DermSafe Technical Summary

Invisicare® - A Unique Technology

Invisicare is a polymer delivery system that enhances the delivery of ingredients to the skin. It is backed by over 20 years of research and development. Invisicare is an innovative skin delivery system that allows topical products to work better. It is a powerful yet flexible combination of polymers (like "tubes") that incorporate key ingredients within its structure. Simply put, Invisicare helps provide the following benefits:

- **Advanced Skin Binding** - Binds ingredients to the skin resisting both rub-off & wash-off while allowing your skin to breathe and perspire naturally.
- **Superior Delivery-** "Super Charges" ingredients and delivers targeted levels of the ingredient's benefits over time.
- **Enhances Ingredients** - Stabilizes ingredients and prevents their breakdown thus allowing the ingredients to treat the skin as they were intended to.
- **Skin Friendly** - Improves the skin's natural barrier function by retaining water / moisture in your skin.
- Fewer Additives - Invisicare products do not contain alcohol, parabens, waxes or organic solvents.

How Invisicare is Used in DermSafe

Scientists have spent over 6 years developing and refining DermSafe hand sanitizer. The combination of chlorhexidine gluconate and Invisicare has resulted in a unique formulation that cannot be duplicated. Invisicare provides a protective bond that is resistant to wash-off, and it delivers targeted levels of chlorhexidine gluconate (CHG) directly onto the skin. Over time, the invisible polymer compositions wear off as part of the natural exfoliation process. Numerous bacterial and viral studies have been conducted on DermSafe at recognized and approved FDA and EU equivalent laboratories. In vitro studies showed a greater than 99% kill on bacteria such as: Enterrococus faecalis, Serratia marcescens, Staphylococcus aureus (MRSA), Escherichia coli, and Pseudomonas aeruginosa, as well as Type A Influenza viruses that include H1N1 ("Swine flu"); H3N2 (Influenza A); subtype H5N1 virus, commonly known as "avian influenza" or "bird flu"; Influenza B virus; Hepatitis C virus. Ex vivo studies performed on H5N1 known as "bird flu" showed a greater than 99% kill lasting up to four hours.

1. **"**Ovation Science Provides Update to DermSafe Status, Sales and Manufacturing." *Ovation Science Inc.*, 26 May 2020, ovationscience.com/ovation-science-update-dermsafe-status-sales-manufacturing/.
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3. "Our Science". Ovation Science Inc., 28 Aug 2020, https://www.DermSafe.com/science/

DermSafe Technical Studies

Evaluation of Antiviral Properties Using a Virucidal Suspension Assay:

1. REDUCTION IN HUMAN CORONAVIRUS (Beta Coronavirus strain OC43 - surrogate for SARS-CoV-2)

a. The purpose of the study was to evaluate the ability of Ovation's DermSafe hand sanitizer to kill a human beta coronavirus strain. The in-vitro time-kill study used the standardized ASTM E1052-11 test method: "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension." The test involved the product (DermSafe) being placed in a vial and the virus was added for an exposure of one minute and five minutes. The efficacy at these time points was then measured.
b. The study verified the effectiveness of DermSafe hand sanitizer made with chlorhexidine gluconate to kill a human beta coronavirus at time points of 1 and 5 minutes. The in-vitro time-kill study used the standardized ASTM E1052-11 test method: "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension." The test involved the product (DermSafe) being placed in a vial and the virus was added for an exposure of one minute and five minutes. The efficacy at these time points was then measured.
c. *Tests conducted by Bioscience Laboratories, Inc., Bozeman, Montana (US FDA compliant / independent lab):*

1. REDUCTION IN INFLUENZA VIRUSES (#PCS-003 July/06):

a. The virucidal activity of DermSafe was assessed against A/New Caledonia/20/99 (H1N1), A/Panama/2007/99 (H3N2) and B/Guangdong/120/00 viruses. The viruses were placed for a 60 second contact time on 96-well plates which contained DermSafe. The virus titre was then measured by titration on MDCK cells and virus was detected by Haemagglutination assay. Untreated virus was used as control. The results show a >99.9968% reduction in the virus H1N1 (swine flu), >99.9998% reduction in H3N2 (influenza virus) and a >99.9684% reduction in Guangdong virus (Influenza B).
b. *Tests conducted by independent lab, Retroscreen Virology Ltd., Center for Infectious Diseases Bart's & The London Queen Mary's School of Medicine and Dentistry, London, United Kingdom:*

