Stephens

A Global Research Company

Stephens Study Numbers: C09-C101; C09-C122; C09-D123; C10-D053; C09-C215 (safety)

Clinical Safety of Mannatech LIFT™ Skin Care Products

Nathan S. Trookman, M.D.[1], Ronald L. Rizer, Ph.D.[1], Lynn Ehrhardt, M.D.[2], Monya L. Sigler, Ph.D.[2]
[1] Thomas J. Stephens & Associates, Inc., Colorado Research Center, Colorado Springs, CO 80915
[2] Thomas J. Stephens & Associates, Inc., Carrollton, TX 75006

OBJECTIVES

Safety testing was conducted on the Mannatech LIFT skin care line to ensure that the products do not induce allergic contact dermatitis and are non-comedogenic. Eye safety testing was conducted on the Day Moisturizer, Night Repair Crème and Multiphase Serum.

HUMAN REPEAT INSULT PATCH TEST

Study Participants

One hundred and thirty-nine subjects were enrolled to participate in the study. One hundred and nine subjects completed the study. Thirty subjects discontinued study participation for reasons not related to the Sponsor's test materials. Subject demographic information is presented in Table 1.

Table 1: Subject Demographics

		All Subjects (n=109)
Age (Years)	Mean Age ± Standard Deviation	46.63 ± 11.63
	Minimum Age	20.55
	Maximum Age	65.30
Gender	Female	86 (78.9%)
	Male	23 (21.1%)
Ethnicity	Caucasian	60 (55.0%)
	Hispanic	23 (21.1%)
	African American	18 (16.5%)
	Asian	4 (3.7%)
	Other	4 (3.7%)

Study Design

Prior to study enrollment, subjects completed an Eligibility and Health Questionnaire, and read and signed an Informed Consent Agreement and a Confidentiality Agreement.

Cotton patches dosed with 100 microliters of each test material were applied to test sites on the subjects' upper backs nine times at 48- to 72-hour intervals. A patch dosed with 1% sodium lauryl sulfate served as positive control, while an undosed patch served as negative control. Twelve to 24 days after the last application, challenge patches were applied to the original and naïve sites for 48 hours. Delayed contact sensitization grading took place approximately 48 to 96 hours post-application of the challenge patch (at least two hours after removal of patches).

Products

Exfoliating Facial Cleanser #34-105
Multiphase Serum #34-155
Day Moisturizer #34-109
Night Repair Crème #34-117
Body Lotion #34-125

Results

The Human Repeat Insult Patch Test showed that none of the five products induced delayed contact sensitization (allergic contact dermatitis) in any subject completing the study.

COMEDOGENICITY TEST

Study Participants

Seventeen subjects were enrolled to participate in this study. Nine subjects completed the study. Eight subjects discontinued study participation for reasons not related to the test materials. Subject demographic information is presented in Table 2.

Table 2: Subject Demographics

		All Subjects (n=9)
Age (Years)	Mean Age ± Standard Deviation	32.76 ± 5.5
	Minimum Age	22
	Maximum Age	39
Gender	Female	8 (88.9%)
	Male	1 (11.1%)
Ethnicity	Caucasian	6 (66.7%)
	Hispanic	3 (33.3%)

Study Design

Prior to study enrollment, subjects completed an Eligibility and Health Questionnaire, and read and signed an Informed Consent Agreement, a Confidentiality Agreement and a HIPAA Agreement.

Cotton patches dosed with 100 microliters of each test material were applied to test sites on the subjects' upper backs 12 times at 48- to 72-hour intervals. An undosed patch served as negative control. Test material and negative control sites were graded for irritation at each visit, and the size and number of microcomedones were assessed on the final visit.

