eurofins | CRL

Panel #: 146-20

CRLNJ Study #: CRLNJ 2020-0495

Protocol #: DSM PA 2020

Subject #: 01 to 50

The below criteria were reviewed during the enrollment visit and confirmed that all 50 subjects enrolled in the study have met all the inclusion criteria and none of the exclusion criteria:

	Inclusion Criteria
1	Subject is male or female between 18 and 75 years of age;
2	Subject has a Fitzpatrick Skin Types I – III, based on the first 30 to 45 minutes of sun exposure after a winter season of no sun exposure;
3	Subject agrees to avoid excessive sun exposure of the test sites and to refrain from visits to tanning salons during this study;
4	Subject does not exhibit any skin diseases or abnormalities which might be confused with a skin reaction from the test material;
5	Subject agrees not to introduce any new cosmetic or toiletry products during the study;
6	Subject agrees to refrain from getting patches wet and from scrubbing or washing the test area with soap or applying powders, lotions or personal care products to the area during the course of the study;
7	Subject is dependable and able to follow directions as outlined in the protocol and anticipates being available for all study visits;
8	Subject is willing to participate in all study evaluations;
9	Subject is in generally good health and has a current Panelist Profile Form on file at CRL;
10	Subject has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;
11	Subject understands and is willing to sign an Informed Consent Form in conformance with 21 CFR Part 50: "Protection of Human Subjects."
	Exclusion Criteria
1	Female subject is pregnant, nursing, planning a pregnancy, or not using adequate birth control; Male NA ☐
2	Subjects with a prior history of phototoxic or photoallergic reactions or those taking medication which might produce an abnormal response to sunlight;
3	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;
4	Subject has a history of acute or chronic dermatologic, medical, and/or physical conditions which would preclude application of the test material and/or could influence the outcome of the study;
5	Subject is under treatment for a skin and/or systemic bacterial infection;
6	Subject reports a history of allergies to tape adhesives;
7	Subject is currently taking certain medications which, in the opinion of the Principal Investigator, may interfere with the study;
8	Subject has known allergies to sunscreen, skin treatment products or cosmetics, toiletries, and/or topical drugs;
9	Subject has a known communicable disease (e.g., HIV, sexually transmitted diseases, Hepatitis B, Hepatitis C, etc.);
10	Subject has insulin-dependent diabetes;
11	Subject has a history of cancer;
12	Subject exhibits sunburn, suntan, uneven skin tone, blemishes, moles or excess hair in the test site area.

Gladys Osis
Principal Investigator