TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 03/05/84 OUT 04/13/84

Reviewed by James E. Wilson, Jr. Date 04/12/84

EPA Reg. No. or File Symbol 51558-R

EPA Petition or EUP No.

Date Division Received 03/05/84

Type Product(s): I,(D), H, F, N, R, S

Data Accession No(s) 252545

Product Mgr. No. 31 (LEE)

Product Name Protecto plus II

Company Name The Crystal Tissue Company

Submission Purpose New Application

Chemical & Formulation

Active Ingredient	%
Cetyl pyridinium chloride	0.6

BACKGROUND

Protecto Plus II is an impregnated tissue toilet seat cover which claims to control the Herpes simplex Type 2 virus.

In a telephone conversation with this office late in 1983, it was agreed that the company would only have to submit skin irritation and dermal sensitization data on the product based on the proposed use pattern and physical form.

RECOMMENDATIONS

Based on the data reviewed the product should be placed in toxicity category 4 for dermal irritation. Data also indicate that the product is not a dermal sensitizer.

It was requested that the statement "Keep Out of Reach of Children" be omitted from the front panel. Since the product appears to be safe for use by children and we have previously granted this request to registrants marketing impregnated tissues, it is recommended that the request be granted.

DATA REVIEW

Primary Skin Irritation

Report by Hill Top Research, Inc. submitted to Crystal Tissue, Inc., Middletown, OH 45042, dated February 10, 1984. (Accession No. 25245).

Method - A 0.5 g patch of the product moistened with 1.0 ml saline was placed on two intact and two abraded sites of six rabbits for four hours. The sites were observed 4, 24, 48, and 72 hours after application.

Conclusion - The product is not a skin irritant.

Dermal Sensitization

Report by Hill Top Research, Inc., submitted ... (same as above) ....

Method - A 1"X 1" unmoistened patch of the product was applied to the clipped backs of 20 guinea pigs for 6 hours. All animals received one application per week for three weeks. A challenge application was made two weeks after the last of the three induction applications. Ten additional animals received the patch application (naive controls) during the challenge phase.

Results - One animal died during the first restraint period and was not replaced. Irritation was absent both during the induction and challenge Phases.

Conclusion - The product is not a dermal sensitizer under the conditions tested.