

# **A Comparison of the Effectiveness and Wash-Off Resistance of Four Dimethicone Skin Barrier Creams**

**Gary Grove, PhD, cyberDERM Clinical Studies, Broomall, PA, USA**

**Timothy Houser, BS, cyberDERM Special Projects Group, Media, PA, USA**

**Charles Zerweck, PhD, cyberDERM Clinical Studies, Broomall, PA, USA**

## Abstract

Moisture barriers are an important element in a well-structured patient skin care program and dimethicone is one of the more common active ingredients used in moisture barriers. Dimethicone is approved by the FDA as an active ingredient for use in Over The Counter (OTC) moisture barriers from 1% to 30% through a publication known as the Skin Protectant Drug Monograph and manufacturers generally rely on this monograph as documentation of product efficacy.<sup>1</sup> However, this monograph only specifies the allowable ranges of active ingredients and does not specify tests to assure efficacy of the final product. It is well documented that inactive ingredients which deliver active ingredients to the skin can affect performance of drug products,<sup>2</sup> and with dimethicone moisture barriers, these inactive ingredients differ considerably between products. Therefore, selection of a dimethicone moisture barrier should be based on efficacy testing rather than simple reliance on compliance with the published FDA monograph as documentation of efficacy.

The objective of this study was to measure and compare moisture barrier effectiveness of four dimethicone skin protectants 30 minutes after application to the skin and following each of the three simulated normal washes. Four marketed dimethicone moisture barrier creams were tested for moisture barrier effectiveness using a previously published procedure which sequentially follows products through multiple standardized water challenges and simulated normal washes.<sup>3</sup> This procedure tests both the initial effectiveness of the moisture barrier and its ability to resist wash-off.

The results of this test showed that there were significant differences in moisture barrier effectiveness between the four products. Cavilon™ Durable Barrier Cream provided superior moisture barrier effectiveness compared to Secura™ Dimethicone Protectant Cream, Remedy™ Dimethicone Skin Protectant, and Proshield® Plus Skin Protectant. These differences were significant initially after application and through three simulated normal washes. Two of the products (Secura and Proshield Plus) did not provide any moisture barrier effectiveness compared to the untreated control at any time during the study. **There also appeared to be no correlation between the amount of dimethicone contained in the product and moisture barrier effectiveness**, again emphasizing the need to select dimethicone moisture barriers based on results of efficacy testing.

These results show that inactive ingredients can significantly affect performance of dimethicone moisture barriers independent of the amount of dimethicone contained in the product. These results also emphasize the need for health care professionals to select dimethicone moisture barriers based on results of efficacy testing rather than product label claims based only on FDA OTC monograph compliance.

## Background

The FDA defines a skin protectant as a topical Over The Counter (OTC) drug that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces. Dimethicone (1% to 30%) is one of several ingredients approved by the FDA as an active ingredient for OTC skin protectant drug products.<sup>1</sup>

Manufacturers generally rely on compliance with the FDA Skin Protectant Drug Monograph as documentation of product efficacy. The implication being that if the active ingredient is approved by the FDA, then the product itself must be effective for the approved uses (e.g. protection from incontinence). However, this monograph only specifies: 1) allowable active ingredients, 2) allowable ranges of ingredients, and 3) allowable claims for the various active ingredients.

***It is important to note that the FDA Skin Protectant Drug Monograph does not require or specify testing to assure efficacy of the final product.***

Inactive ingredients which deliver the active ingredients to the skin can greatly affect performance of the product.<sup>2</sup> However, a quick survey of skin protectant ingredient lists confirms that inactive ingredients differ considerably between products. Therefore, it is imperative that manufacturers provide documentation of skin protectant claims beyond simple reliance on the list of approved active ingredients in the published FDA monograph.

Since one of the primary uses of a skin protectant in patient skin care is to shield the skin from incontinence and other sources of external moisture, it is reasonable to expect that the product should be an effective moisture barrier. It is well documented that as the skin becomes increasingly hydrated due to exposure to moisture, there is a corresponding increase in electrical conductivity.<sup>4</sup> Efficacy of moisture barriers can therefore be assessed by their effectiveness at preventing this increase in skin electrical conductance following exposure of the skin to a standardized water challenge.<sup>3</sup>

## Objective

The objective of this study was to measure and compare moisture barrier effectiveness of four dimethicone skin protectants 30 minutes after application to the skin and following each of the three simulated normal washes.

