

Samantha Poweski
 Eurofins CRL Cosmetics, LLC
 371 Hoes Lane, Suite 100
 New Jersey
 USA

11/07/2024

Subject: Study Requirement Statement

Rolf Schuetz,

Please see Inclusion/Exclusion criteria below for CRLNJ2020-0493. All subjects that were enrolled, completed, and/or discontinued from this study met all study requirements.

Inclusion Criteria		Yes	No	N/A
a)	Subject is male or female between 18 and 75 years of age.	<input type="checkbox"/>	<input type="checkbox"/>	
b)	Subject does not exhibit any skin diseases or abnormalities which might be confused with a skin reaction from the test material.	<input type="checkbox"/>	<input type="checkbox"/>	
c)	Subject agrees to avoid excessive sun exposure of the test sites and to refrain from visits to tanning salons during the course of this study.	<input type="checkbox"/>	<input type="checkbox"/>	
d)	Subject agrees to refrain from getting patches wet, scrubbing or washing the test area with soap, and applying powders, lotions or personal care products to the area during the course of the study.	<input type="checkbox"/>	<input type="checkbox"/>	
e)	Subject agrees not to introduce any new cosmetic or toiletry products during the study.	<input type="checkbox"/>	<input type="checkbox"/>	
f)	Subject is dependable and able to follow directions as outlined in the protocol.	<input type="checkbox"/>	<input type="checkbox"/>	
g)	Subject is willing to participate in all study evaluations.	<input type="checkbox"/>	<input type="checkbox"/>	
h)	Subject is in generally good health and has a current Panelist Profile Form and Medical History Form on file at CRL.	<input type="checkbox"/>	<input type="checkbox"/>	
i)	Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164.	<input type="checkbox"/>	<input type="checkbox"/>	
j)	Subject understands and is willing to sign an Informed Consent Form in conformance with 21 CFR Part 50: "Protection of Human Subjects."	<input type="checkbox"/>	<input type="checkbox"/>	
Exclusion Criteria		Yes	No	N/A
a)	Female subject is pregnant, nursing, planning a pregnancy, or not using adequate birth control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b)	Subject has known allergy to any of the following ingredients: Ingredients INCI names: a. BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENOL TRIAZINE; b. ALCOHOL; c. C12-15 ALKYL BENZOATE; d. CAPRYLIC/CAPRIC TRIGLYCERIDE; e. DICAPRYLYL CARBONATE; f. ISOPROPYL MYRISTATE g. PETROLATUM; h. PHENETHYL BENZOATE	<input type="checkbox"/>	<input type="checkbox"/>	
c)	Subject has received treatment with sympathomimetics, antihistamines, vasoconstrictors, non-steroidal anti-inflammatory agents, and/or systemic or topical corticosteroids within one week prior to initiation of the study.	<input type="checkbox"/>	<input type="checkbox"/>	
d)	Subject has a history of acute or chronic dermatologic (including active eczema or psoriasis on the test sites), medical, and/or physical conditions which would preclude application of the test material and/or could influence the outcome of the study.	<input type="checkbox"/>	<input type="checkbox"/>	
e)	Subject is under treatment for a skin and/or systemic bacterial infection.	<input type="checkbox"/>	<input type="checkbox"/>	

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f)	Subject has scheduled, or is planning to undergo, any medical or surgical procedures during the 7 week course of the study.	<input type="checkbox"/>	<input type="checkbox"/>
g)	Subject exhibits birthmarks, moles, vitiligo, keloids, or any dermal markings on the back that might interfere with grading.	<input type="checkbox"/>	<input type="checkbox"/>
h)	Subject has a known communicable disease (e.g., HIV, sexually transmitted diseases, Hepatitis B, Hepatitis C, etc.)	<input type="checkbox"/>	<input type="checkbox"/>
i)	Subject is an insulin-dependent diabetic.	<input type="checkbox"/>	<input type="checkbox"/>
j)	Subject has a history of skin cancer or is currently undergoing treatment for active cancer of any type.	<input type="checkbox"/>	<input type="checkbox"/>
k)	Subject reports a history of allergies to tape adhesives.	<input type="checkbox"/>	<input type="checkbox"/>
l)	Subject is currently taking certain medications which, in the opinion of the Principal Investigator, may interfere with the study.	<input type="checkbox"/>	<input type="checkbox"/>
m)	Subject has known allergies to skin treatment products or cosmetics, toiletries, and/or topical drugs.	<input type="checkbox"/>	<input type="checkbox"/>

Sincerely,

Samantha Poweski
Principal Investigator

Samantha
Poweski

 Digitally signed by Samantha Poweski
Date: 2024.11.08 15:44:34 -05'00'

Signature/Date

Winston Moy, MD
Sub-Investigator/Board Certified Dermatologist

Winston Moy MD

 Digitally signed by Winston Moy MD
Date: 2024.11.08 21:39:55 -05'00'

Signature/Date