



HILL TOP RESEARCH, INC.

VOLUME 2

REPORT FOR

EFFICACY EVALUATION OF
HEALTH CARE PERSONNEL HANDWASH PRODUCTS

HTR STUDY NO. 03-122085-106

Final Report

August 21, 2003

FOR
BAYER CHEMICALS CORPORATION
100 Bayer Road, Building #14
Pittsburgh, PA 15205-9741

BY
HILL TOP RESEARCH, INC.
Main and Mill Sts.
Miamiaville, OH 45147

BOOK II

August 26, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

RE: Topical Antimicrobial Drug Products for Over-the-Counter
Human Use; Health-Care Antiseptic Drug Products; Reopening of the
Administrative Record -
**Supplemental Data Related to Bayer's Citizen Petition Dated December 28,
2002 to Classify Triclocarban Category I for Efficacy**
Docket 75N-183H

To Whom It May Concern:

In response to the above referenced reopening of the administrative record for rulemaking (Docket 75N-183H), enclosed are three (3) copies of supplemental product performance (efficacy) data. Subsequent to Bayer's December 28, 2002 Citizen's Petition, both a clinical hand wash study and a time-kill study were conducted to demonstrate the efficacy of a representative liquid soap containing 0.7% Triclocarban, which is the typical concentration of Triclocarban used in personal health care products. The clinical hand wash study employed *Staphylococcus aureus* as the indicator organism due to its frequent association with nosocomial infections.

The enclosed new data further support classification of the use of Triclocarban at 0.7% as a Category I ingredient for use as a health care personnel hand wash or an antiseptic hand wash. Specifically, the health care personnel hand wash test (ASTM E1174) demonstrated that a 0.7% Triclocarban containing product achieved a 2.82 log₁₀ reduction following a single wash and a 3.09 log₁₀ reduction following 10 subsequent washes. This compares to 1.84 and 1.99 log₁₀ reductions for the placebo product, and 2.25 and 2.38 log₁₀ reductions for a 4% chlorhexidine gluconate product. These data demonstrate the superiority of a Triclocarban containing hand wash product at clearing a Gram positive microorganism, *S. aureus*, from the hands.

The enclosed time kill study emphasizes determination of product performance against gram positive microorganisms and provides both confirmatory data and data on gram positive microorganisms not previously tested.

These studies were conducted with the following test articles:

3554-196 (TCC - 0.7%)

Active Ingredient: Triclocarban

Other Ingredients: Dipropylene Glycol, Water, Sodium Laureth Sulfate, Glycerin, Cocamidopropyl Betaine, Disodium Lauryl Sulfosuccinate, PEG-8, Ethoxydiglycol, Polyquaternium 10, Fragrance, Sodium Chloride, Citric Acid, DMDM Hydantoin & Iodopropynyl Butylcarbamate, Tetrasodium EDTA.

3554-194 (Placebo)

Active Ingredient: not applicable

Ingredients: Dipropylene Glycol, Water, Sodium Laureth Sulfate, Glycerin, Cocamidopropyl Betaine, Disodium Lauryl Sulfosuccinate, PEG-8, Ethoxydiglycol, Polyquaternium 10, Fragrance, Sodium Chloride, Citric Acid, DMDM Hydantoin & Iodopropynyl Butylcarbamate, Tetrasodium EDTA.

This submission consists of this letter and three (3) volumes:

- Volume 1 - Book I of "Efficacy Evaluation of Health Care Personnel Handwash Products," HTR Study No. 03-122085-106, Final Report dated August 21, 2003, by Hill Top Research, Inc. for Bayer Chemicals Corporation
- Volume 2 - Book II of "Efficacy Evaluation of Health Care Personnel Handwash Products," HTR Study No. 03-122085-106, Final Report dated August 21, 2003, by Hill Top Research, Inc. for Bayer Chemicals Corporation
- Volume 3 - "Assessment of Rapid Germicidal (Time Kill) Activity for Hand Product", HTP Study No. 03-122096-106, Final Report dated August 14, 2003, by Hill Top Research, Inc. for Bayer Chemicals Corporation

If you have any questions regarding this submission, please feel free to contact me by phone at (412) 777-3934 or by email at kevin.ajoku@bayerchemicals.com.

Sincerely,



Kevin I. Ajoku
Market Segment Manager
Bayer Corporation

HILL TOP RESEARCH, INC.

VOLUME 2

REPORT FOR

EFFICACY EVALUATION OF
HEALTH CARE PERSONNEL HANDWASH PRODUCTS

HTR STUDY NO. 03-122085-106

Final Report

August 21, 2003

FOR
BAYER CHEMICALS CORPORATION
100 Bayer Road, Building #14
Pittsburgh, PA 15205-9741

BY
HILL TOP RESEARCH, INC.
Main and Mill Sts.
Miamiville, OH 45147

BOOK II