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2. REDUCTION IN H5N1 AVIAN FLU VIRUS AT VARIOUS TIME POINTS (#PCF-001 Dec/05):

a. The virucidal activity of DermSafe was assessed against H5N1 (avian flu virus) at 15 and 30 seconds as well as 1, 5 and 10 minute contact times. The viruses were placed the various contact times on 96-well plates which contained DermSafe. The results showed a 99.00% to 99.90% reduction in virus from DermSafe over the various time points.
b. *Tests conducted by independent lab, Retroscreen Virology Ltd., Center for Infectious Diseases Bart's & The London Queen Mary's School of Medicine and Dentistry, London, United Kingdom:*

3. REDUCTION IN H3N2 INFLUENZA A VIRUS AT VARIOUS TIME POINTS (#AO3812 March/06):

a. The virucidal activity of DermSafe was assessed against H3N2 (influenza virus) for a 15, 30 and 60 second contact times. DermSafe was placed in a tube and then the virus was added for the contact times. The results respectively showed a 99.00% at 15 seconds, 99.94% at 30 seconds and 99.98% at 60 seconds reduction in virus from DermSafe over the various time points.
b. *Test conducted by ATS Labs., Eagan, Minnesota (US FDA compliant / independent lab):*

Evaluation of Antiviral Properties Testing Virucidal Activity on Skin:

1. REDUCTION IN H5N1 BIRD FLU VIRUS / Ex-VIVO STUDY (Pig Skin) (#PCF-002 June/06):

a. The virucidal activity of DermSafe was assessed using an ex-vivo (pig skin) study at both short-term and long-term time points. The virus was placed on sections of pig skin which had been treated with DermSafe. The results showed that DermSafe killed the H5N1 virus by 99.44% at 5 minutes and 99.9% at 10 minutes. The longer-term durations resulted in a 98.22% reduction in the H5N1 virus at both 2 hours and 4 hours (without reapplication).
b. *Tests conducted by independent lab, Retroscreen Virology Ltd., Center for Infectious Diseases Bart's & The London Queen Mary's School of Medicine and Dentistry, London, United Kingdom:*

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Evaluation of Persistence Properties

1. **Evaluation of the Persistent Antimicrobial Efficacy on E.coli (Anti-Bacterial) of DermSafe at 2 and 4 Hours after Application (Oct/09):**

    a. The persistent antimicrobial properties of DermSafe was tested against Escherichia coli (e-Coli) (ATCC #43888). The hands of 13 subjects were contaminated with a suspension of e-Coli and measured. The subjects then applied DermSafe and measurements of e-Coli were taken at 2 and 4 hours following product application. This evaluation is based on ASTM 2752-10 Standard Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products.
    b. The results at 2 hours post-application showed a 99.12% kill of e-Coli and at 4 hours post-application a 99.38% kill.
    c. *Test conducted by Bioscience Laboratories, Inc., Bozeman, Montana (US FDA compliant / independent lab):*

2. **Invisicare Persistence Study (September/98):**

    a. Study to demonstrate the ability of a hand sanitizer made with Invisicare polymers to adhere to skin under conditions that simulate normal working conditions (i.e. multiple hand washings in a hospital setting). The sanitizer was applied to the forearms of 30 subjects, followed by a scrub for 2 minutes with gauze saturated with 5% Ammonium Hydroxide at 3 time intervals being, 10 minutes, 2 hours and 4 hours.
    b. Results revealed the sanitizer made with Invisicare polymer was bound to skin for greater than 4 hours, even after 6 minutes of scrubbing. At 4 hours the sanitizer product began to exfoliate from the skin. These results show that the sanitizer made with Invisicare polymer has the ability to persist on skin throughout multiple hand washes and exposure to detergents, chemicals and solvents for a minimum of 4 hours.
    c. *Test conducted by California Skin Research Institute, San Diego, CA (US FDA compliant / independent lab):*

