b) Address the observation that products with significantly different absorption spectra can have similar "critical wavelength" values.

Comment

The observation that products with significantly different absorption spectra can have similar critical wavelength is neither surprising nor a concern since it is already known to be the case for SPF, i.e., two products with significantly different absorption spectra can have similar SPFs. However, this observation is best addressed in more detail by considering the following example.

Example of products with different absorption spectra and similar critical wavelengths

The best illustration of the observation that "*. . . products with significantly different absorption spectra can have similar critical wavelength values*" is taken from the March 3, 2000 submission by L'Orèal Research/Cosmair Cosmetics Corp.[14], and is reproduced below:

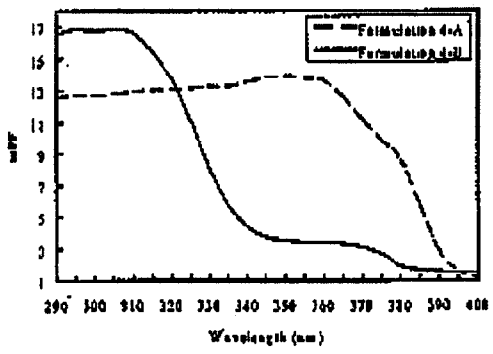


Figure 1: Monochromatic Protection Factor Curves of Two Prototype Formulations*.

Product Code	SPF (*in vivo*)	λ_c (nm)	UVA$_c$PF
4-A (408-312)	7.4	379	10.2
4-B (408-320)	7.5	372	5.2

* Reference is made to our May 15, 1998 submission to the Sunscreen Docket for specific data presented in this figure and corresponding summary data table.

It is quite apparent from this example that the absorption spectra, presented as the monochromatic protection factor (mPF) for Products 4-A and 4-B are different. As well, the critical wavelengths for these products are different, reflective of the absorption spectra. However, it is equally important that the visual difference, presented above as the mPF vs. wavelength, be considered in its entirety.

[14] March 3, 2000 Letter/report from L'Orèal Research/Cosmair Cosmetics Corp. to Docket No. 78N-00388: Sunscreen Drug Products for Over-the-Counter Human Use.

The ability of a sunscreen product to attenuate radiation can be expressed as absorbance, transmittance or a monochromatic protection factor. These three mathematically related terms are derived from the ratio of the amount of energy delivered by a constant UV source through a substrate without product and the amount of energy delivered through a substrate with product. The relationship among the different terms can be expressed as follows:

$mPF = 1/T$ (*equation.* 1)
$T = 1/ 10^{A}$ (*equation.* 2)
$\text{Log } mPF = A$ (*equation.* 3)

mPF = monochromatic protection factor, T = transmittance, A = absorbance

Using substrate spectrophotometry, absorbance /transmittance of UV can be measured and UV attenuation curves constructed with these mathematically related terms, i.e., mPF, transmittance or absorbance at specific wavelengths.

Using the data provided in the above figure for Products 4A and 4B, we have plotted mPF, absorbance, % transmittance and % absorbance (100 - % transmittance) at wavelengths from 290 to 400 nm (Figs. 1-4). **It is particular meaningful to recognize that these graphs are the same data, mathematically transformed using equations 1-3, and for Figs. 3 & 4 expressed as a percent.**

The visual difference between Product 4-A and 4-B of Fig. 1 (mPF vs. wavelength) is considerably less in Figs. 2, 3 & 4 when the absorbance, % absorbance or % transmission is plotted versus wavelength. This, of course, does not change the fact that Products 4A and 4B have different absorption spectra but rather provides a more complete visual image and illustrates that the difference is really not that large.

Fig. 1

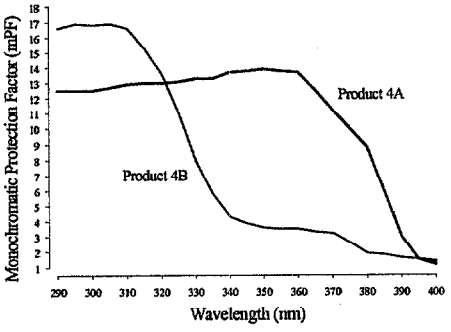


Fig. 3

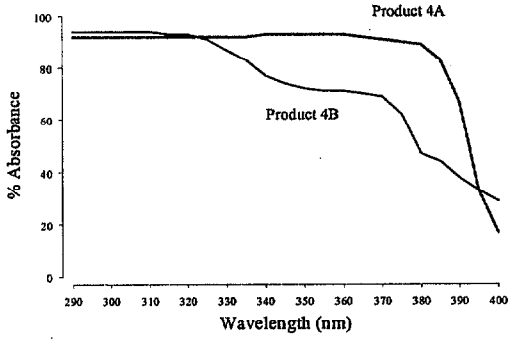


Fig. 2

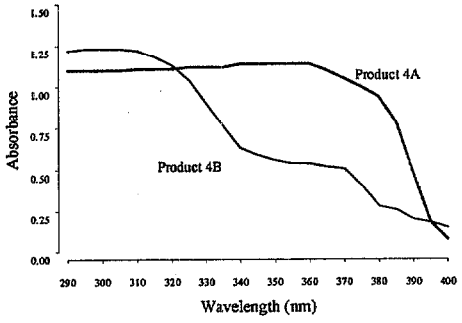
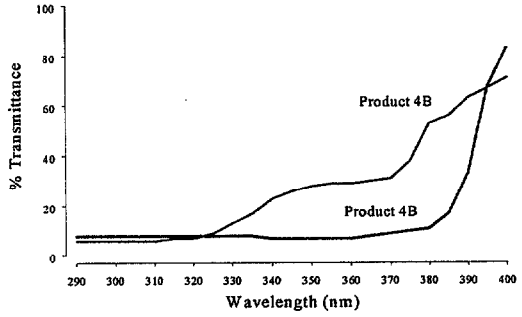


Fig. 4



The true issue is how might these products be classified? For example, if a singular cut-off of 370 nm were used as a means of establishing the presence or absence of long wave UVA protection, then both Products 4-A and 4-B would be in the same category and *similarly* labeled. Thus, sunscreen products may have different absorbance curves and critical wavelengths but be **classified** the same.

We support and recommend such an approach since both of these hypothetical products provide broad-spectrum UV protection (i.e., critical wavelengths > 370 nm). Most important, both products substantially reduce UV transmittance throughout the entire spectrum (Fig 3 & 4). Moreover, the critical wavelength is an inherent property of the product which does not change with dose or application density and therefore will always provide the same breadth of protection.

What can be learned from this example?

Certainly products may be classified similarly even though they have slightly different absorption spectra and critical wavelengths. Obviously, the determination of a single cut-off as proposed using a critical wavelength ≥ 370 nm classifying sunscreen products as "broad spectrum" would place some products with slightly different absorption spectra in the same category. What is important is that a product identified as broad spectrum would, by definition, attenuate longwave UV thereby ensuring consumers are protected independent of the amount of product applied and together with adequate SPF protect the consumer against the entire UV spectrum.