Controlling the Spreading of Sunscreen Products

Christopher D. Vaughan, Susan M. Porter and Sherine Bichara
SPF Consulting Labs, Inc., Pompano Beach, Florida, USA

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Abstract

Spreading control agents used in the formulation of topically applied drugs, especially sunscreens, provide a method to control dosage and improve effectiveness. These materials have recently begun to solve the problem of insufficient product application in actual use.

Most commercial sunscreens fail to deliver their labeled potency in actual usage. SPF value is determined using a 2 mg/cm^2 thick sunscreen film on the subjects' skin, however we have shown that most formulations will spread to a much thinner layer in normal usage. This accounts for results from prior studies which show that consumers fail to apply the correct amount of sunscreen needed in order to produce the labeled level of sun protection. Our investigation examined the spreadability of current commercial sunscreens and the effects of several potential "leveling" agents for their ability to limit the spreading of three standard sunscreen formulas. These "leveled" formulas, when applied in actual usage, provided the full SPF level as labeled.

How Much Sunscreen Do We Really Need?

According to Dr. Brian Diffey, a number of factors affect the amount of UV protection we need. He cites the latitude, the season, the altitude, the skin's sensitivity and the properties of the formulation, among others.[1] Of these variables, we believe that the formulation properties produce a greater level of unpredictability in the potency of sunscreen products than any of Diffey's factors.

It is clear that there are many formulation variables. These variations make it impossible to determine how much sunscreen one might need, especially when the actual use level can vary from 30% to 120% of the FDA standard thickness. However if consumers could rely on receiving the labeled potency from their sunscreen product, their estimate of their own required protection would then depend on more obvious cues, such as weather, skin sensitivity and exposure time.

To most people the term SPF (Sun Protection Factor) is confusing. Many people we surveyed on Miami's South Beach[2] understood that higher SPF numbers indicate more protection. However, none of the more than 250 surveyed beachgoers could tell us very precisely how long their sun product would protect them.

Exposed body surface area is yet another variable that may contribute to consumer confusion about how much sunscreen to use. We measured the skin surface of four typical sunbathers, from large to small. From these measurements we calculated the sunscreen amount needed to provide the FDA's "SPF delivering" standard (2 mg/cm^2) layer. This amount varied from 0.75 oz for a small woman to 1.5 oz for a large man. We believe it is impossible for consumers to judge whether they have dispensed 0.75 oz or 1.5 oz when they are applying their sunscreen. Previous studies suggest that consumers consistently under-apply sunscreen. Even unit dosage, such as packets or towelettes, would have to be "sized" to match the user to avoid misdosage by up to 50%.

Improper dosage of sunscreen product is an endemic and persistent problem, with possibly serious consequences. It is no secret that skin cancer rates are skyrocketing. Various scientists have blamed everything from triclosan to the ozone hole, but the general consensus is a suspicion that inadequate or improper use of sunscreens is to blame. Recent controlled studies of daily application of sunscreen resulted in a significant reduction in skin cancers.

The ability to deliver a product that spreads to its proper thickness would be a major advance in the field. We hope this article contains enough specific information to make that possible throughout the field. Only a few responsible sunscreen producers are currently using this technique. It is a new concept, so new in fact that no patents have yet been issued on the subject.

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Strength vs. Potency

Major formula variations are becoming obvious to label readers, now that sunscreens must declare their percentage of "active ingredients" on the label. We surveyed 10 commercial SPF 30 products sold in Florida this year and discovered that they range from 7% to 27% total active ingredient by weight, yet they provide the same level of UVB protection. These products have differing "strengths" but the same "potency." Strength is a chemical term, but potency is biological.

Consumers may be misled to believe that greater percentages of active ingredients (strength) provide greater protection (potency). In fact just the opposite is often true. Some products with high levels of UV absorbers can thin out on application. Then they provide far less real protection than an efficient formula with low UV absorber percentages but controlled film application. In most drug categories, strength and potency are related. But unlike other drug classes, potency and strength of sunscreens are not related, except in batch-to-batch comparisons of the same product formula.

