

US EPA ARCHIVE DOCUMENT

(2-21-2005)



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **ORD-X372**

DP Barcode: **D312505**
Manufacturing-use []

Reg. No. or File Symbol: **3008-ON**
End-use Product [X]

Active Ingredient Composition:

Copper carbonate..... 35.37%
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate.....12.80%

TO: Adam Heyward PM 34

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

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

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This application for a new product registration, covering the subject water based antimicrobial preservative for treating wood articles, was by the registrant, Osrose, Inc.

The registrant, in this new product application, has requested approval to

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~~INERT INGREDIENT INFORMATION IS NOT INCLUDED~~

register **ORD-372** a new end-use product formulated for the industrial treatment of wood to prevent decay. The proposed product is formulated with two EPA registered active ingredients tby use of a non-integrated manufacturing process.

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter dated December 3, 2004, proposed Basic CSF dated December 1, 2004, proposed product label dated 12/09/04 and Product Chemistry Data for Guideline Series 830 Group A under MRID # 464441-01 dated December 2, 2004 and Guideline Series 830 Group B under MRID # 464381-02 dated October 6, 2004.

Additionally, a "primary" chemistry review of pending EPA Reg. No. 3008-ON was made by CSC/DynCorp and all relevant comments from the February 21, 2005 DynCorp review were incorporated into this Product Chemistry Review.

FINDINGS:

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the proposed Basic CSF agreed with the percentages declared on the label.

The registrant having declared copper carbonate as an active ingredient did not declare the equivalent metallic copper as part of the ingredient declaration sub-statement.

2. The active ingredients utilized, copper carbonate and didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate are both EPA registered.

3. The dispersant [REDACTED] listed in the CSF are not in the Agency's inert database. Complete percentage formula disclosures with chemical names and CAS RN will need to be provided to the Agency for these two new inert ingredients. All remaining inert ingredients utilized in the Basic CSF are approved for use in pesticide formulations.

4. The upper and lower certified limits for both the active and inert ingredients are acceptable.

5. The CAS numbers for didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate were not provided on the CSF as is required.

6. The product chemistry package was complete and consistent with the chemical and physical characteristics of the proposed formulation.

More specifically the data provided included

830 Series, Group A (MRID 464441-01): The Group A studies for 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1620 (Description of Production Process), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), 830.1700 (Preliminary Analysis), 830.1750 (Certified Limits), and 830.1800 (Enforcement Analytical Methods) were complete and acceptable.

The applicant has provided a justification for not being required to satisfy the requirements of the following Part A product chemistry data requirements: 830.1620 (Description of Production Process), and 830.1700 (Preliminary Analysis). ORD-X372 is an end-use product that is formulated from registered manufacturing use products by simple mixing.

830 Series, Part B: The registrant provided justifications for not being required to satisfy the requirements of : 830.6314 (Oxidation/Reduction), 830.6315 (Flammability/Flame Extension), 830.6316 (Explosibility), 830.6319 (Miscibility) and 830.6321 (Dielectric Breakdown Voltage). The product does not contain oxidizing or reducing agents, has no flammable or explosive ingredients, is not to be diluted with petroleum solvents, and will not be used around electrical equipment.

Studies for 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristic) have been initiated and are projected to be completed in September 2005.

A Good Laboratory Practices (GLP) statement was included with this data package, stating that the study does not contain work subject to Environmental Protection Agency GLP Standards (40 CFR Part 160).

830 Series, Part B (MRID 464381-02): The Physical and Chemical Properties studies for 830.6302 (Color), 830.6303 (Physical State), 830.6304 (Odor), 830.7000 (pH), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density) were acceptable and complete.

A Good Laboratory Practices (GLP) statement was included with this data package, stating that the studies were conducted in accordance with the requirements of 40 CFR Part 160. A Quality Assurance Unit (QAU) statement also was provided.

7. All other elements of the data submissions and the proposed Basic CSF were acceptable.

RECOMMENDATIONS:

This new product application, in support of the registration of **ORD-X372**, is not accepted.

Registrant must arrange to have the formula disclosures sent to the Agency as requested in item # 3 of the Findings.

Registrant should also address the comments made in item #1 and #5, also listed under Findings.

04/20/05 AT

February 21, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF ORD-X372

DP Barcode: D312505
Manufacturing-use []

Reg. No. Or File Symbol: 3008-ON
End-use Product [X]

TO: Wallace Powell, EPA Work Assignment Manager
FROM: Joan Cuddeback, CSC/DynCorp Work Assignment Manager

This is a review of the following Product Chemistry 830 Series study packages provided to CSC/DynCorp for preliminary review:

Product Chemistry Data (MRID 464441-01)

830 Series, Part A: 830.1550 (Product Identity and Composition), 830.1600 (Description of Materials Used to Produce the Product), 830.1620 (Description of Production Process), 830.1650 (Description of Formulation Process), 830.1670 (Discussion of Formation of Impurities), 830.1700 (Preliminary Analysis), 830.1750 (Certified Limits), and 830.1800 (Enforcement Analytical Methods)

830 Series, Part B: 830.6314 (Oxidation/Reduction), 830.6315 (Flammability/Flame Extension), 830.6316 (Explosibility), 830.6317 (Storage Stability), 830.6319 (Miscibility), 830.6320 (Corrosion Characteristics), and 830.6321 (Dielectric Breakdown Voltage)

Characterization and Product Chemistry Evaluation (MRID 464381-02)

830 Series, Part B: 830.6302 (Color), 830.6303 (Physical State), 830.6304 (Odor), 830.7000 (pH), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density)

Product Formulation

Active Ingredients:	% by wt.:
Copper Carbonate*	35.37%
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate**	12.80%

* From

**From

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BACKGROUND:

Osmose, Inc. is submitting an application for registration of ORD-X372, a new end-use product. ORD-X372 is formulated from currently registered manufacturing use products, through a non-integrated system.