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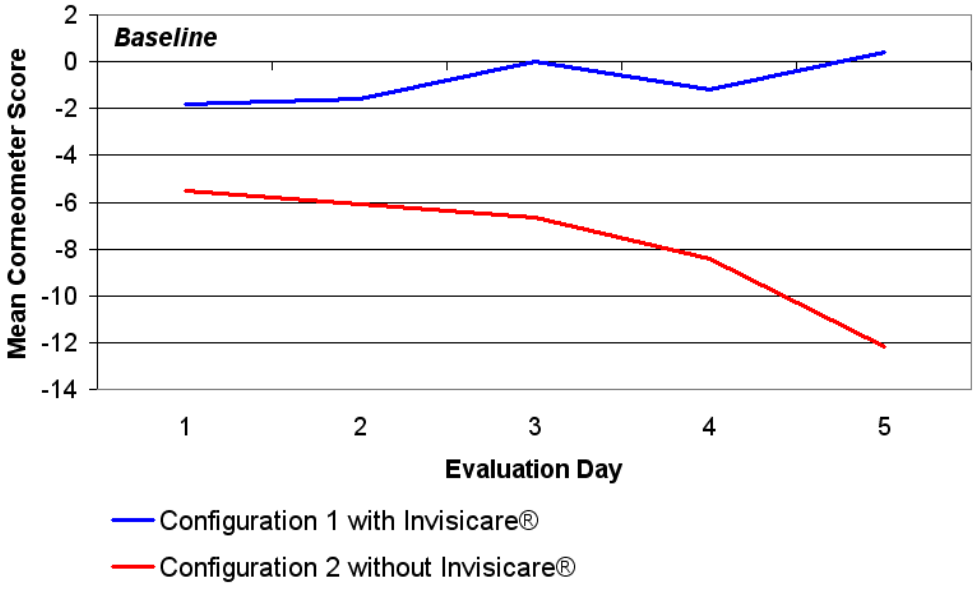
3. Multiple Hand Wash – Moisture Study

a. The study was performed to determine the effectiveness of Invisicare as a protective barrier in preserving skin health as compared to the effects of repetitive hand washing using a standard hospital antimicrobial soap.
   i. 20 subjects:
      1. 10 subjects used Invisicare product
      2. 10 did not

b. Method:
   i. 30 Second Wash / 30 Second Rinse
   ii. 10 Times per Day for 5 days
   iii.

c. Results:
   i. Four subjects without Invisicare dropped out due to dermatitis
   ii. Trans-epidermal water loss and corneal moisture readings showed increased moisture with Invisicare formulation

Chart Begins after Day 1 of Study



d. Test Conducted By: Bioscience Laboratories, Inc., Bozeman, Montana

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DermSafe Safety / Sensitivity Studies

1. **DermSafe Oral Toxicity Study:**

    a. **FHSA Acute Oral Toxicity Screen**
        i. Study conducted to illustrate the acute toxicity of DermSafe in rats.
        ii. Results: An oral dose of 5000mg/kg (body weight) of the test article (4% Chlorhexidine Gluconate) produced no mortalities or abnormalities in five male and five female Sprague-Dawley rats.

    b. *Test Conducted by Northview Pacific Laboratories, Inc., Hercules, CA*

2. **DermSafe Skin Sensitivity Studies:**

    a. **In-Vitro Evaluation of Various Materials for Skin Irritation Using the MTT ET-50 Reduction Method:**
        i. Results: The ET-50 determined for Product 1, Chlorhexidine Hand Sanitizer was .51 hours or 30.60 minutes. Based upon this ET-50, an In-Vivo dermal irritation categorization of "Moderate Irritation" would be expected.
        ii. Test Conducted by Bioscience Laboratories, Inc., Bozeman, MO

    b. **DermSafe – In-Vivo Human Repeated Insult Patch Test (HRIPT):**
        i. Study conducted to demonstrate how the incidence of allergic reaction to DermSafe.
        ii. Results: Under the conditions of the challenge study, ninety-five (95) subjects exhibited no reaction to the Skinvisible 2.25% Chlorhexidine (equivalent to 4% Chlorhexidine Gluconate) hand sanitizer. Five (5) subjects exhibited reactions in the challenge phase of the study, indicative of allergic contact dermatitis.
        iii. Test Conducted by PRACS Institute, Ltd., San Diego, CA

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