

Novel Graft Polymer Boosts SPF Performance

Polyacrylate 15 (and) polyacrylate 17 boosts the efficacy of traditional organic UV absorbers in an SPF 15 sunscreen by nearly 300%.

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SUNSCREEN FORMULATORS face several challenges when creating marketable consumer products. Consumers require formulas that are easy to dispense and apply; are non-irritating; provide maximum broad spectrum protection; are aesthetically pleasing and are affordable. Yet, in order to accomplish many of these objectives, a formulator is required to choose from a limited number of FDA-approved active ingredients. Many of these UV absorbers appear to also create the potential for skin irritation, formula phase separation, additional batch processing requirements, unsightly film deposits and higher costs.

Recently, Interpolymer introduced a grafted polymer, polyacrylate 15 (and) polyacrylate 17, which boosts the efficacy of traditional organic UV absorbers in an SPF 15 sunscreen lotion by nearly 300%. This recent finding suggests that it may be possible to increase SPF claims beyond 15 without the addition of problematic inorganic UV absorbers. Alternatively, these findings also suggest that it may be possible to formulate an SPF 15 product without the use of 10-

15% organic active ingredients, thus reducing the potential for skin irritation and unnecessary costs.

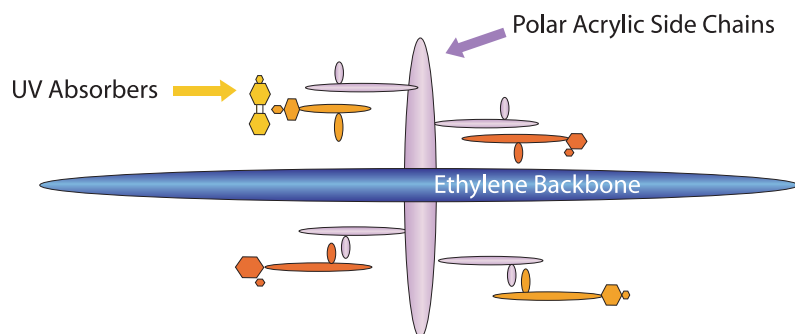
This article details the chemical composition of the grafted polymer, the mechanism of action for synergistic potentiation and the results of screening tests performed using in vitro and in vivo methodologies.

Solvatochromism: Mechanism of Action

A possible mechanism of action can be found in the ordering of organic structures during the film formation process. In heterogeneous formulations as found in sun care products, the primary hierarchical organization of the film that occurs during the application and drying process is determined to a large degree by the covalent linkages of the film components. These components are the building blocks consisting of polymers and other higher molecular weight molecules blended together by the formulator or chemist. Higher order structures of these building blocks and lower molecular weight components are then assembled during the drying process through the intra- and inter- molecular associations. Formation of higher order structures are aided by non-covalent forces such as hydrogen bonding, hydrophobic stacking, solvation effects and electrostatic interactions. It is these higher order associations that could explain the mechanism of action for the SPF boosting observed from the inclusion of Polyacrylate 15 (and) polyacrylate 17 into films containing standard UV absorbers.

Polyacrylate 15 (and) polyacrylate 17 consists of an olefin graft polymer with semi-crystalline and amorphous segments. By itself, the polymer possesses minimal SPF contribution. However, due to its unique structure the graft polymer has an affinity for UV absorbers, such as ethyl hexyl methoxycinnamate, benzophenone and ethyl hexyl salicylate. This affinity, or solvation, leads to more ordered structures and therefore better exposes the UV segments to photoexcitation. In addition to its unique composition, the polymer contains a significant number of polar groups which assist in the formation of the dipoles necessary to change the spectral position of the UV absorbers.

Fig. 1: Control with 3% NV Synttran PC 5227



This shift is attributed to the change in the polarity of the system. During the application and drying process, the secondary energy forces permit the UV absorbers to aggregate in an ordered manner along the semi-crystalline segments of the polymer. While there is no induced ionization or complexation, the polar groups modify the energy structure of the now oriented UV absorbers. The resulting shift in UV spectra via the use of polarity and solvation is called solvatochromism. (Figure 1)

Additionally, because of its affinity for the UV absorbers, the polymer prevents some of the UV absorber from being completely buried in the hydrophobic components of the sun care product like typical oleophilic materials and thereby being rendered less effective. This essentially increases the amount of UV absorber available for photoexcitation. Lastly, a unique feature observed is that the solvent and chromatic effect is generated by a polymeric material which provides secondary

benefits such as uniform film formation and improved wear resistance.¹

In Vitro Test Screening

Using a Labsphere UV-1000S Ultraviolet Transmittance Analyzer, an FDA-registered independent laboratory conducted in vitro tests on the material. For each tested sunscreen formula, 2mg/cm² were distributed over five separate, non-overlapping 2-square inch pieces of 3M Transpore Tape which was laid on top of a standard 2cm quartz slide. The Transpore Tape was selected for its uneven topography that distributes the sunscreen in a way similar to human skin. The spectral transmittance of the sampled sunscreens in the ultraviolet spectral range was used to predict an in vitro SPF value based on standard erythema and solar data.² In addition, UVA/UVB ratios were calculated and reported.

