

PRODUCT SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - I

Reviewed by Michael Nieves Date 10-13-98

LAN Code *Michael E. Nieves*

EPA Reg. No. or File Symbol 00791-R

EPA Petition or EUP No. None

Date Division Received 07-28-98

Type Product Hospital Disinfectant

MRID No(s) 446166-01

Product Management Team PM 34

Product Name Spectrum 500

Company Name Envirosystem 500

Submission Purpose:

The registrant is submitting a new application with
proposed labeling.

Type Formulation Liquid

Active Ingredients(s)

Chloroxylenol..... .01%

(1)

PRODUCT SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - II

EPA Reg. No. or File Symbol 70791-R

EPA Petition or EUP No. None

Date Division Received 07-28-98

Type Product Hospital Disinfectant

MRID No(s) 446166-01

Product Management Team PM 34

Product Name Spectrum 500

Company Name Envirosystem 500

200.0 **Introduction:**

200.1 **Uses:**

Hospital Disinfectant

200.2 **Background Information:**

The registrant is submitting a new application with proposed labeling.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 **Data Summary**

None

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Tests:**

"Efficacy Data: AOAC Use Dilution Test- Pseudomonas aeruginosa, Escherichia coli, Salmonella choleraesuis, Staphylococcus aureus and Candida albicans" by EnviroSystems, Inc., 50 Airport Parkway, San Jose, CA 95110, dated July 17, 1998, MRID. No. 446166-01.

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

202.0 **Recommendations**

202.1 **Additional Data Required To Support Efficacy**

"Efficacy Data: AOAC Use Dilution Test- Pseudomonas aeruginosa, Escherichia coli, Salmonella choleraesuis, Staphylococcus aureus and Candida albicans" by EnviroSystems, Inc., 50 Airport Parkway, San Jose, CA 95110, dated July 17, 1998, MRID. No. 446166-01.

The data in MRID No. 446166-01 is deficient in the following manners:

The registrant did not submit data for a 60 day sample, and the phenol coefficient results were not reported for the other two samples. The registrant must submit a complete data package with three sample lots tested, one of which must be 60 days old.

203.0 **Labeling:**

The proposed labeling has not been evaluated due to the data deficiencies stated above.

NOTE TO PM:

The registrant has been granted a time limited registration and will be submitting a new and complete data package correcting the data deficiencies stated above. According to the registrant the new package will have data for all three sample lots including the 60 sample and the appropriate phenol coefficient results.