

US EPA ARCHIVE DOCUMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN: 9/17/96 OUT: 10/14/96

Reviewed by Michael Nieves Date 10/19/96
LAN Code 10492-4.597 *Michael E. Egan*
EPA Reg. No. or File Symbol 10492-4
EPA Petition or EUP No. None
Date Division Received 8/21/96
Type Product Disinfecting Towelettes
MRID No(s) 440917-01, 02
Product Management Team Martha Terry PM 31
Product Name DISCIDE Disinfecting Towelettes
Company Name Palmero Health Care

Submission Purpose:

The registrant has submitted efficacy data and proposed labeling to add claims against Methicillin Resistant Staphylococcus aureus (MRSA) and Vancomycin Resistant Enterococcus faecalis (VRE).

Type Formulation Liquid

Active Ingredients(s)

n-Alkyl dimethyl benzyl ammonium chloride..... .12%
n-alkyl dimethyl ethyl benzyl ammonium chloride..... .12%
Isopropyl alcohol..... 63.25%

200.0 **Introduction:**

200.1 **Uses:**

Hospital Disinfectant

200.2 **Background Information:**

The registrant has submitted efficacy data and proposed labeling to add claims against Methicillin Resistant Staphylococcus aureus (MRSA) and Vancomycin Resistant Enterococcus faecalis (VRE).

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:**

1. "The Evaluation of the Efficacy of DisCide Disinfecting Towelettes against Methicillin Resistant Staphylococcus aureus (MRSA)" by Mary Bennet of ViroMed, 6101 Blue Circle, Minneapolis, MN 55343, dated June 12, 1996, MRID No. 440917-01.

2. "The Evaluation of the Efficacy of DisCide Disinfecting Towelettes against Vancomycin Resistant Vancomycin Resistant Enterococcus faecalis (VRE)" by Mary Bennet of ViroMed, 6101 Blue Circle, Minneapolis, MN 55343, dated May 29, 1996, MRID No. 440917-02.

201.3 **Data Summaries**

None

201.4 **Other Summarized Results:**

See Recommendations under 202.0.

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202.0 **Recommendations**

202.1 **Efficacy Supported By The Data:**

1. "The Evaluation of the Efficacy of DisCide Disinfecting Towelettes against Methicillin Resistant Staphylococcus aureus (MRSA)" by Mary Bennet of ViroMed, 6101 Blue Circle, Minneapolis, MN 55343, dated June 12, 1996, MRID No. 440917-01.

The submitted efficacy data developed under the AOAC Towelette Disinfectant Test Method appear to be effective as disinfectant against Methicillin Resistant Staphylococcus aureus (MRSA) ATCC 33592 when used undiluted on hard, non-porous surfaces for a contact time of one minute at 23°C.

2. "The Evaluation of the Efficacy of DisCide Disinfecting Towelettes against Vancomycin Resistant Vancomycin Resistant Enterococcus faecalis (VRE)" by Mary Bennet of ViroMed, 6101 Blue Circle, Minneapolis, MN 55343, dated May 29, 1996, MRID No. 440917-02.

The submitted efficacy data developed under the AOAC Towelette Disinfectant Test Method appear to be effective as disinfectant against Vancomycin Resistant Vancomycin Resistant Enterococcus faecalis (VRE) ATCC 51299 when used undiluted on hard, non-porous surfaces for a contact time of one minute at 23°C.

203.0 **Labeling:**

The **proposed** product labeling is **UNACCEPTABLE**. See comments below:

Specifically, the following proposed label amendments are unacceptable:

1. The use of the words **VIRUCIDAL** and **HERPECIDAL** in the front panel must be changed to **VIRUCIDAL*** and **HERPECIDAL****. The asterisk must denote the specific viruses that have been tested.

2. On the front panel, in the paragraph ending "...Single-Use Towelettes in 1 minute at 23°C."; modify the last sentence to read "...Single-Use Towelettes in 1 minute at 23°C on pre-cleaned, hard, non-porous, environmental surfaces".

3. The registrant added various new use sites for this product. The following two are unacceptable: **food service** and **consumer use**. These two sites are too broad, and may lead to confusion. However the use of the term "**non-food contact surfaces**" is acceptable.