

PRODUCT SUPPORT BRANCH

ANTIMICROBIAL DIVISION

EFFICACY REVIEW - I

Reviewed by M. Nieves ⁴⁻²²⁻⁹⁸ Date 04-21-98
LAN Code 70791-R-498 *Michael E. Nieves*
EPA Reg. No. or File Symbol 70791-R
EPA Petition or EUP No. None
Date Division Received 02-18-98
Type Product Hospital Disinfectant
MRID No (s) 444921-01
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%

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EPA Reg. No. or File Symbol 70791-R
EPA Petition or EUP No. None
Date Division Received 02-18-98
Type Product Hospital Disinfectant
MRID No(s) 444921-01
Product Management Team PM 34
Product Name Spectrum 500
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- 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 November 17, 1997, MRID. No. 44921-01.
- 201.3 **Data Summaries**
None
- 201.4 **Other Summarized Results:**
See Recommendations under 202.0.

202.0 Recommendations

202.1 UNACCEPTABLE Data

"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 November 17, 1997, MRID. No. 44921-01.

The submitted efficacy data is unacceptable for registration purposes because the data was not developed as described in the attached DIS/TSS sheets 1,2,3,4,6,10, 17. In addition, the registrant must be advised to submit data packages that detail the scientific findings of the studies. The information provided in MRID No. 44921-01 has been summarized to the point that it is difficult for the reviewer to determine the integrity of the data. For example the data was developed using a 1:500 dilution yet no information was provided detailing the actual preparation of the solution; also note that if the product is ready-to-use (no dilution necessary) then the solution used in the AOAC testing and that in the actual product container must be equivalent.

203.0 Labeling:

The proposed labeling has not been evaluated due to the data deficiencies stated above. However, I do have the following comments:

The label states that the product is a "one-step ready-to-use disinfectant bactericide, fungicide, sanitizer...": the registrant has not submitted efficacy data for sanitizer on either food or non-food contact surfaces. If the registrant wants to make food contact sanitizing claims (e.g. food processing plants) Please refer the registrant to the attached DIS/TSS 4 and 10.

The registrant makes the following **unacceptable** claims:

The following terms are unacceptable: "NON-TOXIC" and "FAST-ACTING".

"It is a fast acting (in 30 seconds), does not irritate the eyes or skin and toxicity and inhalation potential is negligible"

"...not harmful to humans, animals or plants."