

MANNATECH SKIN CARE PRODUCT SAFETY AND EFFICACY TESTING



The Food, Drug & Cosmetics Act does not require that cosmetics be tested for safety. The U.S. Food and Drug Administration (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.

The FDA has required adverse event reporting (AERs) for dietary supplements since 2007. In 1997, Mannatech initiated a Product Safety Monitoring program, overseen by a qualified physician. According to Mannatech's systematic and comprehensive monitoring system, reported health complaints are regularly reviewed for indications of possible adverse reactions from the use of our products. Mannatech also elected to use this system to track skin care product experiences. The cumulative data from this program indicate that there have been no conclusive health complaints with the Mannatech skin care line other than what might be expected in general from the use of other skin care products when known allergies or sensitivities to specific ingredients are present. Data from this program has also not revealed any serious adverse events related to the use of these products: Emprizone[®] gel and FIRM with Ambrotose[®] moisturizing cream (launched in 1995), Uth™ Cleanser and Moisturizer (launched in 2010) and Uth Rejuvenation Crème (launched in 2013).

Mannatech also elected to submit our cosmetic products for rigorous human safety and efficacy testing to a company with recognized expertise in this area: Thomas J. Stephens & Associates, Inc., Carrollton, TX. Sixteen clinical studies, conducted by Board Certified Dermatologists and Ophthalmologists on over 400 subjects, have validated the safety and efficacy of these products.* A summary of study details are provided below.

Product	Test	Subjects	Methods	Results	Conclusions
U th Rejuvenation Crème	Modified Human Repeat Insult Patch Test (HRIPT)	53 adults: 98.1% women; 100% Asian. Age: mean 40.4 years, range 23-59 years.	Occlusively patched with U th Rejuvenation Crème or negative control 12 times at 48- to 72-h intervals.	Negative control and product was non-irritating. Product did not induce contact sensitization (allergic contact dermatitis) in any subject who completed the study.	U th Rejuvenation Crème is hypoallergenic.

	Comedogenicity	15 adults: 73.3% women; 46.7% Caucasian, 40% Black or African American; 13.4% other ethnicities. Age: mean 31.5 years, range 21-39 years.	Occlusively patched with U th Rejuvenation Crème or negative control 12 times at 48- to 72-h intervals.	No significant differences in size or number of microcomedones between U th crème and negative control.	U th Rejuvenation Crème is non-comedogenic.
	Eye Safety	31 adults with mild to moderate photodamaged skin: 83.9% women; 80.6% Caucasian, 12.9% Asian, 6.5% Hispanic/Latino. Age: mean 54.7 years, range 41-74 years.	Subjects applied U th Rejuvenation Crème to face and eye area twice a day for 4 weeks.	Visual acuity testing and ophthalmological examination showed that U th crème was mild and well-tolerated by all subjects.	U th Rejuvenation Crème is safe to use around the eye area.
	Safety and efficacy		Subjects applied U th Rejuvenation Crème to face and eye area twice a day for 8 weeks.	Products were well-tolerated and significantly improved numerous efficacy parameters at 4 and 8 weeks. Self-assessment questionnaires were positive.	U th Rejuvenation Crème is safe and effective. It significantly improved numerous parameters, including skin firmness and lift, skin tone, and fine lines and wrinkles.
U th Facial Cleanser or Moisturizer (products tested separately)*	HRIPT	109 adults: 79% female; 55% Caucasian, 21% Hispanic, 16% African American, 4% Asian, 4% other ethnicities. Age: mean 47 years, range 20-65 years.	Occlusively patched with products or controls (negative or positive) 9 times at 48- to 72-hour intervals. 12-24 days later, challenge patches were applied to original and naïve sites.	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.	U th Facial Cleanser and U th Moisturizer are hypoallergenic.

	Comedogenicity	9 adults: 89% female; 67% Caucasian, 33% Hispanic. Age: mean 33 years, range 22-39 years.	Occlusively patched with products or negative control 12 times at 48- to 72-h intervals.	No significant differences in size or number of microcomedones between products and negative control.	U th Facial Cleanser and U th Moisturizer are non-comedogenic.
	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 4 weeks.	Products were safe to use around the eyes.	U th Facial Cleanser and U th Moisturizer are safe to use around the eye area.
	Safety and Efficacy	44 female adults with self-perceived dry skin and mild to moderate fine lines and coarse wrinkles around the eyes; 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.	Products were well-tolerated and significantly improved all efficacy parameters at 8 and 12 weeks. Self-assessment questionnaire were overwhelmingly positive for the products, reporting that their skin felt healthy, clean, firm, radiant and had an even texture and tone and a reduced appearance of fine lines and wrinkles.*	U th Facial Cleanser and U th Moisturizer

Emprizone® gel	Modified 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) 9 times at 48- to 72-h intervals. 12-24 days later, challenge patches were applied to original and naïve sites.	Negative control and Emprizone gel caused no irritation; positive control was a cumulative irritant. Emprizone gel did not induce allergic contact dermatitis in any subject.	Emprizone gel is hypoallergenic.
	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 Emprizone gel 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.	Emprizone 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. Significant improvements were documented in numerous parameters, including reducing irritation, reducing redness due to irritation, relieving dry itchy skin, and soothing nicks and cuts after shaving.

FIRM with Ambrotose® Body Crème	Modified 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) 9 times at 48- to 72-h intervals. 12-24 days later, challenge patches were applied to original and naïve sites.	Negative control and FIRM crème caused no experimental irritation; positive control was an experimental cumulative irritant. FIRM crème did not induce allergic contact dermatitis in any subject.	FIRM crème is hypoallergenic.
	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 FIRM crème and negative control.	FIRM crème is non-comedogenic.

*Individual results may vary.