In sunscreens, the *inactive* ingredients often have a strong effect on the performance of the UV absorbers. Hewitt has shown that sometimes a more than 2× increase in potency can result from changes in refraction of UV by inactive ingredients or from emulsion recovery time.[3] Likewise, our study of leveling agents shows that a sunscreen product's strength provided by the film thickness does not proportionally match potency, as delivered in the SPF we receive in actual usage.

The Effect of Too Thin Application of Sunscreen

Many researchers have addressed the shortcomings of inadequate film formation by sunscreen products, beginning with Stenberg and Larko,[4] who compared SPF produced by 2 mg/cm^2 sunscreen films with film half as thick (1 mg/cm^2), and reported a 50% loss in protection.

These results are generally in agreement with theoretical projections based on Beer's Law of light absorption; yet opposing results have been reported by Gottleib et al.,[5] who recorded no significant loss of protection by films of half thickness. We believe such a divergence of results may be explained by the two competing theories of light blocking, which will be explained in a moment.

To exacerbate the film-thinning effect, O'Neill[6] calculated that "unevenness" in film application can result in drastically reduced levels of protection. Additionally, Stansfield[7] has recently described negative deviations from Beer's law from photoinstability of UV absorber, projecting how a film of half the initial sunscreen content (strength) can provide less than half the expected protection (potency) (Figure 1).

Two Theories of Light Blocking by Sunscreen Actives

Beer's Law: UV absorbers in sunscreens generally follow the Bouguer-Beer-Lambert Law[8] if they are soluble in their formula vehicle and passing through a film of UV absorber:

$$\%T = I_t/I_o \times 100\%$$

where %T is the percent of transmitted light, I_o is the intensity of the original light beam, and I_t is the intensity of the light beam after transmission.

Or, to complicate matters, the nontransmission of light is often reported using a nonlinear log scale because it is proportional to concentration of the absorber:

$$A = -\log\{I/I_o\} = \log\{I_o/I\}$$

where A, called absorbance, is the negative log of the decimal value of the transmittance, where an absorbance of 1 signifies 90% light absorbed; an absorbance of 2 signifies 99% light absorbed.

Simplified, this law provides a uniform method to predict the effect of UV absorbers on UV light. What it tells us is that adding some UV absorber to a transparent material blocks a percentage of any UV light that might shine through it. The more you add, the less it appears to do. If you were to add

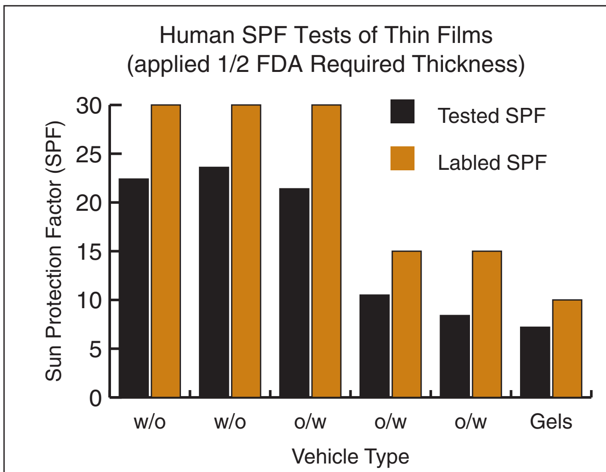

Figure 1. What happens when your sunscreen is too thin

enough absorber to block 25% of the UV, the mixture would then let 75% percent of the incident UV through. But, if you were to add the same amount of absorber again, the second dose would only stop an added 18.75% of the original beam. This is because the second addition would block 25% of the *remaining* UV light, not 25% of the original UV.

Because a second dose of absorber will block less, and the third even less, we have an example of the law of diminishing returns. As you add more and more UV absorber, and it does less and less, eventually it does almost nothing.

From this we can see that we will never be able block all the UV no matter how much absorber we use. Thus, sunscreen chemists know well that you cannot get much more than an SPF of 8 with octinoxate in mineral oil no matter how much you use. Higher SPF values require tricks including smoke and mirrors (light reflection and scattering)!

