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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 23, 2002

MEMORANDUM

Subject: Efficacy Review for File Symbol 1839-RTI / Solvent Free Disinfectant Wipes

DP Barcode: D279149
Case No.: 071283

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Applicant: Stephan Company

Formulation From Label:

Active Ingredient(s)	% by wt
Octyl decyl dimethyl ammonium chloride	0.03990
Dioctyl dimethyl ammonium chloride	0.01995
Didecyl dimethyl ammonium chloride	0.01995
Alkyl dimethyl benzyl ammonium chloride	0.05320
Inert Ingredient(s)	99.86700
Total	100.00

I **BACKGROUND:** The Stepan Company has submitted a product antimicrobial efficacy study to support their product, EPA File Symbol 1839-RTI. The study only tested the product against the two bacterial species *Escherichia coli* (ATCC 11229) and *Salmonella choleraesuis* (ATCC 10708) and is intended to be used to register this product as a Limited Claims Disinfectant. Stepan Company conducted the actual disinfectant study themselves. The MRID Number is 455230-01.

II Use Directions

"Antibacterial formula cleans and disinfects. Kills 99.9% of bacteria (*Salmonella choleraesuis* and *Escherichia coli*)."

"**DISINFECTING:** Kills *Salmonella choleraesuis* and *E. coli* on hard, non-porous surfaces. Wipe surface to be disinfected. Allow surface to remain wet for 10 minutes before use. Let surface dry. A rinse is required for surfaces in direct contact with food."

III Agency Standards for Proposed Claims

The DIS/TSS states:

(a) Limited efficacy claims. The label of a disinfectant which is effective against a specific major group of microorganisms only (e.g., Gram-positive or Gram-negative) must specify the major group against which it is effective.

(1) Test requirements. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products) is required. Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gram-negative bacteria) or Staphylococcus aureus ATCC 6538 (for effectiveness against Gram-positive bacteria). (Sixty carriers per sample; a total of 180 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.

Concerning the choice of tests to use for disinfectant wipes, Subdivision G states: "...the AOAC Germicidal Spray Products Test appears to be the one most readily modified for this situation. Instead of spraying the inoculated surface of the glass

slide, the product should be tested by wiping the surface of the glass slide with the saturated towelette, and then subculturing the slides after the specified holding time. All remaining liquid should be expressed from the used towelette and should also be subcultured."

(B) "The towelette should be removed from its container and subsequently handled with sterile gloves. One towelette should be used to wipe 60 inoculated slides. The area of the towelette used for wiping should be rotated so as to expose a maximum amount of its surface in the course of wiping a set of slides. After wiping the last slide for a particular towelette, all of the liquid remaining in the material should be expressed into an empty sterile container by squeezing the towelette; after a specified holding time (equal to the contact time stated on the product label), an aliquot from this container (ca. 0.1 ml) should be subcultured in the same manner as the slides."

However, PSB/AD policy allows one towelette to be used to wipe only **ten** carriers or slides instead of the 60 slides listed in Subdivision G.

IV Comments on the Submitted Efficacy Studies

1 MRID Number 455230-01: "Hard Surface Towelette Disinfectant Testing of Solvent Free Disinfectant Wipes" by Deanna Santarinala. Stepan Company. Project Number 5224.

This study was conducted to assess the ability of Solvent Free Wipes to act as a limited-claims disinfectant of surfaces inoculated/ contaminated with *Escherichia coli* (ATCC 11229) or *Salmonella choleraesuis* (ATCC 10708). Five percent horse serum was included in the culture suspension used to inoculate the glass carriers to simulate an organic soil load. Each glass slide carrier was inoculated with 0.01 mL or *Escherichia coli* or 0.02 mL of *Salmonella choleraesuis*. As the product comes in the form of a pre-moistened towelette, no dilution was used. One towelette was used to wipe the contaminated portions of 10 carriers. the area of the towelette used was rotated so as to expose a maximum amount of the towelette during the course of the wiping procedure. The treated carriers were allowed to stay in contact with the test liquid for 10 minutes. Following treatment of the ten carriers, the used towelette was placed into a sterile petri dish and was also held for 10 minutes. After 10 minutes, each treated carrier was subcultured to 20 mL Letheen broth bottles. A 0.1 mL aliquot of the liquid expressed from each towelette was also subcultured into Letheen broth. If sufficient liquid could not be expressed from the bottle, the entire towelette was transferred to a bottled containing20 mL of Letheen broth. Subculture bottles were incubated at 36°C for at least 48 hours, and observed for the presence of

turbidity from the growth of the test organism. The test was considered valid if the count of organisms on dried control carriers was $\geq 10^4$ cfu/carrier.

V Results

Table 1. Derived from MRID Number 455230-01.

Sample ID (Lot Number)	Test Organism	Primary Subculture	
		Carriers Exposed	Carriers Showing Growth
2496-61-1	*E. coli*	10	0
	S. choleraesuis	10	0
2496-61-2	*E. coli*	10	0
	S. choleraesuis	10	0
2496-62-1	*E. coli*	10	0
	S. choleraesuis	10	0
2496-62-2	*E. coli*	10	0
	S. choleraesuis	10	0
2496-63-1	*E. coli*	10	0
	S. choleraesuis	10	0
2496-63-2	*E. coli*	10	0
	S. choleraesuis	10	0
2496-64-1	*E. coli*	10	0
	S. choleraesuis	10	0
2496-64-2	*E. coli*	10	1
	S. choleraesuis	10	0
2496-65-1	*E. coli*	10	0
	S. choleraesuis	10	0
2496-65-2	*E. coli*	10	0
	S. choleraesuis	10	0

Table 2. Derived from MRID Number 455230-01.

Test System	Carrier Count (cfu/carrier)
Escherichia coli	35,000
Salmonella choleraesuis	22,000

VI Conclusions

EPA File Symbol 1839-RTI when tested by wiping 10 slides with one towelette and allowing a contact period of 10 minutes at room temperature in the presence of an organic soil load was an effective disinfectant of *Escherichia coli* (ATCC 11229) and *Salmonella choleraesuis* (ATCC 10708) inoculated surfaces.

VII Recommendations

1. The request to add label claims of File Symbol 1839-RTI as a limited disinfectant against *Salmonella choleraesuis* (ATCC 10708) and/or *Escherichia coli* (ATCC 11229) is approved.

2. The statement "Kills 99.9% of Bacteria" must be removed from the product label.

3. The submitted lists label sites that may be disinfected. The listed sites include microwaves and refrigerators. The statement must be changed to state that the product may be used to disinfect the outside of microwaves, refrigerators and other similar appliances. PSB/AD does not feel that the inside of such appliances can be disinfected.

4. Switches are not a site that can be disinfected. "Switches" must be removed from the list of sites that can be disinfected.

5. The label must state which part(s) of the telephone can disinfected.

6. The label also lists high chairs and dining room tables as sites/areas that may be disinfected. Areas such as these are considered to be food contact areas and must be deleted from the list of sites that may be disinfected.

7. The complete nomenclature of all organisms must be listed on the label. That is *Escherichia coli* (or E. coli) must be changed to *Escherichia coli* (ATCC 11229).

February 5, 2002

Note To PM 31:

The label lists high chairs as a site that may be disinfected. PSB/AD does not allow disinfectants to be used on high chairs.