An O/W control sunscreen formula was developed using three of the most common organic UV absorbers in an effort to obtain an SPF 15 lotion. The formula was as follows:

Fig. 2: Control with 3% NV Syntran PC 5227

Broad spectrum UVA/UVB protection was enhanced with the addition of the polymer.

SPF Reading: 43.18. UVA/UVB Ratio: 0.47

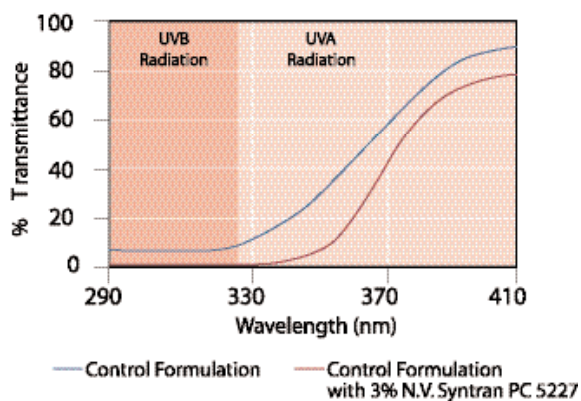
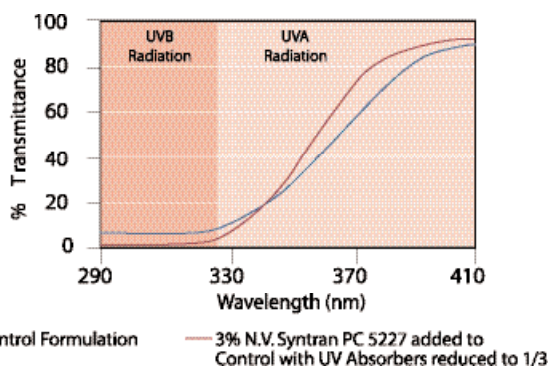


Fig. 3: Modified Control with 3% NV Syntran PC 5227

UV absorbers in control formulation were reduced by 66% from 13.5% to 4.5% in an effort to reduce costs
SPF Reading: 21.39. UVA/UVB Ratio: 0.28



Ingredient	% Wt.
Phase A	
Distilled Water	59.07
Dissolvine Na2S (Akzo Nobel) (Disodium EDTA)	0.05
Propylene Glycol	2.00
Phase B	
Finsolv TN (Finetex) (C12-15 Alkyl Benzoate)	3.00
Protachem SMO (Protameen) (Sorbitan Oleate)	0.20
Escalol 557 (ISP) (Ethylhexyl Methoxycinnamate)	7.50
Benzophenone-3	3.00
Escalol 587 (ISP) (Ethylhexyl Salicylate)	3.00
Crodafos CES (Croda)	4.00
(Cetearyl Alcohol (and) Ceteth-10 Phosphate (and) Dicapryl Phosphate)	
Cetearyl Alcohol 50/50 (RITA)	4.00
Crodafos CS20 Acid (Croda) (Cetearyl Alcohol (and) Ceteth-20 Phosphate (and) Dicapryl Phosphate)	1.33
Phase C	
Distilled Water	12.00
Phase D	
Liquid Germall Plus (ISP) (Diazolidinyl Urea, IPBC)	0.60
Fragrance	0.15
TEA 99%	0.10

Procedure: Combine A and heat to 75°C. Melt all ingredients in B and add to A at 75°C. Stir with high shear and cool. At 60°C. add C. Continue cooling. At 45°C, add D. Adjust pH to 6-7.

Fig. 4: Control with 1.5% N.V. Syntran PC 5227

Polymer was reduced by 50% from 3% to 1.5% in an effort to optimize formulation synergies.

