



FLORAMAC® 10 BOOSTS SPF OF INORGANIC SUNSCREENS

CS 19-125



Floramac 10 in an Inorganic Sunscreen Formula Boosted SPF



Objective:

To evaluate Floramac 10 for its potential to boost SPF when used in a mineral sunscreen that contained 15.0% zinc oxide and 4.8% titanium dioxide.

Method:

Sunscreens with 5% and 12% Floramac 10 were evaluated for SPF according to US FDA Final Rule; 21 CFR Parts 201 and 310.

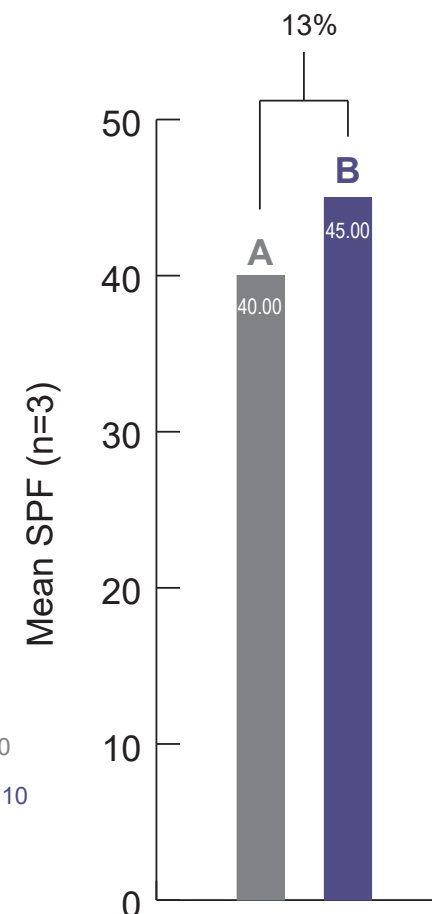
Results:

The sunscreen containing 12% *Floramac 10* boosted SPF by 13% more than the *sunscreen* with 5% Floramac 10.

A = vehicle sunscreen + 5% Floramac 10 / B = vehicle sunscreen + 12% Floramac 10

Vehicle Sunscreen (%wt/wt): Cyclopentasiloxane (25.9%), Zinc Oxide (and) Cyclopentasiloxane (and) PEG-10 Dimethicone (25.0%), Titanium Dioxide (and) Cyclopentasiloxane (and) Hexyl Laurate (and) PEG-10 Dimethicone (and) Polyglyceryl-4 Isostearate (and) Stearic Acid (and) Alumina (15.0%), Water (10.0%), Cetyl PEG/PPG-10/1 Dimethicone (2.5%), Cyclopentasiloxane (and) Disteardimonium Hectorite (and) Propylene Carbonate (2.5%), Polymethylsilsequioxane (2.5%), Butylene Glycol (2.0%), Glycerin (2.0%), Phenoxyethanol (0.4%), and Tocopheryl Acetate (0.2%). (Floramac 10 replaced with Caprylic/Capric Triglyceride.)

Static SPF



A - vehicle + 5% Floramac 10
B - vehicle + 12% Floramac 10

Floratech Ingredient: Floramac 10

The clinical study of Floratech® test formulations (CTL_15-059) was conducted by Eurofins CRL on 4 separate panels, with a total of 12 male and female subjects aged 25-62 for static SPF testing (n=3 per test article). Testing was conducted according to the US FDA Final Rule; 21 CFR Parts 201 and 310. The Minimum Erythema Dose (MED) is the lowest UV dose required to produce perceptible erythema. The MED for each of the three subjects was measured and used to determine the proper UV exposure during testing of the sunscreen formulas. The static SPF value was calculated using the MED of sunscreen protected skin (MEDp) relative to the MED of unprotected skin (MEDu) on each subject using the following equation: MEDp/MEDu. The erythema evaluations were conducted by a trained evaluator under controlled temperature and humidity conditions. This study was double-blind and randomized. The xenon arc solar simulator was Model 16S (Solar Light Co., Philadelphia, PA). (Final reports available upon request.)