

21-Day Cumulative Irritancy Patch Test: *Comfort Bath™ Cleansing System*

INTRODUCTION

The Comfort Bath™ Cleansing System, manufactured by Sage Products Inc., is specifically marketed as a non-irritating, no-rinse, cleansing and moisturizing product replacing the traditional soap and water basin bath.

In 1968, Lanman et al., reported that several days of repeated exposures to mildly irritating cosmetic products¹ produced a method to discriminate among low-level irritants. This method or modifications^{2,3} 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 materials, specifically the Comfort Bath Cleansing System formula, to induce contact skin irritancy, under occlusion, as a result of repeated applications for 21 days.

METHODS

A total of 26 subjects, 4 male and 22 female were empaneled. No subject was enrolled if he or she exhibited, or had any history of, any dermatological or other medical or physical condition which would preclude application or reading the results. Each subject provided written informed consent.

A 1% solution of Sodium Lauryl Sulfate served as the positive irritancy control while a 0.9% solution of Sodium Chloride (physiological saline) was used as a

negative irritancy control. The Comfort Bath Cleansing System formulation was provided by Sage Products, Inc.

A Finn Chamber patch containing the test articles on filter paper was uniformly applied to the skin of the left scapular region, removed 1-2 hours prior to reading and reapplied to the same site for 23 hours daily over 21 consecutive days. The chamber sites for each test article were randomized and double-blinded for the investigator, as well as each subject, with reapplication of each test article in the same chamber daily.

Each subject was instructed that the patch was to remain in place and kept dry for 23 +/-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 symptoms were 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.

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

This study was sponsored by Sage Products, Inc. and conducted by Andrew Scheman, MD, Clinical Assistant Professor of Dermatology and Dennis P. West, PhD, FCCP, Professor of Dermatology, both at Northwestern University Department of Dermatology in Chicago, during May and June, 1998.

METHODS CONTINUED

Class	Score	Classification	Description of Observed Responses
1	0-124	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	125-499	Probably mild in normal use	Evidence of slight potential for very mild cumulative irritation under conditions of test.
3	500-1124	Possibly mild in normal use	Evidence of moderate potential for mild cumulative irritation under conditions of test.
4	1125-1450	Experimental cumulative irritant	Evidence of strong potential for mild to moderate cumulative irritation under conditions of test.
5	1451-1575	Experimental primary irritant	Evidence of potential for primary irritant irritation under conditions of test.

RESULTS

	Positive Control	Negative Control	Comfort Bath Formula
Score	1359	47	24
Class	4	1	1

Positive Control - Sodium Lauryl Sulfate 1% solution

Negative Control - Sodium Chloride 0.9% solution (physiological)

Under double-blind conditions, the Comfort Bath Cleansing System formula and Sodium Chloride 0.9% 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 Comfort Bath Cleansing System formula, when used on human skin under occlusion daily for 21 days, was proven to be gentle and non-irritating.

REFERENCES

1. 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.
2. Phillips L, et al. Comparison of rabbit and human skin response to certain irritants. *Toxicol Appl. Pharmacol.* 1972, 21:369-82.
3. 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.