SPF Reading: 40.3; UVA/UVB Ratio: 0.46

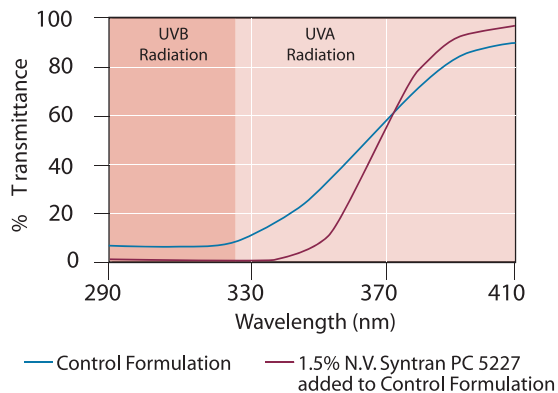
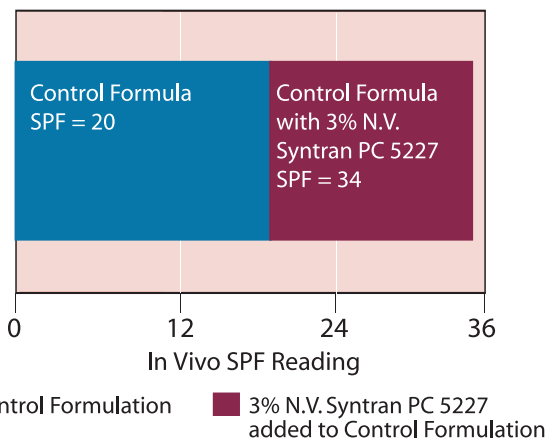


Fig. 5: In Vivo Screening Results

Initial screening to determine in vivo SPF performance for control formula vs. the control with 3% N.V. Syntran PC 5227 showed an increase of approximately 70%



The above control formula obtained an SPF score of 15.67 and a UVA/UVB ratio of 0.39, providing the base data for which all subsequent tests and formulas would be compared.

In order to measure the net effect of a polymeric effect to the SPF performance, three percent non volatile solids of a 30% active solution of polyacrylate 15 (and) polyacrylate 17 were incorporated into phase C of the control formulation. The total water in phase A of the formulation was reduced to 61%. The resultant scoring yielded an SPF of 43 and a UVA/UVB ratio of 0.47. (Figure 2)

Attention next turned to the hypothesis that if a potential threefold boost could occur with the addition of a polymer; what might happen if the amount of active ingredients were reduced to a 1/3? The control formula was modified to include only 2.5% of ethyl hexyl methoxy cinnamate, and 1% ben-

zophenone-3, and ethyl hexyl salicylate respectively, or a 66% reduction in the overall active ingredients' solids content. In an effort to maintain an equilibrium among the oil phase, nine percent additional Finesolv was added to the control formula. The in vitro scores revealed an SPF of 21.39 and a UVA/UVB of 0.28. (Figure 3)

Finally, in an effort to further delineate the optimal synergistic range of the polymeric booster, only 1.5% N.V. of polyacrylate 15 (and) polyacrylate 17 was added to the original SPF 15 control formula, and an additional five percent distilled water was added during phase A. The resultant in vitro SPF was 40.3, or 255% greater than the control formula. A UVA/UVB ratio of 0.46 was obtained. (Figure 4)

In Vivo Test Screening

The FDA Final Monograph³ describes the procedures for determining the static sun protection factor. The Static SPF is defined by the ratio of the minimal erythema dose (MED) of ultraviolet radiation for sunscreen-protected skin to that of unprotected skin. The MED is the dose of UV radiation that produces mild erythema, or sunburn, reaching the borders of the exposure site, 22 to 24 hours after administration. Timed UV radiation doses are administered using a xenon arc lamp that simulates solar radiation. The technician will monitor the output of solar simulator using a calibrated radiometer to ensure that the erythemally effective irradiance is constant. Readings of erythemally effective irradiance will be recorded and doses will be corrected for variations in effective irradiance as necessary. The study was conducted under non-randomized, blinded conditions.

Ten volunteers with varying skin types I through III were tested with the control formula and the control formula with 3% N.V. polyacrylate 15 (and) polyacrylate 17, which provided a 70% SPF boost. The mean results are tabulated in Figure 5.

Validation and Conclusion

Based on in vitro tests and validated with in vivo results, it would appear that polyacrylate 15 (and) polyacrylate 17 may provide a significant synergistic boost to the SPF of sun care products containing the common UV absorbers described in this article. In addition, in vitro results demonstrated that the control formula's UVA/UVB ratio was enhanced by 18-21% with the addition of the polymer, which appeared to increase the broad spectrum coverage into more of the UVA range. ●

Reference

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3. U.S. Food and Drug Administration. Sunscreen Drug Products for Over-The-Counter Human Use, Final Monograph; 21 CFR Parts 310, 352, 700, and 740. Federal Register 64 (98) May 21, 1999. Pp. 27666-27693.

For more information on these graft polymers, contact Interpolymer, 781.821.2485 or www.interpolymer.com.

