

**3M**

**Cavilon™**

Skin Care Solutions

**3M™ Cavilon™ Advanced Skin Protectant**

# **Summary of Clinical Evidence**

*Journal of Wound, Ostomy and Continence Nursing 2017; 44(2):172-180*

## Clinical Evaluation of a Skin Protectant for the Management of Incontinence-associated Dermatitis (IAD) in an open label, non-randomized, prospective study

*Brennan MR, Milne CT, Agrell-Kann M, Ekholm BP*

### STUDY TYPE

Open-label, non-randomised, prospective clinical study on incontinent patients, n=16.

### OBJECTIVE OF STUDY

Evaluate the efficacy of an investigational skin protectant product for managing severe Incontinence-associated Dermatitis.

### KEY FINDINGS / ANALYSIS

At enrollment, 12 patients had epidermal skin loss and 4 had severe redness with no skin breakdown. Cavilon Advanced Skin Protectant led to a reduction in the Incontinence-associated Dermatitis (IAD) score in 13 of 16 patients. The score remained unchanged in one patient, and deteriorated in 2 patients. Among patients with improvements in IAD scores, the median percent improvement was 96%, which was significantly different from zero ( $p=0.013$ ). Four of the patients with epidermal skin loss had complete re-epithelialisation of the skin surface with 4-6 applications of the skin protectant, and five had substantial improvement. The four patients with severe erythema returned to healthy normal skin with 2-4 applications of the product. Substantial pain reduction was reported by all 9 patients reporting pain at enrollment. No adverse events associated with the skin protectant application were reported during data collection.

This initial clinical study indicates that Cavilon Advanced Skin Protectant led to improvement in skin condition and was effective in protecting skin even in the presence of continued incontinence.

*Data on file at 3M (Study EM-05-013924)*

## Study to Assess the Durability of Film-Forming Barriers Using the Activated Carbon Retention Method

*Grove GL, Zerweck C, Fendrick D*

### STUDY TYPE

Study on healthy volunteers, n=21.

### OBJECTIVE OF STUDY

Measure and compare the ability of 4 products (Cavilon Advanced Skin Protectant, Medline Marathon® Liquid Skin Protectant, Smith & Nephew No-Sting Skin Prep®, and Medline SurePrep® No-Sting Skin Protective Barrier) to last up to 7 days after a single application on healthy skin using the activated carbon retention method. Volar forearms were cleansed and activated carbon was applied on four ¾" diameter circles on each arm. Each of the 4 tested products was applied over a different test site in a randomised fashion on each arm. Digital photographs were taken and used to grade colour intensity prior to application (baseline), after application (maximum intensity), and on Days 1, 2, 3, 4, and 7. Subjects were instructed to shower at home at least once daily between visits. The percent of film left intact was assessed using photos and rated on a scale (1=0% of film intact to 7=100% of film intact). A person blinded to the treatment randomisation performed the assessments and assigned rankings. The colour intensity, i.e. amount of carbon remaining on the skin over time, was used as a measurement of barrier durability.

### KEY FINDINGS / ANALYSIS

Cavilon Advanced Skin Protectant had a significantly higher percent of film intact than all other tested products at all time points.

*Advances in Wound Care 2016 (in press). Published online: <http://online.liebertpub.com/doi/pdfplus/10.1089/wound.2016.0706>*

## Effect on microbial growth of a new skin protectant formulation

*Stoffel J and Bernatchez SF*

### STUDY TYPE

In vitro bench study.

### OBJECTIVE OF STUDY

Evaluate the effect of a new investigational skin protectant formulation on the growth of various microorganisms in vitro.

### KEY FINDINGS / ANALYSIS

A stripe of 3M™ Cavilon™ Advanced Skin Protectant was coated on agar plates and the plates were then seeded with one of 10 bacterial species (including Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa*) and 3 yeasts including *Candida albicans*. No growth was noted at the end of a 48 hour incubation period.

Cavilon Advanced Skin Protectant did not support the growth of any organisms tested. Cavilon Advanced Skin Protectant forms a film barrier to bacteria and yeast associated with incontinence.

*Advances in Wound Care 2016 (in press). Published online: <http://online.liebertpub.com/doi/pdfplus/10.1089/wound.2016.0705>*

## Skin protectants made of curable polymers: effect of application on local skin temperature

*Walt M, Atwood N, Bernatchez SF, Ekholm BP, Asmus R*

### STUDY TYPE

Study on healthy volunteers, n=12.

### OBJECTIVE OF STUDY

Measure the post-application skin temperature of a new skin protectant intended for Incontinence-associated Dermatitis (IAD), compared to a commercial product with a pure cyanoacrylate-based chemistry.

