



mdpen
PROFESSIONAL SKINCARE

CLINICAL STUDY
EVALUATION

Quality Assurance Statement

This study (ETC Panel No.: 15377; ETC Entry No.: 28635) was conducted in accordance with the intent and purpose of the Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects — Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

For purposes of this clinical study:

- ☒ Informed Consent was obtained.
- ☐ Informed Consent was not obtained.
- ☒ An IRB review was not required.
- ☐ An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This report is considered a true and accurate reflection of the testing methods and source data.



Sherri L Sayles *18 Sep 2015*

Sherri L. Sayles, MS

Date

Sherri L. Sayles, MS
- Manager, Quality Assurance

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TABLE 1 - INDIVIDUAL SCORES

1.0 OBJECTIVE

The objective of this study was to determine the irritation and/or sensitization potential of the test article after repeated application under semi-occlusive patch test conditions to the skin of human subjects (non-exclusive panel).

2.0 SPONSOR

MDPen
2727 Paces Ferry Road SE
Building ONE, Suite 750
Atlanta, GA 30339

3.0 CLINICAL TESTING FACILITY

The study was conducted by:
Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

4.0 CLINICAL INVESTIGATORS

Study Director: Annemarie E. Hollenback, BA
Principal Investigator: Toni F. Miller, PhD, DABT, BCFE
Medical Investigator: John A. Erianne, MD,
Board-Certified Dermatologist

5.0 STUDY DATES

Study initiation: July 29, 2015
Final evaluation: September 4, 2015

All **MDPen** Professional Skincare Products are vegan formulations containing organic ingredients that are paraben, petrochemical and SLS/SLE free-without any animal testing.



Cellular Renewal Serum

MDPen Cellular Renewal Serum contains natural botanical extracts designed to enhance the firmness and elasticity of the skin, while reducing the appearance of wrinkles and promoting cellular renewal.



Copper + HA Mist

MDPen Copper + HA Mist formula includes hyaluronic acid for significant hydration, and copper peptides to boost collagen, act as antioxidants, and promote firmer, smoother skin. Our unique Mist gives patients a hands-free way to nourish their newly-treated skin.



Pure Hyaluronic Acid Serum

Hyaluronic acid is considered to have a greater capacity to hold moisture than any other polymer. MDPen Pure Hyaluronic Acid Serum replenishes the skin's moisture reservoir, restoring firmness and elasticity, while providing significant skin improvement.

6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of the Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures.

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the Informed Consent was provided to each subject.

7.0 TEST MATERIAL

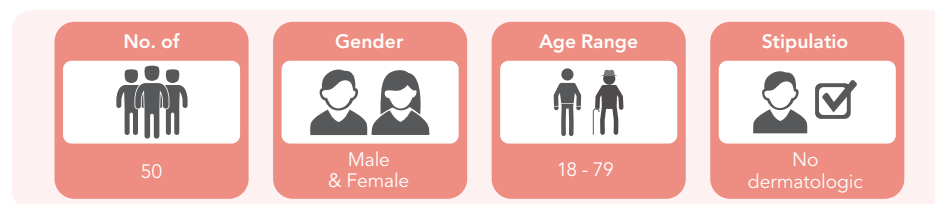
It was received on July 20, 2015 and identified as follows:

ETC Entry No. 28635

Test Article ID: MDPen Skincare Formulation

Description: Transparent Colorless Viscous Liquid

8.0 TEST SUBJECTS



The subjects chosen were dependable and able to read and understand instructions. The subjects did not exhibit any physical or dermatologic condition that would preclude application of the test article or the determination of potential effects of the test article.



Tighten + Lift Serum

MDPen Tighten + Lift Serum features the IntegriACTIVE Firmlift™ conditioning blend with sweet almond seed extract, which helps to lift and firm the skin, making it an excellent addition to any anti-aging skincare regimen.



