3-22-90

Alternate Formulations:
Confirmatory Efficacy Data

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

IN 03/19/90 OUT 03/22/90

EPA Reg. No. or File Symbol 49199-1

EPA Petition or EUP No. None

Date Division Received 01-26-90

Type Product (s): Hospital disinfectant (Saturated Towelette)

MRID No(s) None

Product Manager PM 31 (Lee)

Product Name Isotex 70

Company Name Isotex, Inc.

Submission Purpose Deletion of [redacted]

and [redacted].

Type Formulation Saturated Towelette

Active Ingredient (s): %

Isopropyl alcohol.....63.00

Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chloride..... 0.12

Alkyl (50% C14, 30% C14, 17% C16, 3% C18)
dimethyl ethylbenzyl ammonium chloride..... 0.12

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Recommendations:

No confirmatory efficacy data are required to be submitted for this alternate formulation.

Srinivas Gowda

Reviewed by Srinivas Gowda Date 03/22/90

WEC 3/26/90

69104

Part II

Antimicrobial Program Branch

Efficacy Evaluation & Technical Management Section Review

EPA Reg. No. or File Symbol	# 10492-4
Date Division Received	(07-11-91)
Data Acc., No(s)	MRID No. (414914-02, 414914-01, 415215-02, 415215-01
Product Mgr. No	PM-31 (Lee)
Product Name(s)	Isotex 70 Disinfecting Towelettes
Company Name	Palmero Sales Compnay, Inc.,

202.0 Recommendations

202.1 Efficacy Supported by the Data

A. Virucidal Test (AIDS Virus)

USEPA Pesticide Assessment Guidelines (Sub-Div. G, Product Performance, 1982, Section 91-30, pp 72-76). Testing performed by Southern Research Institute, Birmingham, AL 35255, SRI Project #7042. (MRID # 415215-02). Reports by: Bonnie J. Bowdon.

The submitted virucidal data are supportive of the product effectiveness against HIV-1 (AIDS virus) on hard, non-porous inanimate surfaces in the presence of a moderate amount of 5% fetal bovine serum when used undiluted for a contact time of 1 minute at room temperature(23^0C). (Lots Isotex 70A, Decide A-199-1 & D-139-1)

B. Tuberculocidal Test (Quantitative Log Reduction Method).

Testing performed by Nelson Laboratories, Inc, 4535 South 2300, Salt Lake City, UT 84117. (MRID #415215-01). (Validation Data). Reports by Dennis Ransom & Jerry R. Nelson.

The submitted validation data are adequate and are supportive of the product effectiveness as a tuberculocide against M. tuberculosis when the product is used undiluted; however, the acceptance is pending the clarification or submission of acceptable basic tuberculocidal efficacy data for an efficacy determination. The submitted basic tuberculocidal data for the report are inadequate and must be clarified. (Isotex 70 Lot #510-91 & Ideal Lot #119-19).

202.2 Additional Data Required to Support Efficacy

A. Tuberculocidal Test (Quanitative Log Reduction Method).

Shaldra Biotest, Inc. W. Bethesda, MD 20817. Official Methods of the AOAC, chapter 4, 15th ed., 1990 (Basic Data Reports)(MRID #414914-01). Tester: Robin Smith.

The basic tuberculocidal data report is deficient. The submitted data do not reflect 4 separate studies for each exposure period as required by the Quantitative Log Reduction Protocol. The submitted data are reflective only of one study per exposed test period. This deficiency makes the conclusions invalid. Each test lot must be supported by an additional 3 separate studies for each exposure period which will provide for a total of 4 separate studies per lot. Refer to pages 4, 5, and 6 of the TB Data Call-In Notice of June 13, 1986.

In addition, it is not clear what neutralizer was used for the test. The neutralizer used as per the submitted protocol (2% sodium bisulfite) is inappropriate. Also, the submitted summary data are not sufficient for review. The details of the procedure used, the data obtained (including graphs and tables) must be submitted for review. Note: For guidance in developing and reporting of data, refer to DIS/TSS-3 enclosure.

A tuberculocidal contact time of less than 5 minutes is not accurate and therefore not permissible for the Quantitative Log Reduction Method.

The GLP compliance and QA statements do not contain the minimal required information. This can only be interpreted as a lack of GLP compliance and lack of a Quality Assurance Unit.

B. Fungicidal Tests

Shaldra Biotest, Inc, W. Bethesda, MD, by Robin A. Smith, data developed by the AOAC Fungicidal Test, 14th Ed., 1984, against Trichophyton mentagrophytes (MRID # 414914-01).

The submitted summary data developed by the AOAC Fungicidal Test Method to support the product effectiveness as a fungicide against Trichophyton mentagrophytes is inadequate. Because of the reduced contact time (4 minutes), raw data must be submitted for review to determine satisfactory performance for the undiluted test product as a fungicide against Trichophyton mentagrophytes.

The GLP compliance and QA statements do not contain the minimal required information. This can only be interpreted as a lack of GLP compliance and lack of a Quality Assurance Unit.

C. Virucidal Tests (H. simplex II & Poliovirus I)

Data developed by Intregrity Bioservices, Rockville, MD 20852. (MRID # 414914-02) Reports by: Philip R. Roane.

The submitted virucidal one page summary data are not acceptable. Studies required for review of products claiming minimal contact times must consist of more than one page summaries. They must contain all procedural and result information for the APB reviewers to reach independent conclusions on the product efficacy.

The reported data are also not acceptable because they were not inspected by a Quality Assurance Unit; the complete test procedure and data were not submitted; the virus volume (0.5 ml) placed on carrier should be 0.2 ml in order to achieve adequate

drying; the extremely critical drying conditions (2 hr at 20° C) do not follow with the approved protocol; the GLP compliance statements do not contain the minimal required information. This can only be interpreted as a lack of GLP compliance.

D. Bactericidal Studies

Shaldra Biotest Inc, W. Bethesda, MD, by Robin A. Smith & Kyle Sibinovich. The Data for Required Test Organisms developed against Ps. aeruginosa, S. aureus and S. choleraesuis by the Official Methods of the AOAC, 14th ed., 1984. (MRID #414914-01)

The basic efficacy data submitted against Ps. aeruginosa, S. choleraesuis and S. aureus are deficient in:

Not giving the carrier drying conditions or times (this information is critical in determination of the efficacy level);

The applicant needs to provide data to show the results from secondary subcultures as specified in item 7 of DIS/TSS-2.

Also, data must be provided to show the control studies for the organic soil studies for each organism as specified in items 4 and 6 of DIS/TSS-2 enclosure.

Note: the generated data must include the appropriate sub-culture medium as specified in the Official Methods of the AOAC.

The GLP compliance and QA statements do not contain the minimal required information. This can only be interpreted as a lack of GLP compliance and lack of a Quality Assurance Unit.

203.0 Additional Labeling Information Required to Initiate Review:

A complete label review cannot be provided until the data requirements requested above are submitted and reviewed.