### KEY FINDINGS / ANALYSIS

A drop of 1.2°C (endothermic reaction) in skin surface temperature was noted upon application of Cavilon Advanced Skin Protectant. In contrast, a pure cyanoacrylate product (Medline Marathon®) displayed an exothermic rise in skin surface temperature of +0.3°C. Cavilon Advanced Skin Protectant was designed to mitigate the temperature rise that is characteristic of cyanoacrylates. Because application of Cavilon Advanced Skin Protectant results in a decrease in skin surface temperature, it may be more comfortable for application to damaged skin than a pure cyanoacrylate formulation.

*Wound Repair and Regeneration* 2016; 24:851-859. Published online: <http://onlinelibrary.wiley.com/doi/10.1111/wrr.12455/epdf>

## In vivo methods to evaluate a new skin protectant for loss of skin integrity

Been RA, Bernatchez SF, Conrad-Vlasak DM, Asmus RA, Ekholm BP, Parks PJ

### STUDY TYPE

3 animal models.

### OBJECTIVE OF STUDY

Evaluate capabilities of a new skin protectant formulation and propose an integrated preclinical testing strategy for effectiveness.

### KEY FINDINGS / ANALYSIS

A hairless guinea pig model with intact skin was used to test the ability of the skin protectant to prevent skin irritation from a caustic irritant applied for 48 hours. In this model, untreated sites had 8.5 times more irritation than sites covered with the new product ( $p < 0.001$ )

A pig partial-thickness wound model was used to: 1) test the ability of the skin protectant to adhere in the presence of oozing and to control exudate over 96 hours and 2) test the ability of the skin protectant to allow wound re-epithelialisation in the presence of a caustic irritant applied to the wound for 96 hours. In this model, a single application of the new product successfully attached to intact peri-wound skin and to denuded, weepy skin. It significantly reduced the amount of fluid weeping from the wounds ( $p \leq 0.001$ ) and continued to perform throughout the 96 hours experiment. The percent of re-epithelialisation was significantly greater for the wounds covered with the new product than for the control wounds ( $p = 0.003$ ; on average 18.3% greater, with a 95% confidence interval of 9.2% to 27.5%). These results suggest that the new skin protectant protects intact and denuded skin from irritants and provides an environment favorable to healing, offering promise for the management of various conditions involving loss of epidermis.

Data on file at 3M (Study 05-013121)

## Effect of 3M™ Cavilon™ Advanced Skin Protectant on Adhesion to Skin: Characteristics of Six Wound Care Dressings

Behr L, Wood M, Brown B, Ekholm BP

### STUDY TYPE

Study on healthy volunteers, n=24.

### OBJECTIVE OF STUDY

Evaluate adhesion to skin characteristics of wound care dressings applied to test sites on the skin of healthy volunteers coated with Cavilon Advanced Skin Protectant compared to a soap and water control. Wound care dressings evaluated in this study included: 3M™ Tegaderm™ High Performance Foam Adhesive Dressing, 3M™ Tegaderm™ Silicone Foam Border Dressing, 3M™ Tegaderm™ Absorbent Clear Acrylic Dressing, Molnlycke Mepilex® Border Dressing, Smith & Nephew Allevyn Life and Medline Optifoam® Adhesive Dressing. A ¾" x 3" portion of the adhesive border of each dressing was evaluated.

### KEY FINDINGS / ANALYSIS

Parameters assessed were: peel force upon removal, product lift, residue, edge residue, skin irritation, and skin stripping. Test sites were assessed within 5-15 minutes after application to assess initial adhesion, and then at 24 and 72 hours.

No statistically significant differences in mean adhesion to skin values were observed between Cavilon Advanced Skin Protectant and soap and water (control) sites with Molnlycke Mepilex® Border, Smith & Nephew Allevyn Life, Tegaderm Silicone Foam Border Dressing and Medline Optifoam® at any of the assessment time points (T0, T24 & T72). Mean adhesion to skin values for Tegaderm Foam Adhesive Dressing were significantly higher at all time points for Cavilon Advanced Skin Protectant compared to the control. Tegaderm Absorbent Clear Acrylic dressings had significantly higher mean adhesion over Cavilon Advanced Skin Protectant compared to the control at T72 hours only. The data from this study showed that Cavilon Advanced Skin Protectant does not interfere with effective use of adhesive products. Increased adhesion was noted with the Tegaderm Foam Adhesive Dressing and Tegaderm Absorbent Clear Acrylic Dressing. Although statistical differences occurred, adhesion characteristics (adhesion to skin, lift and residue) for both silicone and acrylate adhesive dressings were acceptable.

Data on file at 3M (Study 05-012907)

## Evaluation of Skin Cleansers on the Integrity of 3M™ Cavilon™ Advanced Skin Protectant

Behr L, Mathisen M, Smith G, Walters SA

### STUDY TYPE

Study on healthy volunteers, n=18.