This law is more commonly attributed to August Beer (1825-1863), however, it was Pierre Bouguer[9] in 1729 who first determined that the thickness of a sample is inversely related to the passage of light. Around 1760, J.H. Lambert[10] applied the following differential to equate absorbance to sample thickness:

$$dI/I = -a \times dx$$

where "a" is a constant Lambert called opacity and dx is an infinitesimal distance through the sample.

Two and a half centuries later, most studies of sunscreen application have found that the effect of soluble UV absorber is proportional to the thickness of the film. The thicker the film, the better the protection. Such observations are in agreement with Bouguer's hypothesis and Lambert's equation for sunscreens, as well as our human SPF test results on films of varying thicknesses.

Rayleigh's scattering equation: Particulate UV blockers such as titanium dioxide or zinc oxide are the "smoke and mirrors" of the sunscreen science. They do not obey Dr. Beer when used in concentrations above 0.1%. In suspension, pigments tend to reflect or scatter incident UV light waves and the amount of light passing through a film of particles – whether it be the rings of Saturn or an oxide sunscreen layer – diminishes with the concentration of particles. This blocking effect differs from the diminishing returns of Beer's Law.

For sunscreens, light that is not reflected and that passes through a film is generally defined by what's left after we subtract reflection; this is the transmission (%T) equation.[11] The reflection equation was developed by John Strutt in 1871, before he became Lord Rayleigh. Our equation is a variation of the famous Rayleigh Equation:

$$\%T = (I_o - I_\pi)/(I_o + I_\pi) \times 100\%$$

where %T is the percent of transmitted light, I_o is the intensity of the original light beam and I_π is the intensity of the light reflected or scattered.[a]

The resulting relationship can be envisioned as what happens when sand is scattered on the floor. The first portion covers some measurable percent of the floor. The second portion fills in the holes and covers almost an additional equal percentage. Soon the floor is covered and the last holes are filled in. If the particles can pack well together, insoluble pigments have the ability to block much

[a] *Author's note: We re-worked Rayleigh's equation for reflection to predict transmittance*

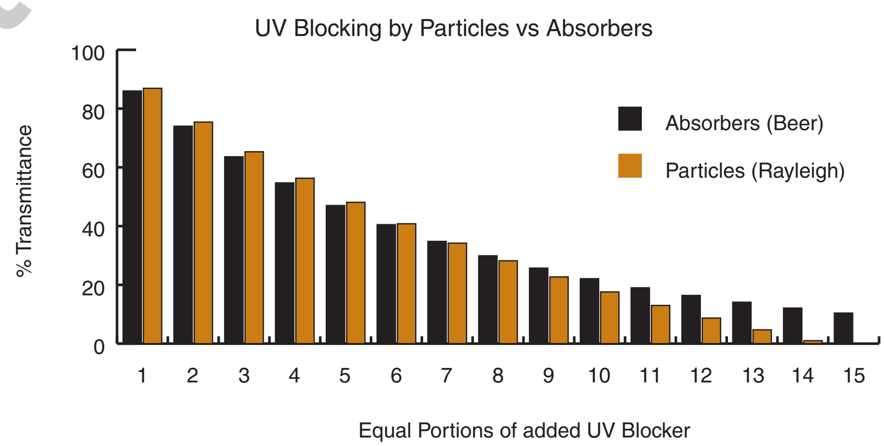

Figure 2. Relative effects of concentration on passage of UV light (Beer's Law vs. Rayleigh's Equation)

Table 1. Spreading of 16 Commercial Sunscreens

Sample	Brand	Label SPF	Film Thickness	Drying Time (sec)	Brookfield Viscosity (Spindle 7/100 rpm)
1	A	70	1.40	51	1500
2	A	50	1.20	65	1260
3	B*	48	1.92	35	2960
4	C*	45	1.18	45	240
5	D	45	1.60	130	2240
6	E*	36	2.08	55	3400
7	C*	30	1.71	59	6920
8	F	30	1.37	58	5400
9	C	30	1.41	40	2560
10	F	30	1.24	55	4120
11	G	30	1.39	45	2360
12	H	30	1.26	80	2600
13	J	30	1.51	75	3000
14	K	30	1.37	100	1440
15	L	15	1.46	50	6640
16	M	15	1.58	16	3400

* product contains a leveling agent

higher percentages of light than do soluble absorbers.

