

MANNATECH SKIN CARE PRODUCT SAFETY AND EFFICACY TESTING

The Food, Drug & Cosmetics Act does not require that cosmetics be tested for safety. The FDA does advise cosmetic manufacturers to employ whatever testing is appropriate and effective for substantiating the safety of their products. It remains the responsibility of the manufacturer to substantiate the safety of both ingredients and finished cosmetic products prior to marketing. Mannatech elected to submit all cosmetic products for human testing to a company with recognized expertise in this area: Thomas J. Stephens & Associates, Inc., Carrollton, TX. Mannatech paid for this testing. A summary of the results is provided below.

Product	Test	Subjects	Methods	Results	Conclusions
Emprizone® gel	Modified Human Repeat Insult Patch Test (HRIPT)	50 adults: 86% women; 74% Caucasian, 18% Hispanic, 4% other ethnicities. Age: mean 48 years, range 20–70 years.	Occlusively patched with Emprizone gel or controls (negative or positive) nine times at 48- to 72-h intervals. 12–24 days later, challenge patches were applied to original and naïve sites.	Negative control and product caused no irritation; positive control was a cumulative irritant. Product did not induce allergic contact dermatitis in any subject.	Emprizone gel is non-irritating and does not induce dermatitis.
	Comedogenicity	13 acne-prone women: 54% Caucasian, 38% African American, 8% Hispanic. Age: mean 35 years, range 24–43 years.	Occlusively patched with Emprizone gel or negative control 12 times at 48- to 72-hour intervals. 12–24 days later, challenge patches were applied to original and naïve sites.	No difference in size or number of microcomedones between product and negative control.	Emprizone gel is non-comedogenic.

	Safety and efficacy	10 women with mild to moderate photodamaged skin: 60% Caucasian, 30% Hispanic, 1% mixed ethnicities. Age: mean 44 years, range 33–53 years.	8-week controlled trial: applied Emprizone gel to face, after cleansing, at least once a day; applied to lower legs at least once a day and immediately after shaving.	Product was well-tolerated and effective in improving facial skin condition; well-tolerated on the legs. Clinical assessments of facial photoaging, corneometer measurements of skin hydration and self-assessment questionnaires indicated improvements.	Emprizone gel is safe and effective.
FIRM with Ambrotose® Body Crème	HRIPT	50 adults: 86% women; 74% Caucasian, 18% Hispanic, 4% other ethnicities. Age: mean 48 years, range 20–70 years.	Occlusively patched with FIRM crème or controls (negative or positive) nine times at 48- to 72-h intervals. 12–24 days later, challenge patches were applied to original and naïve sites.	Negative control and product caused no experimental irritation; positive control was an experimental cumulative irritant. Product did not induce allergic contact dermatitis in any subject.	FIRM crème is non-irritating and does not induce dermatitis.
	Comedogenicity	13 acne-prone women: 54% Caucasian, 38% African American, 8% Hispanic. Age: mean 35 years, range 24–43 years.	Occlusively patched with FIRM crème or negative control 12 times at 48- to 72-h intervals. 12–24 days later, challenge patches were applied to original and naïve sites.	No difference in size or number of microcomedones between product and negative control.	FIRM crème is non-comedogenic.

<p>Mannatech LIFT™ Skin Care System Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer, Night Repair Crème, Body Lotion (each product tested separately)</p>	<p>Modified Human Repeat Insult Patch Test (HRIPT)</p>	<p>109 adults: 79% female; 55% Caucasian, 21% Hispanic, 16% African American, 4% Asian, 4% Other ethnicity. Age: mean 47 years; range 20–65 years.</p>	<p>Occlusive patches with products or controls (negative or positive) nine times at 48- to 72-hour intervals. 12–24 days later, challenge patches were applied to original and naïve sites.</p>	<p>Negative control and products caused no experimental irritation; positive control was an experimental cumulative irritant. Products did not induce allergic contact dermatitis in any subject.</p>	<p>The Mannatech LIFT Skin Care System Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer, Night Repair Crème and Body Lotion are non-irritating and do not induce dermatitis.</p>
<p>Mannatech LIFT Skin Care System Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer, Night Repair Crème, Body Lotion (each</p>	<p>Comedogenicity</p>	<p>9 adults: 89% female; 67% Caucasian, 33% Hispanic. Age: mean 33 years; range 22–39 years.</p>	<p>Occlusive patches with products or negative control 12 times at 48- to 72-hour intervals.</p>	<p>No difference in size or number of microcomedones between products and negative control.</p>	<p>The Mannatech LIFT Skin Care System Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer, Night Repair Crème and Body Lotion are non-comedogenic.</p>

product tested separately)					
Mannatech LIFT Skin Care System Multiphase Serum, Night Repair Crème (each product tested separately)	Eye Safety	28 female adults; 61% Caucasian, 21% Hispanic, 14% African American, 4% Asian. Age: mean 36 years; range 23–45 years.	Subjects applied products to face and eye area, once daily for four weeks.	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 with no further issues. The Multiphase Serum produced a moderate transient peri-ocular skin response in one subject immediately after application. A rechallenge back test and two-week provocative use test revealed no additional irritation, suggesting that the subject's initial reaction was idiopathic in nature. Visual acuity	The Mannatech LIFT Skin Care System Multiphase Serum and Night Repair Crème are determined to be safe to use around the eye area.

				and ophthalmological testing showed that all other test subjects tolerated the products well.	
Mannatech LIFT Skin Care System Day Moisturizer	Eye Safety	12 female adults; 67% Caucasian, 25% Asian, 8% Hispanic. Age: mean 46 years; range 20–55 years.	Subjects applied products to face and eye area, once daily for four weeks.	Visual acuity and ophthalmological testing showed that the Day Moisturizer was mild and very well tolerated by all subjects.	The Mannatech LIFT Skin Care System Day Moisturizer is determined to be safe to use around the eye area.
Mannatech LIFT Skin Care System Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer, Night Repair Crème, Body Lotion	Safety and Efficacy	44 female adults with self-perceived dry skin and mild to moderate fine lines and coarse wrinkles around the eye; 50% Caucasian, 25% Hispanic, 11.5% African American, 11.5% Asian, 2% Caucasian/Hispanic. Age: mean 49 years; range 36-63 years.	Used products for 12 weeks. Morning: Exfoliating Facial Cleanser, Multiphase Serum, Day Moisturizer. Evening: Exfoliating Facial Cleanser, Night Repair Crème. Anytime: Body Lotion	Products were well-tolerated and significantly improved all efficacy parameters at 8 and 12 weeks. Self-assessment questionnaires were overwhelmingly positive for all products.	The Mannatech LIFT Skin Care System products are safe and effective.