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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 15, 1999

**MEMORANDUM**

**Subject:** Efficacy Review for 3573-AT/S-1 Wipes Disinfectant

DP Barcode: D254230

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**Applicant:** The Procter & Gamble Co.
Cincinnati, OH, USA

**Formulation From Label:**

| Active Ingredient(s) | % by wt |
|---|---|
| Citric Acid | 1.5% |
| Other Ingredient(s) | 98.5% |
| Total | 100.00 |

**BACKGROUND:**

Product manager has requested review of efficacy data (MRID No 447687- 06) in support of registration of the new product S-1 as a limited disinfectant, single use pre-moistened towelette (EPA Reg. No. 3573-AT). A master label has also been included for comment.

**RECOMMENDATIONS:** ESSB findings are:

S-1 wipes were tested for limited disinfectant efficacy against Gram-negative bacteria (*Salmonella choleraesuis, and Pseudomonas aeruginosa)* to support label claim as a limited disinfectant. The product was also tested against other bacteria (*Escherichia coli, Proteus mirabilis, Campylobacter jejuni, and Listeria monocytogenes)* to support label claims against these microorganisms. Results of efficacy data appear to fulfill the test requirements of S-1 Wipes as a limited disinfectant. However the registrant has not clearly identified which test lot was 60 days old. Based on the administrative materials accompanying the Product Performance Efficacy Testing (**MRID 447687-06**) and the dates that the studies were conducted it would appear that SS0613.02 was the 60 day old lot. If this is the case then this needs to be made clear in the efficacy test report itself, preferably in the sample identification section by providing the date of manufacture. Until this is done the efficacy study is not complete and is considered unacceptable.

*LABEL CLAIMS:*

The submitted master label is not acceptable. The Agency and the Antimicrobials Division have in the past allowed the submission of what may be best described as a generic "master" label. These labels have presented not what the specific end use label for a particular product will be, but rather a composite listing of all those potential phrases, claims and components from which a possible label might be assembled. This approach was permitted by the Agency in the belief that it would permit more focused, consistent and economical label development by registrants, and allow the Agency to more efficiently manage review of submitted label materials.

As claims and use sites have proliferated, it has become increasingly difficult for us to anticipate what form the final label appearing on the registered product will take. We are concerned not just with the specific language of a label but also with the message a label presents when viewed in its entirety. It is a relatively easy thing for clear concise instructions and appropriate uses that should lead to a product's achievable benefits to be lost on a label that is excessively long, complicated, obtuse or redundant. The present liberties that have arisen with this generic "master" label approach have now required the Agency to revert to a more predictable and conservative approach of asking for drafts of the specific label the registrant intends to apply to a particular product. This is especially necessary in those instances where products are presenting the Agency and the consumer with a new use pattern, use sites or potential of being used in a manner inconsistent with its approved uses.

An annotated copy of the master label is being returned to the registrant. It provides guidance for the registrant to improve its label content and provide a final product label example for the Agency's consideration. Some of the more notable deficiencies present on

the "master" label include the following. The registrant should remove the use of the term germs. Their product is only supported for claims against bacteria. All references to unacceptable use sites such as toys, food contact surfaces, surfaces that are not hard and non-porous, and surfaces inaccessible to wipes should be eliminated. There is no data to support the efficacy of the product against *Enteroccocus hirae, and Streptococcus faecalis* mentioned at the bottom of page 2 of the Back/Bottom label. These claims should be removed from the label. Also, on the same line, *Salmonella Choleraesuis* should be corrected to *Salmonella choleraesuis* .

Again the registrant is reminded that the corrections provided are not exhaustive but are offered as a form of guidance. The registrant should "clean up " the master label and then provide the Agency with sample proposed label(s) which the registrant intends to apply to the product. Those labels will be considered for approval.

(C:\copies of reviews\S-1 Wipe Disinfectant. wpd)