In real practice, tight packing by a pigment layer is limited by the vehicle. The other ingredients (oils, emulsifiers, preservatives and thickeners) tend to separate the particles and let UV light pass through. Still, the first SPF 50 sunblocks were achieved using micronized titanium dioxide pigment. If excess pigment beyond the amount required for maximum coverage is used, it could theoretically prevent significant reduction of SPF by thinning the applied film. It is unlikely that most manufacturers would be anxious to add extra micronized pigment that costs 10 to 20 dollars per pound, with no immediate SPF benefit. All of the chosen products were SPF tested at half thickness (1 mg/cm^2) and showed significant loss of protection.

Spreading Test of Commercial Sunscreen Products

Protocol: Numerous pharmaceutical researchers have addressed the nature of spreading of topical ointments and lotions.[12] We, however, needed to evaluate product spreadability with a quick, easy and reproducible method using a panel of volunteers. In our test protocol, a sample of test product was dispensed by syringe onto the center of the volar (inner) forearm surface. The volunteer was then asked to spread the product "as far as it would go." The area covered and the spreading or drying time were then measured and recorded. We then calculated the applied film's resulting film density (in units of mg/cm^2) as follows:

Film Density = Sample Weight / Covered Area

We found it necessary to control the temperature and humidity to achieve reproducibility and we also discovered that sweating further reduces the film thickness by 30-50% in conventional sunscreen. We also observed that drying time was proportional to the spreading of sunscreen products.

Spreading results: When we measured the spreadability of our commercial survey products we found that individual application thicknesses of these products ranged from 30% to 140% of the U.S. Food and Drug Administration (FDA)[12] standard (2 mg/cm^2). Some products varied up to +/–50% within the panel of 5-8 volunteer subjects, while other products showed as tight a variation as 10%. The tightest variations were observed in products containing leveling agents.

In Table 1 we report the average (mean) film densities of films spread by our subjects. These range from 59% to 93% of the FDA standard. Spreadability is a property that can easily compromise the performance of many other topically applied drug products beside sunscreens. We also noted that the application of those few commercial products containing leveling agents (to control spreading) and our test samples were not affected much by temperature and humidity.

SPF results: We performed SPF determinations to verify our presumption that the innate spreadability of a sunscreen

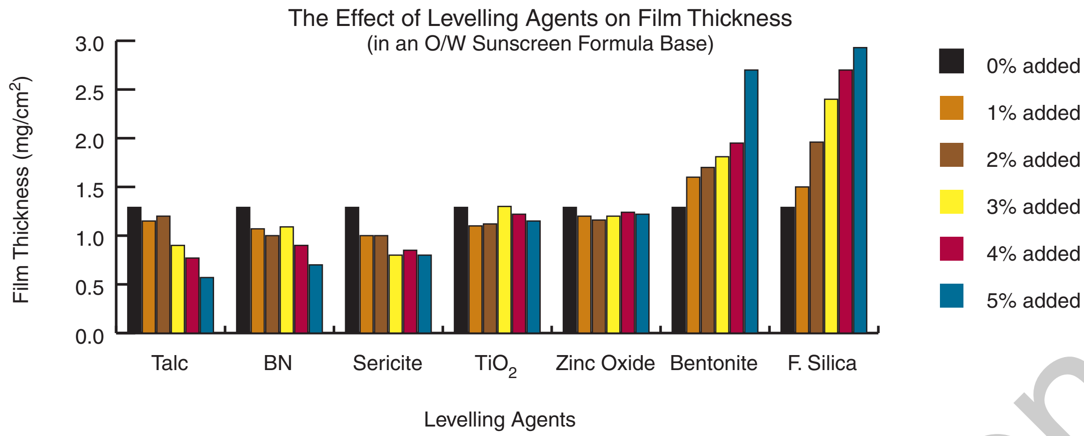

Figure 3. The effect of levelling agents on an O/W vehicle

results in the delivery of a wide variation of protection from brand to brand.