## Methods

### Study Design

The study consisted of 36 healthy adult volunteers and used skin electrical conductance measurements after a standardized 10 minute moisture challenge as a marker of moisture barrier effectiveness. Study procedures are outlined in Figures 1 and 2.

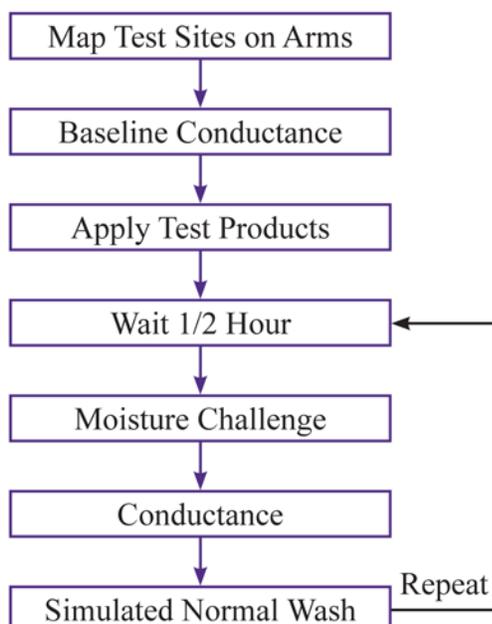
### Measurements

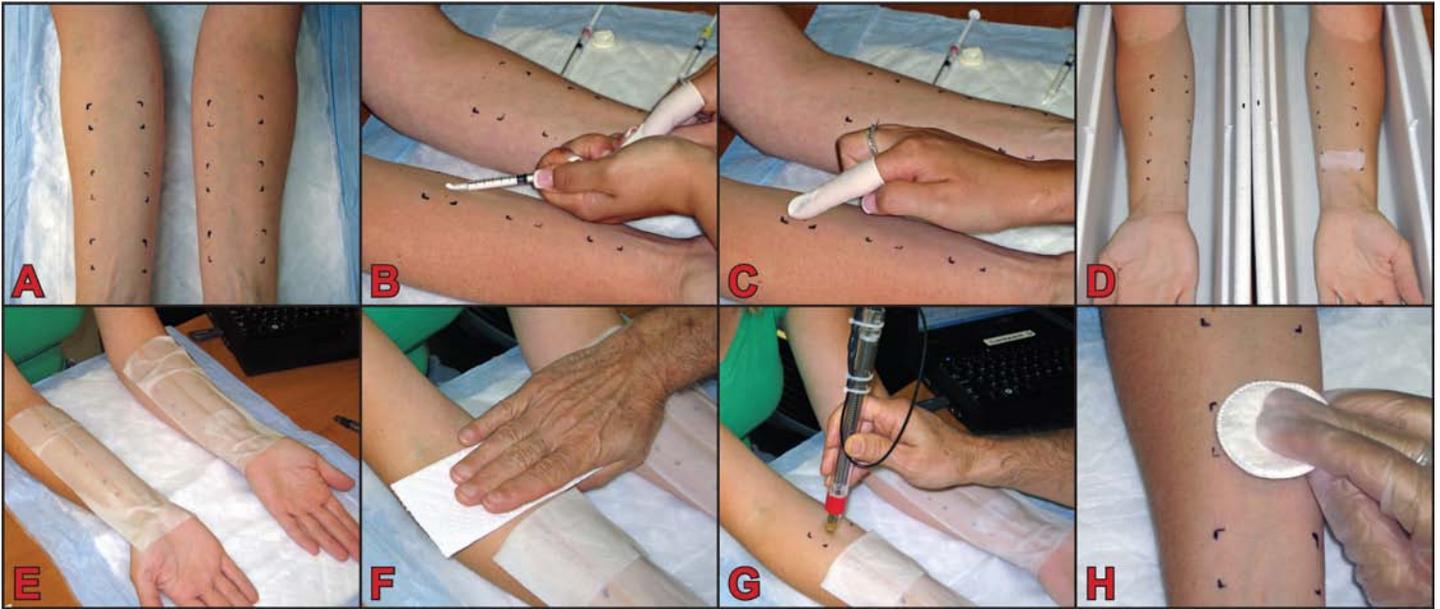
Electrical conductance was measured @ 3.5 MHz with an IBS Skicon-200 meter equipped with a Measurement Technologies probe. Five replicate measurements were taken from each test site and averaged together for a single test site measurement.

