

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
ANTIMICROBIALS DIVISION

Wednesday, May 17, 2006

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:

Reg. No. Or File Symbol: 3008-90 **DP Barcode:**D327924
Manufacturing-use [] **OR** **End-use Product [X]**

TO: Adam Heyward, PM 34/ Stacey Grigsby
Regulatory Management Branch
Antimicrobials Division (7510C)

FROM: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Ian Blackwell

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

Karen P. Hicks
5/18/06

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

Product Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Copper carbonate	35.37
Didecyl dimethyl ammonium carbonate and didecyl dimethyl ammonium bicarbonate	12.80
<u>Other Ingredients:</u>	<u>51.83</u>
Total:	100.0%

PRODUCT CHEMISTRY REVIEW

- 1) **BACKGROUND:** Osmose, Inc., has submitted a storage stability and corrosion characteristic study to support the product chemistry requirements for "ORD-X372". The study was conducted by Osmose, Inc. The MRID Number is 467829-01.

- 2) **FINDINGS:**
 - a) The product's percentage of active ingredients remained within the upper and lower certified limits during the 12-month study. The percentage of active ingredients stayed within the UCL and LCLs of the declared percentage of active of the label declaration.

 - b) There were no signs of degradation or deterioration in any of the sample containers during the study.

- 3) **RECOMMENDATIONS:**
 - (a) The storage stability study is acceptable.

 - (b) The degradation study is acceptable.

For this assessment, the percentages of active ingredients should be as follows:

	Copper Carbonate	Quat
Nominal	20.1%	12.80%
Upper Certified Limit	20.703%	13.44%
Lower Certified Limit	19.497%	12.16%

The results of this assay were:

Time point (Months)	% Copper Carbonate	% Quat
0	20.20	12.62
3	19.88	12.74
6	20.33	12.09
9	19.95	12.64
12	20.11	12.58