Our commercial survey product group was chosen to represent a large percentage of the market. It consisted of 16 commercial sunscreen products, including the major mass-marketed brands. Some products were expected to provide as little as 40% of the labeled SPF when used as directed, due to thin application. From our sampling, we projected that more than 80% of the currently marketed sun protection products fail to provide the SPF indicated on their label. Moreover, we determined that the 80% of commercial products that fail to provide the labeled SPF fail because the products can be easily spread out to a less effective thickness.

The 16 commercial sun protection products we purchased ranged in SPF from 10 to 70. These products were evaluated for their average application thickness by 5-8 human volunteers. Volunteers applied 100 mg on their inner forearms, spreading the material until it dried.

External variables in this test series were monitored, including temperature, humidity, sweatiness of the subject, skin topology and sample drying time. Internal variables (which we controlled) affecting the results, included size of sample applied, viscosity and leveling agent (in the formulation tests). In the end, we settled on a 100 mg sample size because it produced results close to several whole body sunscreen application experiments we conducted on the beach in Ft. Lauderdale, Florida, and Gottlieb's comparison[4] of product application on different body parts.

We calculate that our 16 leading sunscreen products probably represent between 30% and 70% of the commercial market.

Materials Affecting Film Thickness

"Leveling agent" is the term used by the technologists in the paint and coatings industry to describe materials that help deliver a level and uniform film. Leveling agents have been widely researched in the printing ink industry. Uneven layering of an applied ink film results in blotchy color. We found several cosmetic materials that acted similar to the ink additives, but were much safer for application to the skin. These materials produced different effects in the various formulas (Figures 3-5).

The rheology of the best leveling agents exhibited dilatent flow under increasing shear. This means that they tended to resist flow when rapid spreading forces were applied. Some combinations of the tested ingredients showed synergism. Ingredients tested for leveling ability included bentonite[a], boron nitride[b], sericite[c], silica[d], talc[e], titanium dioxide[f] and zinc oxide[g].

Formulation Studies

We were surprised to find that many of the materials we screened for their effect on spreading, such as talc and sericite, increased the formula spread instead of controlling it. Of course, the sunscreen base formulas we were applying were much thicker than the ink films we expected to emulate. Nevertheless, we

[a] *Albagel 4444 is a product of Whittaker, Clark & Daniels, South Plainfield, NJ USA*
[b] *BN is a product of Advanced Ceramics, Strongsville, OH USA*
[c] *SL-012 is a product of Presperse, Somerset, NJ USA*
[d] *Cabosil M5 is a product of Cabot, Tuscola, IL USA*
[e] *Melody is a product of Ultra, Red Bank, NJ USA*
[f] *M262 is a product of Presperse, Somerset, NJ USA*
[g] *Z-Cote is a product of BASF, Mount Olive, NJ USA*

