

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 08/14/96 OUT 09/17/96

Srinivas Gowda

Reviewed by Srinivas Gowda Date 09/17/96

EPA Reg. No. or File Symbol 1677-21 Mehul E. D. Patel

LAN Code 1677-21.610

Date Division Received 06-03-96

Type Product (s) Hospital Disinfectant

MAID No (s) 440238-01 to 440238-02

Product Manager PM 31 (Johnson)

PM Team Reviewer Martha Terry

Product Name Mikro Quat

Company Name Ecolab Inc.

Submission Purpose Amendment to add additional efficacy claims
against Vancomycin-Resistant Enterococcus
faecalis and Clostridium difficile with
efficacy data, and delete PR Notice 94-4
restrictive label statement with revised label

Type Formulation Liquid

Active Ingredient (s): %

Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl
ammonium chloride.....9.00

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202.0 Recommendations

202.1 Efficacy Supported by the Data:

1. "Mikro-Quat Supplemental Hospital Disinfection Efficacy: Vancomycin Resistant *Enterococcus faecalis* (EPA Reg. No. 1677-21)" by Kristen M. Buck, 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated November 9, 1995 (MRID No. 440238-01)

The submitted AOAC Use Dilution Test data appear acceptable to support effectiveness of the product as a disinfectant against Vancomycin-Resistant *Enterococcus faecalis* ATCC 51299 when tested at concentrations of 0.504% (5.04 ml + 994.96 ml sterile distilled water = 2/3 oz. per gallon) and 0.501% (5.01 ml + 999.99 ml sterile distilled water = 2/3 oz. per gallon) on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 10 minutes at 20°C.

2. "Mikro-Quat *Clostridium difficile* Supplemental Hospital Disinfection Efficacy (EPA Reg. No. 1677-21)" by Kristen M. Buck, 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated November 9, 1995 (MRID No. 440238-02)

The submitted AOAC Use Dilution Test data appear acceptable to support effectiveness of the product as a disinfectant against vegetative form of *Clostridium difficile* ATCC 9689 when tested at a concentration of 0.521% (5.21 ml + 994.79 ml sterile distilled water = 2/3 oz. per gallon) on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 10 minutes at 20°C.

203.0 Labeling: (dated May 30, 1996)

The proposed labeling for this product must be revised to include the following comments:

1. Under the heading "Directions for Use" the types of hard surface equipments intended for treatment must be specified. See item 2 of DIS/TSS-15 enclosure (attached). Therefore, change "...hard surface... equipment..." to read "...hard surface...non-medical equipments such as..." or add the following PR Notice 94-4 restrictive label statement:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into

the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".

2. Under the heading "Directions for Use" revise the statement "Prepare fresh solution daily or when visibly soiled" to read "Prepare fresh solution daily or more often if the solution becomes diluted or soiled".

3. Under the heading "Virucidal" specify the strain of "Influenza A2" and change "Newcastle Disease" to read "Newcastle Disease virus".

4. Under the heading "Directions for Use" the level of antimicrobial activity (e.g. disinfection) intended to be provided by this product must be specified. Revise the statement "Apply MIKRO-QUAT to walls, floors, sinks..." to read "For Disinfection-Apply MIKRO-QUAT to walls, floors, sinks..."

5. Under the heading "Directions for Use" include 10 minutes contact time necessary for disinfection. Change "Wet surface thoroughly" to read "Wet surface thoroughly and allow to remain wet for at least 10 minutes".

6. Under "INSERT 1" change "Clostridium dificle" to read "Clostridium difficile (vegetative form)".

Note to PM 31:

Stamp label only after the required changes above have been incorporated.