

# 21-Day Cumulative Irritancy Patch Test:

## *Comfort Shield™ Perineal Care Washcloths*

---

### INTRODUCTION

Comfort Shield™ Perineal Care Washcloths, manufactured by Sage Products Inc., are specifically marketed as the first incontinence care product to offer one-step perineal cleansing, moisturizing, deodorizing, and barrier protection in a soft, durable washcloth. Comfort Shield's disposable washcloths are premoistened with a 3% dimethicone formula to help treat and prevent perineal dermatitis. Comfort Shield combines several steps of incontinence care to reduce patient discomfort, while eliminating additional supplies such as laundered washcloths, wipes, soaps, basins, sprays, foam cleansers and barrier creams.

In 1968, Lanman et al. reported that several days of repeated exposures to mildly irritating cosmetic products<sup>1</sup> produced a method to discriminate among low-level irritants. With modifications,<sup>2,3</sup> this method remains the "gold standard" test for determining a product's potential for inducing cutaneous irritation.

### OBJECTIVE

The purpose of this study was to evaluate the potential of the test material, specifically the Comfort Shield formula, to induce contact skin irritancy in human subjects, as a result of repeated application and occlusion for 21 days.

### METHODS

Twenty-seven subjects were empaneled. A total of 21 subjects, 4 male and 17 female, age 21-56, completed the study. The subjects were racially diverse and represented diverse skin types. No subject was

enrolled if he or she exhibited, or had any history of, any dermatological or other medical or physical condition that would preclude application or reading the results. Each subject provided written, informed consent. No subject was discontinued due to adverse effects to the test articles. Six subjects dropped for various reasons unrelated to the test articles.

A 1% Sodium Lauryl Sulfate solution served as the positive irritancy control, while a preservative-free 0.9% Sodium Chloride solution (physiological saline) was used as the negative irritancy control. The Comfort Shield formulation was provided by Sage Products, Inc.

A Finn Chamber patch containing the test articles was uniformly applied to the skin of the left scapular region, removed 1 to 2 hours prior to reading and reapplied to the same site for 21 consecutive days. The chamber sites for each test article were double-blinded and randomized for each patient, with reapplication in the same chamber each day.

Each subject was instructed that the patch was to remain in place and kept dry for  $23 \pm 1$  hours daily, at which time the patch was to be removed by the subject prior to their clinic visit. Each subject was instructed to return to the clinic at approximately the same time every day.

Test sites were observed for reaction and each subject queried as to whether any reaction was experienced during the previous 24 hours.

Test article scores for each day (and overall total) were ranked within each subject and then analyzed using the Friedman Rank Sum test.

---

*This study was sponsored by Sage Products, Inc. and conducted by **Dennis P. West, PhD, FCCP, Professor of Dermatology, and Meyer Horn, MD, Clinical Research Fellow, both at Northwestern University Department of Dermatology in Chicago, during July and August, 1999.***

## METHODS (CONTINUED)

The following classification system is used to standardize the interpretation of irritation scores:

Class	Score	Classification	Description of Observed Responses
1	0-103	Mild article - no experimental irritation.	Essentially no evidence of cumulative irritation under conditions of test (i.e., continuous reapplication and occlusion at concentration specified).
2	104-418	Probably mild in normal use.	Evidence of slight potential for very mild cumulative irritation under conditions of test.
3	419-943	Possibly mild in normal use.	Evidence of moderate potential for mild cumulative irritation under conditions of test.
4	944-1218	Experimental cumulative irritant.	Evidence of strong potential for mild to moderate cumulative irritation under conditions of test.
5	1219-1323	Experimental primary irritant.	Evidence of potential for primary irritant irritation under conditions of test.

## RESULTS

	Positive Control	Negative Control	Comfort Shield™ Formula
Score	1181*	64	42*
Class	4	1	1

*Positive Control - 1% Sodium Lauryl Sulfate solution*

*Negative Control - 0.9% Sodium Chloride solution (physiological saline)*

*\* p=0.001, Friedman Rank Sum Test*

Under double-blind conditions, the Comfort Shield formula and 0.9% Sodium Chloride solution (physiological saline) ranked as Class 1 materials, i.e., essentially no evidence of cumulative irritation under continuous reapplication and occlusion at the concentrations tested.

## CONCLUSION

The formula for Comfort Shield Perineal Care Washcloths, when used on human skin under occlusion daily for 21 days, was proven to be gentle and non-irritating.

## REFERENCES

- <sup>1</sup> Lanman BM, Elvers EB, Howard CJ, "The role of human patch testing in a product development program," Joint Conference on Cosmetic Sciences, The Toilets Goods Association (currently The Cosmetic, Toiletry and Fragrance Association), Washington, DC, April 21-23, 1968.
- <sup>2</sup> Phillips L, et al., Comparison of rabbit and human skin to certain irritants. *Toxicol Appl. Pharmacol.* 1972, 21:369-82.
- <sup>3</sup> Berger RS, Bowman JP, A reappraisal of the 21-day cumulative irritation test in man, *J. Toxicol. Cut. and Ocular Toxicol.* 1982, 1:109-115.