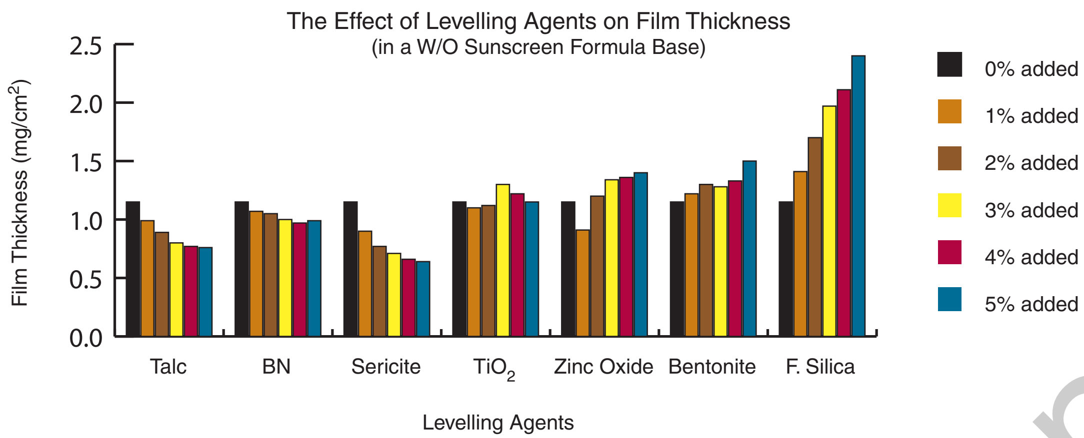

Figure 4. The effect of levelling agents on an O/W vehicle

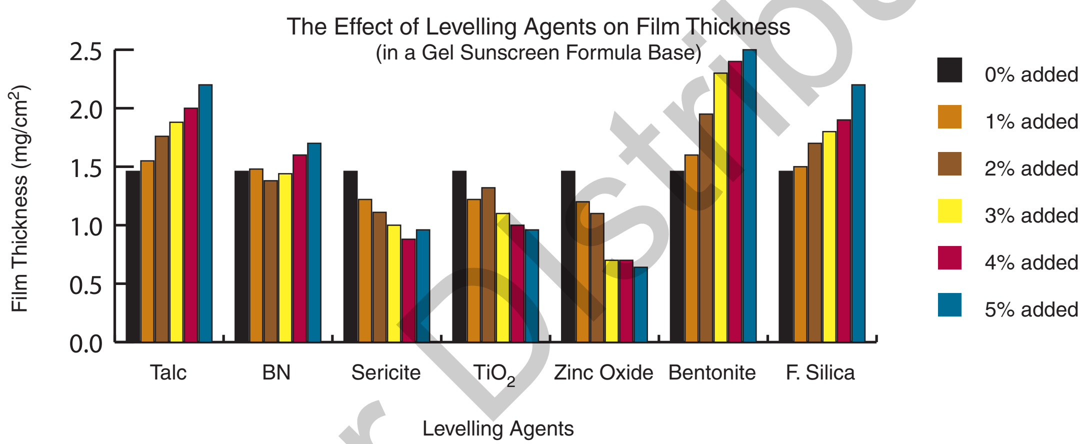

Figure 5. The effect of levelling agents on a gel vehicle

discovered several potent and effective candidates that worked well in our formulas.

Our test formula vehicles were of three varieties; oil-in-water (O/W), water-in-oil (W/O) and gel. Each formula attributes its efficiency to a different principle. The O/W formula was a product with a synergistic UV absorber combination. The W/O formula exhibited exaggerated reflection of UV due to refraction, and the gel formula exhibited strong molecular attraction to keratin.

We discovered that good leveling agents have differing effects in different systems. Silica was the most effective agent in O/W and W/O, but bentonite was more effective in gels. Both emulsion formulas used a combination of absorbers, while the W/O formula included a reflector (titanium dioxide), and the gel used only an absorber (Ensulizole) which is water-soluble.

In our initial in vivo SPF tests, our test formula vehicles – O/W, W/O and gel – all provided approximately 75% of their labeled SPF when applied at half the rated thickness. Because most of the test products spread at 65-75% of their rated thickness, we estimate a mean deficiency of protection of 12-15% across the industry. The W/O and O/W emulsions contained reflectors (scattering UV) and therefore did not show as much loss of protection on thinning as was shown by the gel. Also our results were in agreement with theory which predicts less potential thinning by Rayleigh response (particle reflections) compared to Beer's Law (transparent absorbers). Finally, we observed that formulas with leveling agents show less variability within the test subject panel.

Since we began our investigation into leveling agents, one major marketer and several smaller brands have introduced these additives into their newest formulas. Their products were easily the best performers in our study.

Leveling sunscreen formulations is a very new technology. We expect this new technology to be rapidly adopted throughout the industry because, beyond the health impact, it has a market impact that is hard to ignore. Leveling agents will increase the usage rate and can therefore be expected to increase sales.

Conclusions

Our in vivo SPF test results support the proposition that thinner sunscreen films indeed deliver diminished UVB protection.

The widespread under-performance of commercial sunscreens is a problem being addressed by new leveling technology. Silica and bentonite were the most effective leveling agents in our test formulations. The test formulations incorporating leveling agents achieved full 2 mg/cm^2 films, or more on uncontrolled application.

In vivo product application testing confirmed the effectiveness of incorporating leveling agents in sunscreens to deliver to the marketplace the full labeled SPF of sunscreen products.

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