c) Submit sunscreen product absorbency/transmission data requested for "ratio method" calculations.

Comment

In **Appendix 1**, we have provided substrate spectrophotometric data for 59 commercial products. These data, taken from the Procter & Gamble 1997 submission[8] includes:

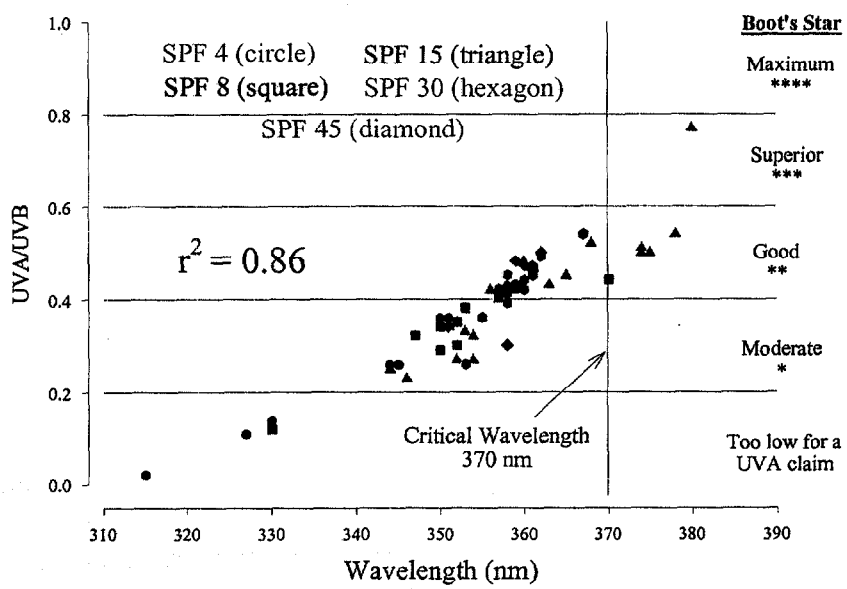
a) the mean of 5 separate measures at 1 nm intervals from 290 - 400 nm
b) the area under the curve for:
   i) UVB (290 - 320 nm)
   ii) UVA (320 - 400 nm)
   iii) UVAII (320 - 340 nm)
   iv) UVAI (340 - 400 nm) regions
c) UV area ratios (i.e., UVA/UVB, UVA-I/UVB, etc.)
d) the critical wavelength
e) absorption spectrum
f) labeled SPF and active ingredients in the product.

These data may be used to calculate any number of *in vitro* endpoints including SPF, UVA/UVB ratios, critical wavelength etc.

Relationship between Critical Wavelength and UV Waveband Ratios

In general, there is a positive relationship between the ratio of UVA/UVB (i.e., Boot's ratio) and critical wavelength. This is best considered using the example presented in the following figure. The relationship between the critical wavelength and the Boot's ratio (UVA/UVB) for 59 commercial products is presented and includes the cut-off for the Boot's Star rating and critical wavelength greater than or equal to 370 nm.

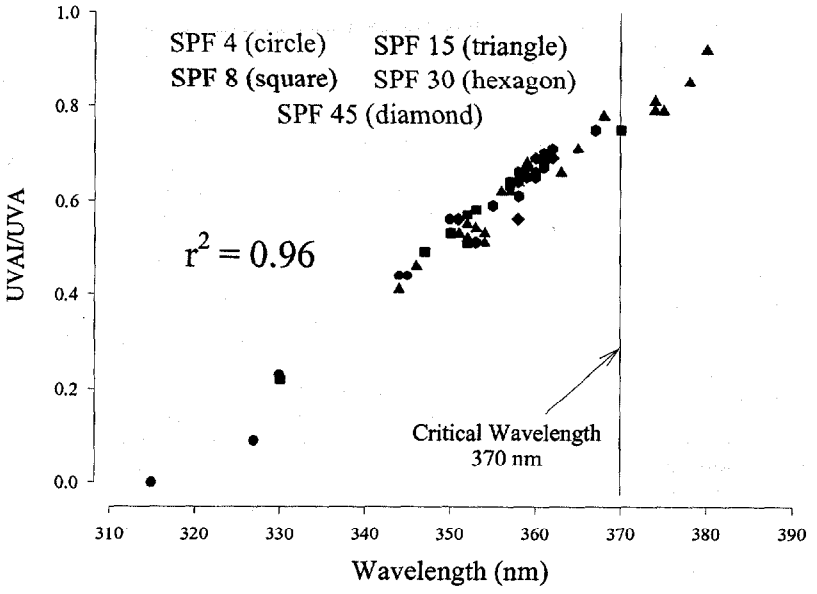
Relationship between Critical Wavelength and the Ratio of UVA/UVB



The correlation analysis for the UVA/UVB ratio and critical wavelength is $r^2 = 0.86$. As can be seen from the figure, the Boot's ratio would classify many products as "good" and very few above this. Of the "good" classification, few achieve a critical wavelength beyond 370 nm. Based on these data, the Boot's ratio appears to be less sensitive than critical wavelength in discriminating products with long wavelength UVA protection. This conclusion is supported by the fact that products having critical wavelengths greater than or equal to 370 nm contain avobenzone, zinc oxide or titanium dioxide, the only FDA-recognized long wave UVA filters (see Table in **Appendix I** for list of ingredients in the products).

The figure below presents the relationship between critical wavelength and the UVAI/UVA ratio. As can be seen, there is a very strong relationship between critical wavelength and UVAI/UVA ratio, $r^2 = 0.96$. Since the UVAI/UVA ratio is a better estimate of long wave UVA protection, it is not surprising that there is a very strong correlation with critical wavelength indicating the value of the either in determining long wave UVA protection.

Relationship between Critical Wavelength and the Ratio of UVAI/UVA



Finally, the correlation analysis for critical wavelength and SPF and UVAI/UVB are listed in the following table:

Correlation Analysis (r^2) of Critical Wavelength and UV Ratios for 59 Commercial Products

	Label SPF	UVA:UVB (Boot's)	UVAI:UVB	UVAI:UVA
Critical Wavelength	0.12	0.86	0.83	0.96

From these data, the critical wavelength is a sensitive means of assessing the breadth of UV protection which is currently what is missing in the evaluation of sunscreen product efficacy testing.