UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 24, 2002

MEMORANDUM

Subject: Efficacy Review for 3573-69 / Z-1
DP Barcode: D279334
Case No.: 065046

From: Ian Blackwell, Biologist
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Through: Emily Mitchell, Team Leader
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Applicant: The Procter and Gamble Company

Formulation From Label:

Active Ingredient(s)	% by wt
Didecyl dimethyl ammonium chloride	0.13
Inert Ingredient(s)	99.87
Total	100.0

I **BACKGROUND:** The Procter and Gamble Company has submitted a product efficacy report to support the addition of labeling claims to their product "Z-1". The report is a hospital disinfectant study. The study was conducted by ViroMed Biosafety Laboratories. The MRID Number is 455395-01.

Z-1 is registered as a fabric sanitizer spray; however, the registrant is seeking to add claims of hard surface disinfection to the product label.

II Use Directions

- Antibacterial spray
- Disinfectant and Fabric Spray
- Multi-surface disinfectant
- Eliminates odors
- Kills 99.9% of bacteria that cause odors
- As it dries it cleans away the odors trapped in fabrics leaving your fabrics free of odor causing bacteria
- Eliminates 99.9% of bacteria of hard surfaces

To Eliminate Odors and Sanitize Fabric: [From a distance of 6-8 inches] Spray evenly until damp to kill bacteria that cause odors. As item dries, odors are eliminated and bacteria that cause odors are killed. Allow sprayed surfaces to dry completely before reuse. Reapply as needed.

To Disinfect (hard, non-porous surfaces): [From a distance of 6-8 inches] Spray until covered with a light mist. Allow to stand 10 minutes, then wipe dry with a clean cloth or paper towel. Wipe surfaces in direct contact with food with a wet towel.

III Agency Standards for Proposed Claims

General or broad-spectrum efficacy claims. Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.

(l) Test requirements. Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Product Test as in (a)(l). Sixty carriers must be tested against each of both S. choleraesuis and S. aureus with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)

(2) Performance requirements. To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.

IV Comments on the Submitted Efficacy Studies

MRID Number 455395-01: "Germicidal Spray Products" by Karen M. Ramm. ViroMed Biosafety Laboratories. Project Number: 8615. Study Completion Date: 2/2/2000.

This study was conducted to assess the ability of "Z-1" to function as a general or broad spectrum disinfectant. This test was performed using *Staphylococcus aureus* (ATCC 6538) and *Salmonella choleraesuis* (ATCC 10708). *Escherichia coli* (ATCC 11229) was also tested. A volume of 0.01 mL of a culture of each test organism was spread over the entire surface of 180 sterile 18 x 36 mm glass slides. Considering there were three batches/lots assayed and each batch was tested using 60 slides, each organism was tested using a total of 180 slides. Each inoculated slide was treated with two sprays at a distance of eight inches. The product is sold in the form of a Ready-To-Use bottle, so no dilution was necessary. Each carrier/slide remained in contact with the test substance for 10 minutes at room temperature (22-23° C). Following the spray treatment, the remaining liquid was drained off. Each medicated carrier was then transferred to 20 mL aliquots of Letheen Broth contained in tubes. For those carriers that were inoculated with *Staphylococcus aureus*, the carriers were transferred from the initial (primary) tubes to secondary tubes that also contained 20 mL of Letheen Broth. The subculture tubes were incubated for 48 hours at 36°C. Following incubation, the medium in each tube was observed for the presence of growth.

V Results:

Table 1. Derived from MRID Number 455395-01

Lot Number	Organism	Number of Carriers	
		Exposed	Showing Growth
SS0637.01	*Staphylococcus aureus* 1°	60	0
	Staphylococcus aureus 2°	60	0
	Salmonella choleraesuis	60	0
	Escherichia coli	60	0
SS0637.02	*Staphylococcus aureus* 1°	60	0
	Staphylococcus aureus 2°	60	0
	Salmonella choleraesuis	60	1
	Escherichia coli	60	0
SS0637.03	*Staphylococcus aureus* 1°	60	0
	Staphylococcus aureus 2°	60	0
	Salmonella choleraesuis	60	0
	Escherichia coli	60	0

Table 2. Derived from MRID Number 455395-01
Control Carrier Results

Test Organism	Result
Staphylococcus aureus	$4.3x\ 10^6$
Salmonella choleraesuis	9.9×10^4
Escherichia coli	$30.\ X\ 10^5$

VI Conclusions

MRID Number 455395-01: Registration Number 3573-69 was an effective disinfectant of *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708) and *Escherichia coli* (ATCC 11229) contaminated surfaces when tested with a 10 minute exposure at 22°C in the presence of a 5% serum soil load.

VII Recommendations

1 The request to add labeling claims of Registration Number 3573-69 being a general or broad spectrum disinfectant is approved. However, none of the batches of test material tested was identified as being over 60 days old. In order to maintain the approval of this labeling claim, the registrant needs to submit information proving that one the three tested batches was at least 60 days old at the time of testing.

2 The request to add labeling claims of Registration Number 3573-69 being an effective disinfectant against *Escherichia coli* (ATCC 11229) is approved.

3 On the "Back Label" (page 2) of the submitted label, remove the claim "... and sanitize fabric." This product has not been approved for the sanitization of fabrics.

4 On the "Back Label" (page 2) of the submitted label, revise the statement "wipe surfaces that come in direct contact with food with a wet towel" to read "For surfaces that may come into contact with food, a potable rinse is required."

5 All labeling statements claiming or otherwise implying that this product is a sanitizer must be removed from the product label. The registrant has not submitted any data verifying that this product is a sanitizer.

6 On page 4, the entire section on surfaces to be sanitized must be removed. These are all porous surfaces, data has not been submitted to support these labeling claims.

7 Remove the statement that this product may be used to disinfect high chairs, children's and babies' toys. In order to use this statement, the label must state that a potable water rinse must be used following the application of this product.

8 Page 5 of the label states that this product may be used to kill bacteria on "soft surfaces". This statement must be removed.

9 Page 5 states that this product is "great for use as a fabric sanitizer". Again, this is stating that this product is approved for use as a sanitizer, which it is not.

10 Page 6 of the submitted label states: "On fabric Z1 kills the following odor-causing bacteria: [*Staphylococcus aureus*] Staph - [*Proteus mirabilis*] Proteus - [*Klebsiella pneumoniae*] - Kleb." This statement is not acceptable and must be removed. Again, this product is not approved to <u>kill</u> bacteria in or on fabrics.