### OBJECTIVE OF STUDY

Determine if various common cleansing products affect the durability of Cavilon Advanced Skin Protectant. Forearm sites were cleansed and three 1-inch diameter circles of pigment were applied on each arm. Cavilon Advanced Skin Protectant was applied over each test site. Sites were cleansed 15 times per day for 4 days using: 1) 3M™ Cavilon™ Bathing & Cleansing Wipe, 2) Sage® Comfort Bath® Washcloths 3) 3M™ Cavilon™ No-Rinse Skin Cleanser, 4) ConvaTec Sensi-care® Perineal Skin Cleanser, 5) Medline Remedy® Antimicrobial Cleanser, or a water control. A visual assessment was performed to determine film remaining.

### KEY FINDINGS / ANALYSIS

Colour intensity, i.e. amount of pigment remaining on the skin was used as a measurement of remaining skin protectant and barrier integrity. After 2 days of wear and 30 episodes of cleansing, 90% of subjects' data points had >90% of pigment intact. After 3 days of wear and 45 cleansing episodes, 71% of subjects' data points had >90% of the pigment intact. After 4 days and 60 cleansing episodes, 5 of the 18 subjects had approximately ≥90% of the pigment intact.

Barrier integrity of Cavilon Advanced Skin Protectant was maintained for approximately 72 hours despite frequent cleansing with the products tested.

Data on file at 3M (Study ToxDocs 13-296, ST-452)

## In vitro skin irritation: Effect of new skin protectant formulations on epidermal viability

Brandwein D

### STUDY TYPE

Laboratory study.

### OBJECTIVE OF STUDY

Assess the human epidermal irritation potential of various formulations of a new skin protectant using the reconstructed human epidermal tissue model, EpiDerm™ (EPI-200-SIT; model validated for skin irritation). Irritation was categorised by tissue viability as indicated by the energy-dependent reduction of MTT dye, and by the levels of the cytokines IL-1 $\alpha$  and IL-8 released into the tissue culture media after exposure for 6, 24, and 48 hours.

### KEY FINDINGS / ANALYSIS

All test formulations of the new skin protectant gave results similar to the negative control, i.e. the EpiDerm™ tissues maintained high viability and secreted similar amounts of inflammatory cytokines. By comparison, EpiDerm™ tissues exposed to positive control substances for irritation or sensitisation exhibited a reduction in viability and an increase in cytokine secretion over the test period. In conclusion, the new skin protectant formulations did not negatively affect the health status of the EpiDerm™ tissues in this model.

Data on file at 3M (Study 05-013122, n=21, and Study 05-013374, n=24)

## Effect of 3M™ Cavilon™ Advanced Skin Protectant on adhesion of ostomy products

Behr L, Rauch D, Wood M, Walters SA, Ekholm B

### STUDY TYPE

Study on healthy volunteers.

### OBJECTIVE OF STUDY

Evaluate the wear characteristics over 96 hours of 7 ostomy products applied to test sites prepped with 3M™ Cavilon™ Advanced Skin Protectant compared to a soap and water control. Ostomy products evaluated in this study included: Coloplast Assura®, ConvaTec Stomahesive®, Hollister SoftFlex, Hollister Flexextend, Hollister FlexWear, Coloplast SenSura®, and ConvaTec SURFIT® Durahesive®. Only the skin barrier material of each product was evaluated.

### KEY FINDINGS / ANALYSIS

The 7 ostomy products adhered well to both the Cavilon Advanced Skin Protectant treated sites and the soap and water control sites. For the first 4 products, there were no significant prep effects with respect to average scores for wear time, lift from skin, erythema and edema, skin stripping, trace denudation, pain upon removal, or residue. For the other 3 products, there were no statistically significant differences between treated and control skin for wear time, erythema and edema, skin stripping and overall residue. Treated sites demonstrated less lift on average compared to soap and water control sites and slightly more pain upon removal (mean scores ranging from 1.39 to 2.08 versus 1.00 to 1.83 on a scale of 1-10). This difference in pain levels is likely related to the better adhesion (less lift) observed for those products. This study confirmed that Cavilon Advanced Skin Protectant does not interfere with the adhesion of commonly used ostomy barriers.

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# Discover how 3M™ Cavilon™ Advanced Skin Protectant can give you the power to stop, reverse, prevent — and help end — IAD.\*

For more information, visit [3M.com.au/CavilonAdvanced](http://3M.com.au/CavilonAdvanced) or [3M.co.nz/CavilonAdvanced](http://3M.co.nz/CavilonAdvanced), contact your 3M Critical & Chronic Care Solutions sales representative, or call the 3M Health Care Customer Helpline at Australia 1300 363 878 or New Zealand 0800 80 81 82.



## Ordering Information

### 3M™ Cavilon™ Advanced Skin Protectant

Cat. No	Size	Items/Box
5050G	2.7ml applicator	20

\* 3M data on file



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