

NEW APPLICATION
RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
EFFICACY REVIEW - I
ANTIMICROBIAL DIVISION

IN 05/21/97 OUT 06/16/97

Reviewed by Srinivas Gowda Date 06/16/97

EPA Reg. No. or File Symbol 4822-UIU

LAN Code 4822-UIU.697 *Michael P. Gowda*

EPA Petition or EUP No. None

Date Division Received 12-24-96

Type Product Hospital Disinfectant

MRID No (s) 441860-09 to 441860-16

Product Manager PM 31 (Edwards)

PM Team Reviewer Barbara Pringle

Product Name BD1

Company Name S.C. Johnson & Son, Inc.

Submission Purpose New Application with efficacy data and
proposed label

Type Formulation Liquid Pump Spray

Active Ingredient (s): 3

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chloride.....0.11

n-Alkyl (68% C12, 32% C14)
dimethyl ethylbenzyl ammonium chloride.....0.11

3-(trimethoxisilyl) propylmethyloctadecyl ammonium chloride.0.11

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

EFFICACY REVIEW -II

ANTIMICROBIAL DIVISION

EPA Reg. No. or File Symbol 4822-UIU

EPA Petition or EUP No. None

Date Division Received 12-24-96

Type Product Hospital Disinfectant

MRID No (s) 441860-09 to 441860-16

Product Manager PM 31 (Edwards)

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Product Name BD1

Company Name S.C.Johnson & Son, Inc.

202.0 **Recommendations**

202.1 **Efficacy Supported by the Data:**

1. The submitted efficacy data (MRID Nos. 441860-09, 441860-15 to 441860-17) developed by the Modified AOAC Germicidal Spray Products Test Method appear adequate to support effectiveness of this product as a hospital disinfectant against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538; as a disinfectant against Escherichia coli 01H51:H7, ATCC 35150 and Vancomycin Resistant Enterococcus faecalis ATCC 51559, Streptococcus faecalis; as a fungicide against Trichophyton mentagrophytes and as a virucide against HIV-1 (AIDS virus), Herpes simplex types 1 and 2, and Influenza virus A2 (H2N2), when used as an undiluted pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minutes at room temperature.

2. Also the submitted confirmatory efficacy data (441860-12 & 441860-13) to support the minor formulation change (fragranced) by the AOAC Germicidal Spray Products Test method are acceptable to support effectiveness of the product as a hospital disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa when used as an undiluted pressurized spray on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minutes at room temperature.

202.2 **Efficacy Not Supported by the Data:**

1. "Residual Antibacterial Test for Bathroom Duck" by Diane M. Falbo, Technology specialist, S.C. Johnson Wax, Inc., 1525 Howe Street, Racine, Wisconsin 53403, dated December 21, 1996 (MRID No. 441860-14)

The submitted residual self-sanitizing data are not acceptable because product failed to demonstrate residual self-sanitizing activity ($\geq 99.9\%$ kill) against Staphylococcus aureus and Escherichia coli, and no organic soil was included to simulate the real use situation. You must submit proposed residual self-sanitizing protocol and proposed use directions/label claims for Agency's review prior to initiation of the test. The 24 hour contact time employed in the test is too long and it should be reduced (eg. 10 minutes) to simulate the real use situation

202.3 **Claims Not Related to Human Health**

The claims for this product for mildew (Aspergillus niger) and odor control are not related to human health, and do not require submission of supporting efficacy data. Therefore, the data developed for Aspergillus niger were not reviewed.

203.0

Labeling:

Delete the phrases, "Long-lasting" and "for up to 7 days" wherever it appears on the label or submit data to support it.

Change "All-purpose Disinfectant" to read "Multi-purpose Disinfectant".

On page 1, specify the species of staphylococcus, Streptococcus and Salmonella. Also change "E. Coli" to read "Escherichia coli."

On page 1, change "porcelain" to read "glazed porcelain".

On page 2, revise the statement "For best results on tough soils, allow product to remain on surface longer" to read "For best results on cleaning tough soils, allow product to remain on surface longer".

On page 3, under the heading "To Disinfect" provide instructions to remove gross filth or heavy soil prior to application of the product.

Delete residual self-sanitizing claim for up to 7 days or submit residual self-sanitizing data developed in the presence of organic soil (5% blood serum) to support it.