### Test Products

- Cavilon Durable Barrier Cream, (3M), 1.3% Dimethicone
- Secura Dimethicone Protectant Cream (Smith & Nephew), 5% Dimethicone
- Remedy Dimethicone Skin Protectant (Medline Industries), 5% Dimethicone
- Proshield Plus Skin Protectant (Healthpoint), 1% Dimethicone

Figure 1: Flowchart of Study Procedures





**Figure 2: Study Procedures**

**A)** Six 2.5 x 5 cm test sites mapped on volar forearms. **B)** 0.05 ml test product applied per site. **C)** Test products applied to the designated test sites according to the study randomization. **D)** Moisture Challenge (10-minute water soak in tepid water). **E)** Soaked towels maintain moisture challenge until measurement. **F)** Test sites blotted of surface moisture prior to measurement. **G)** Measurement of test site. **H)** Simulated normal wash (7 wipes with a cotton pad saturated with 5 ml of 3M Cavilon No-Rinse Skin Cleanser).

**Formula for Calculating % Moisture Barrier Effectiveness**

$$\% \text{ Barrier Effectiveness @ Time X} = 100 - \left[ \frac{\left( \text{Conductance @ Time X} \right) - \left( \text{Conductance @ Baseline} \right)}{\left( \text{Control Conductance @ Time X} \right) - \left( \text{Control Conductance @ Baseline} \right)} \right] \times 100 \%$$

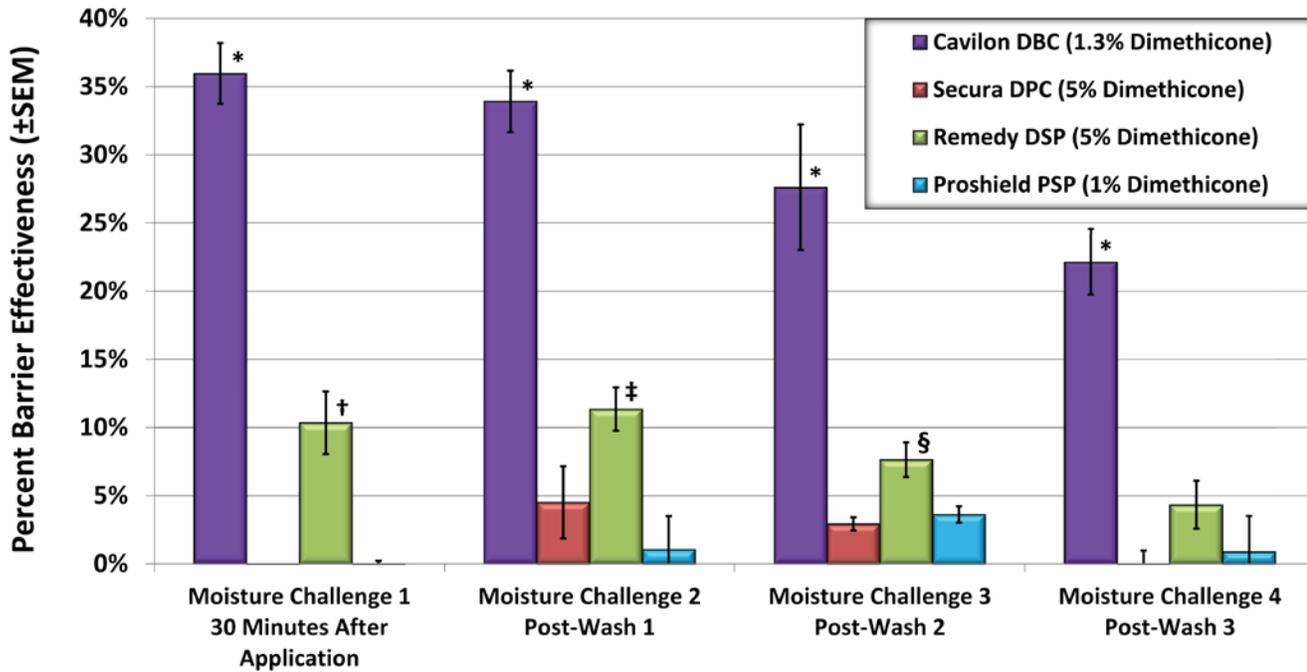
**Statistical Analysis**

ANOVA with Tukey’s pairwise comparisons was used to test for differences in percent moisture barrier effectiveness. This procedure allowed for all possible cross-comparisons of products within each wash/ moisture challenge cycle.

