

Developmental Technical Data Sheet



SurfaTech Corporation

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(New: 07/23/2012)

High Definition Polymers®

Product Name: CosmoSurf® PG 1-IS

SurfaTech Corporation has developed a series of products that are derived from polyglycerol and can be used to provide outstanding skin aesthetics, barrier properties and film formation. These polymer are amphilic (meaning they posses both polar and non-polar groups bonded to the same polymer backbone). They are water insoluble but are soluble in alcohol, esters and oil. These polyesters provide outstanding emoliency and film formation on the skin. The unique solubility of these polymers allow for them to be utilized in may formulation platforms.

These polymers contain multi-domains. Multi-domain polymers are polymers that contain groups of differing solubility and/or physical properties. The physical properties of these polymers can control film formation and aesthetics. There are two categories of the CosmoSurf® PGs: Solid and liquid versions. CosmoSurf® PG 1-IS is a low melting wax that forms a waterproof film after application to the skin. The unique properties of this polymer is attributed to the polymer containing both solid and liquid domains. The solid domains allow for the film to be waxy and water resistant, while the liquid domains provide flexibility and provide easy application.

Proposed INCI: Polyglyceryl Stearate/Isostearate dilinoleate crosspolymer

Natural derived

CosmoSurf® PG 1-IS is derived from four raw materials, including polyglycerol, stearic acid, isostearic acid and dimer acid. It can be ECOCERT certified.

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Typical Properties: CosmoSurf® PG 1-IS

Property	Result
Appearance	Soft Semi-Solid
Foreign Matter	Free of
Color	4 (gardner)

Applications

The CosmoSurf PG 1-IS is recommended for use in hair care, skin care, sun care for water resistance and for mitigation of the dry feel encountered in alcohol based formulations. It functions to improve sun protection factor (SPF) and provide waterproofing in emulsion systems, both water in oil as well as continuous spray systems.

Water Resistance Studies

CosmoSurf® PG 1-IS

Objective

Evaluation of CosmoSurf® PG 1-IS as a waterproofing film former for sunscreen products.

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Method

Formulas were prepared as shown:

Ingredient	Formula A %	Formula B %	Formula C %
Part A			
Water	74.2	72.2	82.9
Carbomer	0.25	0.25	0.25
Disodium Ethylenediaminetetraacetic Acid	0.05	0.05	0.05
Triethanolamine	1.0	1.0	1.0
Part B			
Octocrylene	3.0	3.0	3.0
Octisalate	3.0	3.0	3.0
Oxybenzone	2.0	2.0	2.0
Avobenzone	1.0	1.0	1.0
Stearic Acid	2.0	1.0	1.0
Sorbitan Isostearate	0.0	1.0	1.0
Polyglyceryl-3 Distearate	0.0	1.0	1.0
Glyceryl Stearate Self Emulsifying	3.0	0.0	0.0
Benzyl Alcohol	1.0	1.0	1.0
Dimethylpolysiloxane	0.5	0.5	0.5
Ganex V-220	0.0	0.0	2.0
Methylparaben	0.0	0.2	0.2
Propylparaben	0.0	0.1	0.1
Finnsolv TN	8.0	0.0	0.0
Cosmosurf PS1-IS	0.0	0.2	0.0
Part C			
Liquipar PE(Phenoxyethanol, Isopropylparaben, Isobutylparaben, and n- Butylparaben	1.0	0.0	0.0

The manufacturing procedure was the same for all products; Part A and B heated separately to about 160 F, B added to A while rapidly stirring, cooled with stirring to approximately 105 F and C added with stirring.

All three formulas were SPF tested using a single port Solar Light Model 15S Xenon Arc, Solar Simulator lamp, which has a continuous light spectrum in the UVA and UVB range (290-400

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nanometers). The spectral output of the solar simulator is filtered so that it meets the spectral output requirements for testing Sunscreen Drug Products for over-the-counter human use; Proposed Amendment of Final Monograph, CFR Part 352.70 (b) Light Sources, Federal Register, Vol. 72, No. 165, Aug. 27, 2007 and the International Sun Protection Factor (SPF) Test Method, May 2006.

