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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**

Reg. No. or File Symbol: **3008-ON**

Manufacturing-use []

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)

AT 4/20/05

THRU: Karen P. Hicks, CT Team Leader
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THRU: Michele E. Wingfield, Chief
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BACKGROUND:

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

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

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Inert ingredient information may be entitled to confidential treatment

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] and [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