TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 02-07-83 OUT 03-08-83

Dennis G. Guse 3/9/83

Reviewed By Dennis G. Guse Date 03-08-83

EPA Reg. No. or File Symbol 49199-R

EPA Petition or EUP No. None

Date Division Received 01-31-83

Type Product Hospital Disinfectant (Saturated Towelette)

Data Accession No(s). 249476

Product Manager 31 (Lee)

Product Name ISOTEX 70

Company Name Isotex, Inc.

Submission Purpose New product with efficacy data and label

Type Formulation Single-use disposable towelette saturated with ready-to-use liquid enclosed in a dispenser

Active Ingredient(s):	%
Isopropyl alcohol	63.00
Alkyl (60% C14,30% C16,5% C12,5% C18) dimethyl benzyl ammonium chloride	0.12
Alkyl (50% C12,30% C14,17% C16,3% C18) dimethyl ethyl-benzyl ammonium chloride	0.12

69184

200.0 Introduction.

200.1 Use(s).

Single-use, disposable, saturated towelette for disinfecting hard surfaces in dental operatories.

Based on the product chemistry, the formula would provide ca. 2400 ppm of quaternary in a 63% isopropyl alcohol solution.

201.0 Data Summary.

201.1 Brief Description of Tests.

Data to Support Germicidal Claims of Isotex 70 Towelettes. Report by Robert Dobrin, Luke Tedeschi, and Janet Verna, Bacteriology Laboratory, Framingham Union Hospital, Framingham, Massachusetts, dated 12-28-82 (Accession No. 249476).

201.2 Test Summaries.

a. Method: Simulated-use test modified from the A.O.A.C. Germicidal Spray Products Test.

b. Modifications: For carriers, 5-in. x 6-in. (30 sq. in.) glass plates were employed instead of 1-in. x 1-in. (1 sq. in.) glass slides.

For inoculum, 0.30 ml (30X amount used on 1-sq.-in. slides) of culture spread over each plate with sterile loop and allowed to dry for 40 min. at 37C.

Each of 3 batches of Isotex 70 towelettes was used to wipe the surface of 2 plates for each test organism. Thus, each batch was used to wipe 60 sq. in. of glass (equiv. to 60 1-in. x 1-in. slides) for each organism. A fresh towelette (5-in. x 9-in.) was used for each plate.

For controls, 2 plates for each organism were inoculated but not wiped.

Each wiped and control plate was swabbed thoroughly with sterile cotton swabs moistened with nutrient broth and subcultured.

A section from each towelette used for wiping was also subcultured.

c. Samples: Isotex 70 towelettes, batches 1 (dated 03-10-82), 2 (dated 06-14-82), and 3 (dated 07-21-82); all over 60 days old.

d. Dilution: Undiluted.

e. Exposure: Plates wiped and allowed to air dry before subculture sampling (per directions for use). Exposure time was unspecified.

f. Subculture Media: A.O.A.C. nutrient broth (primary) and tryptic soy agar with 5% defibrinated sheep blood (secondary).

g. Incubation: 48 hrs. at 37C.

h. Neutralization Test: All secondary subcultures from negative tubes were also negative. Re-inoculation of negative tubes from test plates gave significant growth after 24 hrs.

i. Test Organisms: Staphylococcus aureus ATCC 6538 (phenol res. 1:55), Salmonella choleraesuis ATCC 10708 (phenol res. 1:75), and Pseudomonas aeruginosa ATCC 15442 (phenol res. 1:70).

j. Results:

Test Organism	Test Batch	Positive/Total Subcultures Glass Plates	Towelettes
Staphylococcus aureus	1	0/2	0/2
" "	2	0/2	0/2
" "	3	0/2	0/2
" "	Control	2/2	---
Salmonella choleraesuis	1	0/2	0/2
" "	2	0/2	0/2
" "	3	0/2	0/2
" "	Control	2/2	---
Pseudomonas aeruginosa	1	0/2	0/2
" "	2	0/2	0/2
" "	3	0/2	0/2
" "	Control	2/2	---

k. Conclusions: Satisfactory performance vs. all test organisms for both plates and towelettes.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 49199-R

Date Division Received 01-31-83

Data Accession No(s). 249476

Product Manager No. 31 (Lee)

Product Name ISOTEX 70

Company Name Isotex, Inc.

202.0 Recommendations.

202.1 Efficacy Supported by the Data.

The submitted data by a simulated-use test modification of the A.O.A.C. Germicidal Spray Products Method (i.e., glass plates wiped with towelettes; plates and towelettes both subcultured) appear adequate to support effectiveness of the product as a disinfectant for hospital or medical areas (vs. Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa) on clean, hard, non-porous surfaces which are thoroughly wet by the towelette and allowed to dry.

However, the test report is not clear as to the actual exposure time employed in the method. It is assumed that the inoculated plates were wiped and allowed to air dry before sampling; please specify for the record the contact time which elapsed between the time the plates were wiped and the subculturing of the swabs and towelettes.

203.0 Labeling.

a. Change "Meets Latest AOAC Standards . . ." to read similar to the following: "Meets Efficacy Data Requirements . . .".

b. Change "To Disinfect Hard Surfaces: . . ." to read "To Disinfect Clean, Hard, Non-Porous Surfaces: . . .".

c. Correct spelling of "Psuedomonas" to "Pseudomonas".

d. Give examples of the types of surfaces intended for treatment in the dental operatories, such as trays, benchtops, counters, etc.

e. Add a statement to the directions such as "Discard after use".