stability	NA	Copper powder is known to be stable. *[Not required for a TGAI.]*	474783-01
830.6319 Miscibility[1]	A	The TGAI is a solid.	
830.6320 Corrosion Characteristics	NA	The TGAI is not corrosive. *[Not required for a TGAI.]*	474783-01
830.6321 Dielectric Breakdown Voltage	A	The TGAI (and the three-component product) are not for use on electrical equipment.	474783-01 and Label
830.7000 pH[2]	A	The TGAI is not soluble in water.	474783-01
830.7050 UV/Visible Absorption	A	The TGAI is metallic copper.	
830.7100 Viscosity	NA	*[Not required for a TGAI.]*	
830.7200 Melting Point/Melting Range	N	The melting point of sulfur (not copper) was reported. A copy of a GLP-compliant laboratory study characterizing the melting point of the TGAI must be provided.	474783-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	A	The product is a solid.	
830.7300 Density/Relative Density/Bulk Density	N	The density of the product was reported to be 4.5-5.5 g/mL. A copy of the GLP-compliant laboratory study characterizing the density of the TGAI must be provided.	474783-01
830.7370 Dissociation Constants in Water	A	The TGAI is not soluble in water.	
830.7550/830.7560/830.7570 Partition Coefficient	A	The product is not a non-polar organic.	
830.7840/830.7860 Water Solubility	A	The TGAI is not soluble in water.	474783-01
830.7950 Vapor Pressure	NA		

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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