The SPF test for all three formulas was performed on the same subjects. The only difference was that Formula A was performed as a static, non water resistant, test and Formula B and Formula C was performed as an 80 minutes VWR test.

Results

The average values for the SPF tests as reported by Florida Suncare Testing, Inc. was as follows:

Formula	SPF
A	19 (static)
B	28.0 (VWR)
C	29.0 (VWR)

All three formulas were submitted to an independent analytical lab, Allied Analytical Laboratory Services located in Millington, RN.

Formula	Octocrylene	Octisalate	Oxybenzone	Avobenzone
A	3.03	3.12	2.02	1.04
B	2.94	3.04	1.95	0.95
C	3.04	2.96	1.99	1.00

Developmental Technical Data Sheet



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Photo-stability Tests

An important factor when determining the effectiveness of a sunscreen is photo-stability and critical wavelength. To test this, the absorbance spectra was measured before irradiation and after each of 4 irradiation doses. While the estimated SPF (*in vitro*) is not a fair representation of the *in vivo* SPF, it can be a useful tool in testing photo-stability and UVA protection factor.

Method

Formulas were prepared as shown

Material	Formulation				
	1	2	3	4	5
Part A					
Avobenzene	3	3	3	3	3
Homosalate	8.8	8.8	8.8	8.8	8.8
Octinoxate	5	5	5	5	5
Octisalate	5	5	5	5	5
Octocrylene	2.5	2.5	2.5	2.5	2.5
Oxybenzone	5	5	5	5	5
Part B					
Dermacryl	3	3	3	3	3
Cyclomethicone	5	-	-	-	-
CosmoSurf CE-100 Si	-	5	-	-	-
CosmoSurf PG 1-IS	-	-	5	-	-
CosmoSurf PG 4-OS	-	-	-	5	-
CosmoSurf PGSI 2-OS	-	-	-	-	5
Part C					
EtOH	62.7	62.7	62.7	62.7	62.7

Procedure:

Combine part A into a large beaker, heat the mixture to 70 °C and mix until a homogeneous solution occurs. Allow the solution to cool to room temperature. Slowly add part B to the mixture. Finally, add part C to the solution and mix.

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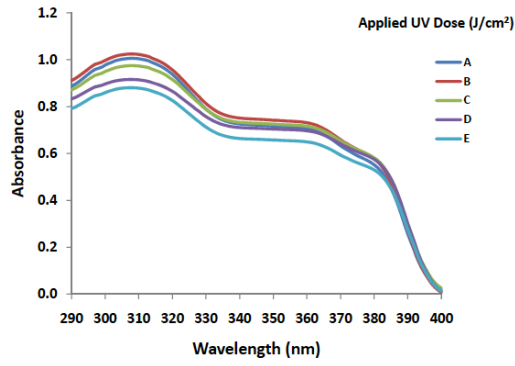
Instrumentation:

Test products were applied to HD-6 substrates (Helioscreen, Creil) at 1.3 mg/cm² by “spotting” the product on each plate and rubbing with a finger tip saturated with the test product for approximately one minute, then allowed to equilibrate in the dark for at least 30 minutes at 35 °C ± 2 °C. A solar simulator (Solar Light Company, Philadelphia) that complied with Colipa specifications was used to irradiate the plates with a series of 4 UV doses (11, 21, 32 and 43 J/cm²), and a calibrated UV-2000 Sunscreen Analyzer (Labsphere, North Sutton, NH) was used to measure the absorbance spectrum of each plate, before UV irradiation and after each UV dose.

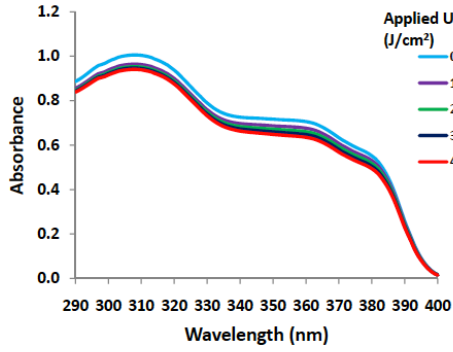
All three formulas were submitted to an independent analytical lab, Suncare Research Laboratories, LLC, located in Winston Salem NC.

