

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 04-25-83 OUT 05-31-83

*05/31/83*

*Dennis G. Guse*

Reviewed By Dennis G. Guse Date 05-31-83

EPA Reg. No. or File Symbol 49199-R

EPA Petition or EUP No. None

Date Division Received 04-20-83

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 Resubmission for a new product with  
information/questions and revised 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<br>ammonium chloride . . . . .         | 0.12  |
| Alkyl (50% C12,30% C14,17% C16,3% C18) dimethyl ethyl-<br>benzyl ammonium chloride . . . . . | 0.12  |

200.0 Introduction.

200.1 Use(s). See attached revised label.

200.2 Background. Refer to the previous review for this product by  
TSS (Efficacy), Disinfectants Branch, RD, dated 03-08-83.

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EPA Reg. No. or File Symbol 49199-R  
Date Division Received 04-20-83  
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Product Manager No. 31 (Lee)  
Product Name ISOTEX 70  
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202.0 Recommendations.

202.1 Answers to Items in Applicant's Letter of 04-13-83.

Item #3. The information with respect to the exposure time utilized in the tests has been noted.

Item #4A. In terms of antimicrobial effectiveness, the 63% isopropanol in this product is considered an active ingredient in addition to the quaternary ammonium compounds. Deletion of the isopropanol from the product would be considered as a major formulation change which would require all microbiological efficacy data to be redeveloped on the revised formula. Deletion of any or all of the remainder of the ingredients (emollient, detergent, scent) would be considered as a minor formula change which would require some minimal efficacy data to be redeveloped on the revised formula.

Item #4B. You may not claim that the isopropanol in this product is not a disinfectant since we consider it an active ingredient from the microbiological point of view.

203.0 Labeling.

The isopropanol should be declared as an active ingredient.