Products

Exfoliating Facial Cleanser #34-105
Multiphase Serum #34-155
Day Moisturizer #34-109
Night Repair Crème #34-117
Body Lotion #34-125

Statistical Methods

Data from the global assessments of microcomedones for the test and control sites were compared statistically for significant differences ($p \leq 0.05$) using ANOVA with pairwise comparisons (Fisher's LSD). Test materials that have mean values of 1 or greater and are statistically greater than the mean value for the negative control are considered positive for comedogenicity.

Results

The comedogenicity test showed that the mean scores for the five products were less than 1 and were not significantly different from the mean comedogenicity score for the negative control. Therefore, the products are judged to be non-comedogenic.

EYE SAFETY TEST

Study Participants

Part 1 – Night Repair Crème and Multiphase Serum: Thirty female subjects were enrolled to participate in this study. Twenty-eight subjects completed the study. Discussion of the two subjects who discontinued the study is below (see Results). Subject demographic information is presented in Table 3.

Table 3: Subject Demographics – Part 1

		All Subjects (n=28)
Age (Years)	Mean Age ± Standard Deviation	35.73 ± 7.07
	Minimum Age	23
	Maximum Age	45
Ethnicity	African American	4 (14.29%)
	Caucasian	17 (60.71%)
	Hispanic	6 (21.43%)
	- Mexican	5 (17.86%)
	- Spanish	1 (3.57%)
	Asian - Filipino	1 (3.57%)
Contact Lens Wearers		3 (10.71%)

Part 2 – Day Moisturizer: Thirteen female subjects were enrolled to participate in this study. Twelve subjects completed the study. One subject discontinued study participation for reasons not related to the test materials. Subject demographic information is presented in Table 4.

Table 4: Subject Demographics – Part 2

		All Subjects (n=12)
Age (Years)	Mean Age ± Standard Deviation	45.71 ± 9.73
	Minimum Age	20.36
	Maximum Age	55.44
Ethnicity	Asian-Chinese	1 (8.3%)
	Asian-Vietnamese	2 (16.7%)
	Caucasian	8 (66.7%)
	Hispanic-Mexican	1 (8.3%)
Contact Lens Wearers		3 (10.71%)

Study Design

Prior to study enrollment, subjects completed an Eligibility and Health Questionnaire, and read and signed an Informed Consent Agreement, a Confidentiality Agreement, a HIPAA Agreement and a Photography Release Form.

Subjects applied the test material to the face and eye area, once daily for four weeks. Clinical evaluations (visual acuity test and ophthalmological examination) of the right and left eyes were performed at baseline, after the first exaggerated application (approximately 0.5 grams per eye) and at the end of 4 weeks.

Products

Night Repair Crème #34-117
Multiphase Serum #34-155
Day Moisturizer #34-109

Results

Eye safety testing of the Day Moisturizer, Night Repair Crème and Multiphase Serum by the use of visual acuity tests and ophthalmological examinations showed that the Sponsor's Day Moisturizer was mild and very well tolerated by the panel of subjects. The Night Repair Crème produced a mild, transient peri-ocular skin response in one subject immediately after application, but the individual was able to complete the full four weeks of product use with no further issues. The Multiphase Serum produced a moderate transient peri-ocular skin response in one subject immediately after exaggerated application. This subject subsequently completed a rechallenge back patch test and a two-week provocative use test on the face. Both tests showed no scores that indicated irritant or allergic contact dermatitis to the Multiphase Serum. The subject's initial short-term peri-orbital skin reaction was judged to be idiopathic in nature. All other test subjects tolerated the products (Night Repair Crème and Multiphase Serum) well and completed four weeks of testing with no negative objective or subjective skin responses.

CONCLUSIONS

Each product in the Mannatech LIFT skin care line was determined to be non-comedogenic and did not cause allergic contact dermatitis. Eye safety testing results indicate that the Day Moisturizer, Night Repair Crème and Multiphase Serum are safe to use around the eye area.

Study funded by Mannatech, Incorporated, 600 South Royal Lane, Suite 200, Coppell, Texas 75019