

US EPA ARCHIVE DOCUMENT

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-05-84 OUT 04-02-84

Reviewed By Dennis G. Guse *DG 4/9/84* Date 04-02-84
EPA Reg. No. or File Symbol 51558-R
EPA Petition or EUP No. None
Date Division Received 02-28-84
Type Product Impregnated self-sanitizing toilet seat cover tissue
Data Accession No(s) 252546
Product Manager 31 (Lee)
Product Name Protecto Plus II

Company Name Crystal Tissue Company (Dist. by Protecto, Inc.)
Submission Purpose Application for new product with efficacy data
and labeling
Type Formulation Chemically impregnated tissue to be used as is

<u>Active Ingredient(s):</u>	<u>%</u>
Cetyl pyridinium chloride	0.6

200.0 Introduction

200.1 Use(s)

The product is a chemically impregnated tissue to be used as a single-use disposable toilet seat cover tissue intended to be self-sanitizing against Herpes simplex Type 2 virus in the presence of moisture.

200.2 Background

Refer to the pre-application correspondence and review for this product by TSS (Efficacy), DB, RD, dated 12-10-82 and 08-23-83, respectively, and to a meeting concerning this product on 11-09-82.

201.0 Data Summary

201.1 Brief Description of Tests

"The Evaluation of a Chemically Impregnated Tissue Paper Product for Virucidal or Self-Sanitizing Efficacy Against Herpes Simplex Virus Type 2" by Gussie Arnett, William Shannon, and Frank Schabel, Southern Research Institute, Birmingham, Alabama 35255, dated 06-22-83 (Accession No. 252546).

201.2 Test Summaries

The above data have been summarized in the pre-application review for this product by TSS (Efficacy), DB, RD, dated 08-23-83.

201.3 Test Conclusions

The submitted data by an approved simulated-use virucidal testing protocol supports effectiveness of the impregnated tissue as self-sanitizing in 20 seconds against Herpes simplex Type 2 virus in the presence of moisture at a concentration of 0.5% cetyl pyridinium chloride in the tissue.

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Product Manager No. 31 (Lee)
Product Name Protecto Plus II
Company Name Crystal Tissue Company (Dist. by Protecto, Inc.)

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data support effectiveness of the product as self-sanitizing in 20 seconds against Herpes simplex Type 2 virus in the presence of moisture at a concentration of 0.5% cetyl pyridinium chloride in the tissue.

203.0 Labeling

The term "Protecto" in the product name is too promising. Expressed or implied claims for protection of health are not acceptable. Since the company distributing this product is named Protecto, Inc., the name could only be considered if the term "Protecto" is qualified in the same type size by the word "Brand", i.e., "Protecto Brand Plus II".