

NEW APPLICATION

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 07/22/96 OUT 09/19/96

Srinivas Gowda

Reviewed by Srinivas Gowda Date 09/19/96

EPA Reg. No. or File Symbol 69972-R

LAN Code _____

Date Division Received 05-01-96

Type Product Solid and Liquid Infectious Medical Waste Sanitizer System

MRID No (s) 440066-01

Product Manager PM 32 (Francis)

PM Team Reviewer Robert Travaglini

Product Name Enchlor 25

Company Name Technology 2100

Submission Purpose New Application with proposed label, and efficacy data to support sanitization claims for treatment of medical waste in Infectious Waste Processor (IWP) Enore 2100

Type Formulation Liquid

Active Ingredient (s): _____ %

Sodium chlorite.....25

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202.0 **Recommendations**

202.1 **Efficacy Supported by the Data:**

"Treatment Efficacy Testing of the Infectious Waste Processor (IWP) Encore-2100" by James R. Scott, Southwest Research Institute, 6220 Culebra Road, P.O. Drawer 28510, San Antonio, Texas 78228, dated December 28, 1995 (MRID No. 440066-01).

The submitted data are acceptable to support effectiveness of the product as a infectious medical waste sanitizer ($\geq 99.9\%$ reduction in the microbial population) when used in Technology 2100's Infectious Waste Processor (IWP) Encore 2100 Hospital Waste Treatment System.

202.2 **Additional Information Required:**

Submit copies of Technology 2100's Infectious Waste Processor (IWP) Encore 2100 Hospital Waste Treatment System's Installation, Operation, and Maintenance Manuals for review and comments.

203.0 **Draft Labeling:** (05-01-96)

Under the heading "Directions for Use" revise the statement "FOR TREATMENT OF INFECTIOUS MEDICAL WASTE" to read TO READ "FOR SANITIZATION/TREATMENT OF INFECTIOUS MEDICAL WASTE".

Under the heading "FOR TREATMENT OF INFECTIOUS MEDICAL WASTE" revise the statement "Enchlor 25 is approved for use in the Technology 2100 Hospital Waste Treatment system for the treatment of infectious hospital waste" to read "Enchlor 25 is recommended for use in the Technology 2100's Infectious Waste Processor (IWP) Encore 2100 Hospital Waste Treatment system for the sanitization/treatment of infectious hospital waste".

Under the product name "ENCHLOR 25" change "Crine Dioxide..." to read "Chlorine Dioxide..."