Broad Spectrum SPF 30+

MDPen Broad Spectrum SPF 30 is formulated with powerful active ingredients designed to protect the skin while adding moisture and hydration with jojoba and is rich in vitamins A, C, and E to condition the skin, synthesize collagen, and block free radicals.



Hydrating Cleanser

MDPen Hydrating Cleanser is a gentle foaming cleanser formulated to remove makeup and surface impurities without drying the skin. Our Cleanser contains Hyaluronic Acid to hydrate and botanical extracts of Aloe, Green Tea, Chamomile and Marigold to soothe, calm and nourish the skin.



Human Derived Growth Factor Gel

MDPen Human Derived Growth Factor Gel contains Tremella Fuciformis Sporocarp Extract, a humectant which acts to reduce moisture loss, while the MariMoist® blend of Chondrus Crispus Extract and Sodium Hyaluronate instantly hydrates and softens. The Conditioned Stem Media contains Epidermal Growth Factors that help promote skin health and youthful appearance. With the addition of Calendula, Aloe and Oat Kernel, the gel is designed to provide the nourishment and calming agents needed to restore the skin after treatment.

9.0 TEST PROCEDURE

The 9 Repeated Insult (semi-occlusive) Patch Test (9-RIPT) I was conducted as follows:

9.1 Induction Phase

A sufficient amount of the test article (approximately 0.2 mL) was placed onto a 2 cm x 2 cm square of Webril® cotton fabric (approximately 0.05 mL/cm² of test material) affixed to Scanpor (Allerderm) semi-occlusive surgical tape. The patch was then applied to the back of each subject between the scapulae and waist, adjacent to the spinal mid-line. This procedure was performed by a trained technician/examiner and repeated every Monday, Wednesday and Friday until 9 applications of the test article had been made.

The subjects were instructed to remove the patch 24 hours after application. Twenty-four hour rest periods followed the Tuesday and Thursday removals and 48-hour rest periods followed each Saturday removal. Subjects returned to the Testing Facility and the site was scored by a trained examiner just prior to the next patch application.

If a subject developed a positive reaction of a level 2 erythema or greater during the Induction phase or if, at the discretion of the Study Director, the skin response warranted a change in site, the patch was applied to a previously unpatched, adjacent site for the next application. If a level 2 reaction or greater occurred at the new site, no further applications were made. However, any reactive subjects were subsequently Challenge patch tested.

9.2 Challenge Phase

After a rest period of approximately 2 weeks (no applications of the test article), the Challenge patch was applied to a previously unpatched (virgin) test site. The site was scored 24 and 72 hours after application. All subjects were instructed to report any delayed skin reactivity that occurred after the final Challenge patch reading. When warranted, selected test subjects were called back to the clinic for additional examinations and scoring to determine possible increases or decreases in Challenge patch reactivity.

Dermal responses for both the Induction and Challenge phases of the study were scored according to the following 6-point scale:

Scale					
0= No evidence of any effect	+= Barely perceptible (Minimal, faint, uniform or spotty erythema)	1= Mild (Pink, uniform erythema covering most of the contact site)	2= Moderate (Pink-red erythema uniform in the entire contact site)	3= Marked (Bright red erythema with/without petechiae or papules)	4= Severe (Deep red erythema with/without vesiculation or weeping)

All other observed dermal sequelae (eg, edema, dryness, hypo- or hyperpigmentation) were appropriately recorded on the data sheet and described as mild, moderate or severe.

1 Marzulji FN, Maibach HI. (1976) Contact allergy: predictive testing in man. Contact Dermatitis. 2, 1-17. Essex Testing Clinic, Inc.

9.0 TEST PROCEDURE (CONT'D)

9.3 Data Interpretation

Edema, vesicles, papules and/or erythema that persist or increase in intensity either during the Induction and/or Challenge phase may be indicative of allergic contact dermatitis. Allergic responses normally do not resolve or improve markedly at 72-96 hours.