FINDINGS:

Chemical Characterization (MRID 464414-01)

830 Series Part A:

- The certified limits provided for inert ingredients were calculated correctly and are in agreement with the standard certified limits with the following exception: for both the basic and alternate formulation, the applicant has provided certified limits on the Confidential Statement of Formula (CSF) only for the pure active ingredient, and has not provided certified limits for the manufacturing product.
- CAS numbers for didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate are not included on the CSF.
- The following Part A product chemistry data requirements seem to be 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 830.1800 (Enforcement Analytical Methods).
- The applicant has provided a justification for not being required to satisfy the requirements of the following Part A product chemistry data requirements: 830.1620 (Description of Production Process), and 830.1700 (Preliminary Analysis). ORD-X372 is an end-use product that is formulated from registered manufacturing use products by simple mixing.
- The label ingredient statement, which lists the nominal concentration, is consistent with the CSF and conforms to recommendations of PR Notice 91-2 with the exception that, while the applicant has declared the chemical name of the copper complex as an active ingredient, it has not declared the equivalent metallic copper as a sub-statement.
- A Good Laboratory Practices (GLP) statement was included with this data package, stating that the study does not contain work subject to Environmental Protection Agency GLP Standards (40 CFR Part 160).

830 Series Part B:

- The following Part B product chemistry data requirements seem to be 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 provided a justification for not being required to satisfy the requirements of the following: 830.6314 (Oxidation/Reduction), 830.6315 (Flammability/Flame Extension), 830.6316 (Explosibility), 830.6319 (Miscibility), and 830.6321 (Dielectric Breakdown Voltage). The product does not contain oxidizing or reducing agents, has no flammable or explosive ingredients, is not to be diluted with petroleum solvents, and will not be used around electrical equipment.
- Studies for the following Part B product chemistry data requirements are underway: 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristic). The applicant projects September 15, 2005 as the completion date.

Characterization and Product Chemistry Evaluation (MRID 464381-02)

- The following Part B chemical characterization data requirements seem to be 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).
- A Good Laboratory Practices (GLP) statement was included with this data package, stating that the studies were conducted in accordance with the requirements of 40 CFR Part 160. A Quality Assurance Unit (QAU) statement also was provided.

RECOMMENDATIONS:

We are not providing recommendations or acceptability statements.

PRODUCT CHEMISTRY REVIEW

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
 - Are all TGAs 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

4d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [x] No [] Flammability N/A. See FINDINGS.

4h. NCs and CLs are acceptable: Yes [] No [X] No CLs provided for MP used in formulation. See FINDINGS.

4i. Active ingredient(s)	NC	LCL	UCL
A. Copper carbonate	35.37%	34.31%	36.43%
B. Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate	12.80%	12.16%	13.44%

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]

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 [] *Flammability and Explodability N/A. See FINDINGS.*

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 [] *Storage Stability and Corrosion Characteristics Studies are underway. See FINDINGS.*

6. **PRODUCT CHEMISTRY (830 Series, Part A)**

6a. <u>Data Requirements</u>	Acceptance of Information	MRID No.
830.1550 ¹ Product Identity		464441-01
830.1600 Description of Materials		464441-01 N/A
830.1620 Production Method ²		464441-01 N/A
830.1650 Formulation process ³		464441-01-01
830.1670 Formation of impurities ⁴		464441-01-01
830.1700 Preliminary Analysis ⁵		464441-01 N/A
830.1750 Certified Limits ⁶		464441-01
830.1800 Analytical Method ⁷ Copper by titrometric determination and Total Quats by titromeric determination		464441-01

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.

Physical and Chemical Characteristics (Series 830, Part B)

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6303 Physical state		liquid; opaque, aqueous dispersion	464381-02
830.7200 Melting point		Product is a liquid at room temperature. NA	
830.7300 Density/Relative density/bulk density		1.3303 @ 25°C. SOP: ORD-11O/0	464381-02
830.7000 pH ¹		8.52 (1% w/w). SOP: ORD-11K/0	464381-02
830.6314 Oxidation/Reduction		Product does not contain oxidizing or reducing agents. NA	464441-01
830.6315 Flammability		Product does not contain flammable agents. NA	464441-01
830.6317 Storage stability		Study is underway.	
830.7100 Viscosity		115.5902 mm ² /s at 20°C 50.2406 mm ² /s at 20°C. SOP: ORD-11L/0	464381-02
830.6319 Miscibility ²		Product is not to be diluted with petroleum solvents. NA	464441-01
830.6320 Corrosion Characteristics		Study is underway.	
830.6321 Dielectric breakdown		Product contains copper, a known conductor, and will not be used around electrical equipment. NA	464441-01

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

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