**Results**

The mean percent moisture barrier effectiveness for each of the test products during each of the moisture challenges are presented in Figure 3. **At all moisture challenges, Cavilon Durable Barrier Cream provided statistically superior moisture barrier effectiveness versus all three of the other dimethicone skin protectants tested.** Remedy Dimethicone Skin Protectant was less effective than Cavilon Durable Barrier Cream, but did provide some moisture barrier effectiveness through two simulated normal washes. Surprisingly, Secura Dimethicone Protectant Cream and Proshield Plus Skin Protectant provided no moisture barrier effectiveness compared to the untreated control at any time during the study.

**Figure 3: Moisture Barrier Effectiveness of Four Dimethicone Creams**



\* Significantly different than the untreated control and all other test products ( $p < 0.0001$ )

†, ‡, § Significantly different than untreated control ( $p = 0.0024$ ,  $p = 0.0011$ ,  $p = 0.0451$ )

## Conclusions

It can be concluded that significant differences exist in the moisture barrier effectiveness of dimethicone containing skin protectants that are ***independent of the amount of dimethicone contained in the product***. Cavilon Durable Barrier Cream provided superior moisture barrier effectiveness compared to Secura Dimethicone Protectant Cream, Remedy Dimethicone Skin Protectant, and Proshield Plus Skin Protectant. These differences were evident immediately after application and through three simulated normal washes. An unexpected result was that two of the products tested provided no significant moisture barrier effectiveness compared to the untreated control at any time during the study, and one of these products (Secura Protectant Cream) contains nearly 4 times the amount of dimethicone as Cavilon Durable Barrier Cream.

*These results suggest that health care professionals should select dimethicone moisture barriers based on results of efficacy testing rather than product label claims based only on FDA OTC monograph compliance.*

## Key Points

- ***Cavilon Durable Barrier Cream provided significantly better moisture barrier effectiveness than all the other dimethicone skin protectants tested.***
- ***Differences in moisture barrier effectiveness are independent of the amount of dimethicone contained in the product.***
- ***Significant differences in moisture barrier effectiveness exist among dimethicone skin protectants.***

## References

1. Skin Protectant Drug Products for Over-the-Counter Human Use; Final Monograph. *Federal Register*. June 4, 2003; Vol. 68, No. 107:33362-33380. Available at URL:  
[http://www.fda.gov/cder/otcmonographs/Skin\\_Protectant/skin\\_protectant\\_FM\\_20030604.pdf](http://www.fda.gov/cder/otcmonographs/Skin_Protectant/skin_protectant_FM_20030604.pdf).  
June 4, 2003.
2. U.S. Code of Federal Regulations 21CFR314.127; Drugs for human use: Application for FDA approval to market a new drug.
3. Lutz JB, Lavoie KA. Comparison of the effectiveness of four dimethicone-based moisture barrier creams. *Presented at the 12th Annual Symposium on Advanced Wound Care, Anaheim, CA. 1999.*
4. Tagami H. Epidermal Hydration: Measurement of High-Frequency Electrical Conductance. In: Serup J, Jemec GBE, Grove GL, eds. *Handbook of non-invasive methods and the skin*. 2nd ed. Boca Raton, Fla. ; London: CRC; 2006:329-336.



**Skin & Wound Care Division**  
**3M Health Care**  
3M Center, Building 275-4W-02  
St. Paul, MN 55144-1000  
U.S.A.  
1-800-228-3957  
[www.3M.com/skinhealth](http://www.3M.com/skinhealth)

Please recycle  
Printed in U.S.A.  
© 3M 2010. All rights reserved.  
70-2010-8204-0

3M and Cavilon are trademarks of 3M Company, St. Paul, MN, USA  
Remedy is a trademark of Medline Industries, Mundelein, IL, USA  
Secura is trademark of Smith & Nephew Inc., Largo, FL, USA  
Proshield Plus is a trademark of Healthpoint, Ltd., Fort Worth, TX, USA