Exceptions to typical skin reactions may occur. These may include, but are not be limited to, symptoms of allergic contact sensitivity early in the Induction period to one or more test products. When this occurs in one subject, such a reaction usually suggests either an idiosyncratic response or that the subject had a preexposure/sensitization to the test material or component(s) of the test material or a cross-reactivity with a similar product/component. Data for such reactions will be included in the study report but will not be included in the final study analysis/conclusion of sensitization.

Induction Phase Summary

Test Article	Induction Scores (Number of Responses)						Evidence of Irritation
	0.5	1	2	3	4	Other	
MDPen Skincare Formulation	0	0	0	0	0	0	No

Challenge Phase Summary

Test Article	Challenge Scores (Number of Responses)						Evidence of Sensitization
	0.5	1	2	3	4	Other	
MDPen Skincare Formulation	0	0	0	0	0	0	No

There was no skin reactivity observed at any time during the course of the

10.0 RESULTS AND DISCUSSION

(See Table 1 for Individual Scores)

A total of 58 subjects (12 males and 46 females ranging in age from 18 to 79 years) were empaneled for the test procedure. Fifty (50/58) subjects satisfactorily completed the test procedure on Test Article: MDPen Skincare Formulation. Eight (8/58) subjects discontinued for personal reasons unrelated to the conduct of the study. Discontinued subject data are shown up to the point of discontinuation, but are not used in the Conclusions section of this final report.

11.0 CONCLUSIONS

Under the conditions of a repeated insult (semi-occlusive) patch test procedure conducted on 50 subjects, Test Article: MDPen Skincare Formulation was "dermatologist-tested" and was not associated with skin irritation or allergic contact dermatitis in human subjects.

TABLE 1: INDIVIDUAL SCORES REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVE

Test Article: MDPen Skincare Formulation

Subj. No.	Induction Evaluation Number									Challenge Vir in Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
1	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	Discontinued					
4	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0
9	0	Discontinued									
10	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	Discontinued			
19	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	Discontinued					
25	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0

Scale

0=

No evidence
of any effect

+ =

Barely perceptible (Minimal,
faint, uniform or spotty
erythema)

1=

Mild (Pink, uniform
erythema covering most
of the contact site)

2=

Moderate (Pink-red
erythema uniform in the
entire contact site)

3=

Marked (Bright red
erythema with/without
petechiae or papules)

4=

Severe (Deep red
erythema with/without
vesiculation or weeping)

TABLE 1 (CONT'D): INDIVIDUAL SCORES REPEATED INSULT PATCH TEST - SEMI-OCCLUSIVETest Article: MDPen Skincare Formulation

Subj. No.	Induction Evaluation Number									Challenge Vir in Site	
	1	2	3	4	5	6	7	8	9	24hr	72hr
31	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	Discontinued							
44	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0
46	0	Discontinued									
47	0	0	Discontinued								
48	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0
53	Discontinued										
54	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0

Scale**0=**No evidence
of any effect**+ =**Barely perceptible (Minimal,
faint, uniform or spotty
erythema)**1=**Mild (Pink, uniform
erythema covering most
of the contact site)**2=**Moderate (Pink-red
erythema uniform in the
entire contact site)**3=**Marked (Bright red
erythema with/without
petechiae or papules)**4=**Severe (Deep red
erythema with/without
vesiculation or weeping)

A collection of md pen skincare products. From left to right: a large jar of 'Moisture + Recovery Gel Mask' with a silver lid, a bottle of 'pure hyaluronic acid serum' with a silver cap, a bottle of 'Hydrating Cream' with a silver cap, and a smaller bottle of 'tighten x 10 serum' with a silver cap. The products are arranged on a white surface against a light background.



NOTES:



CLINICAL STUDY EVALUATION

Your business is important to us!

Our philosophy and responsibility are to contribute to your long lasting success by offering a product that is superior, pricing that is competitive and service that excels.

We'd love to hear from you!

Online: www.mdpen.co

Email: mdpen@mdpen.co

MDPen™ USA, Copyright 2017
Ph: 888.313.1415



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