Results

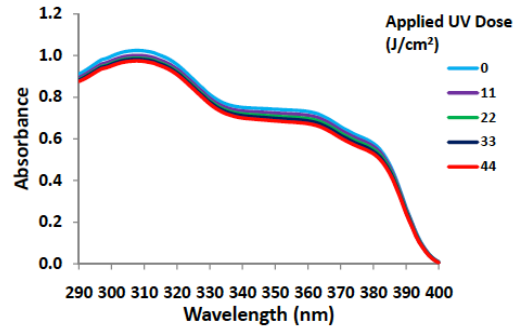
All results were reported by Suncare Research Laboratories LLC.



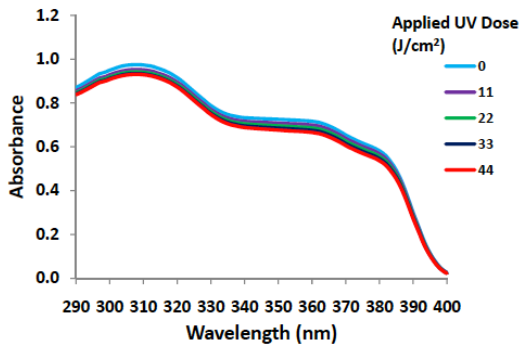
(a)



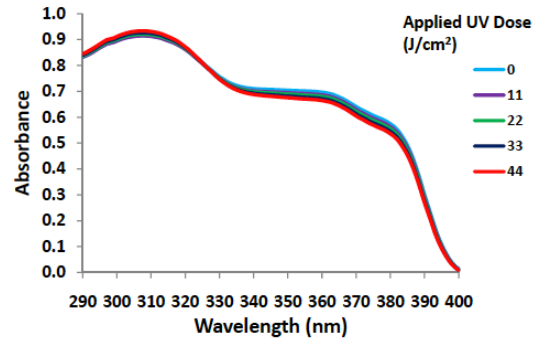
(b)



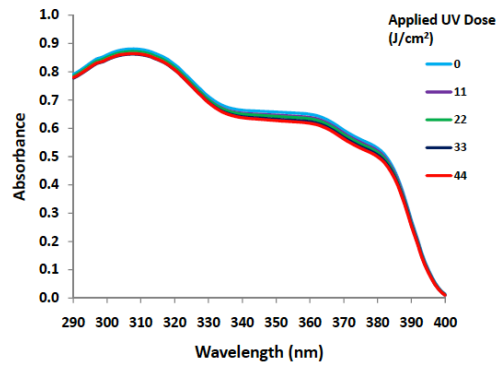
(c)



(d)



(e)



(f)

Figure 2: Absorbance Spectra of formulations (a) 1 – 5, and photo-stability test for formulations (b) 1, (c) 2, (d) 3, (e) 4, (f) 5.

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Analytical results are shown in the table below

Formula	Estimated SPF	SPF / SPF ₀	UVAPF	UVAPF / SPF	Critical Wavelength (nm)
1	8.4	0.92	4.3	0.51	376.5
2	9.0	0.95	4.6	0.51	376.8
3	8.0	0.95	4.6	0.55	377.8
4	7.6	1.00	4.6	0.60	378.0
5	6.9	0.98	4.1	0.59	377.8

Discussion

All three formulas were targeted as an SPF 25. For an SPF 25 the lowest number obtainable is a SPF19. Four of the subjects had MED responses at the SPF 19 level. For a 5 subject study, the values obtained for Formula B and Formula C, with standard deviations of 2.53 and 4.12 respectively are not statistically different.

Conclusion

Based on the results of these SPF tests has significant value as a SPF waterproofing agent when compared to a control formula without a waterproofing film former. Based on the results of this study, SurfaTech CosmoSurf® PS 1-IS was equivalent to the well-known waterproofing film former, VP/Eicosene Copolymer.

The absorbance spectra before irradiation on the samples are similar with number 2 being the highest and 5 being the lowest. This is consistent with the results in the table with in vitro SPF values. It is worth noting that all samples show good photo-stability and the critical wavelength of each sample was shifted to a higher wavenumber.

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