TGA Sunscreen Guidelines – Response to Consultation

Summary of comment

In the sunscreen standard AS/NZS 2604:1998 and the other two standards as referred to in Section X.5, the rate of sunscreen application in *in vivo* SPF tests is prescribed by weight per unit area (2 mg/cm^2). This results in differences in the layer thickness of sunscreens as applied on the skin, depending on their density, thus yielding SPF values that do not properly represent UV protection performance in actual usage. It is suggested that the application rate be prescribed by volume per unit area, e.g. 2 $\mu l/cm^2$.

Details

The *in vivo* SPF testing of sunscreen products involves the laying down of a layer of sunscreen on the back of human subjects, followed by examination of the skin's response to the UV light in the form of erythema.

According to the sunscreen standard AS/NZS 2604:1998 and the other two standards as referred to in Section X.5, the rate of sunscreen application in *in vivo* SPF tests is set at 2 mg/cm^2, i.e. the application rate is prescribed by weight per unit area. This means that the thickness of the sunscreen laid on the skin depends on the density of the sunscreen: the denser the sunscreen, the thinner the layer. On the other hand, consumers would apply a sunscreen on the skin based on the volume of the sunscreen as squeezed out of the tube, not on the weight.[*] It follows that a sunscreen having a higher (lower) density tends to be applied more (less) in real usage than in *in vivo* testing; in other words, if two sunscreens have the same *in vivo* SPF but different densities, the denser one will be more effective in protecting the skin from UV exposure.

The effect described above is insignificant in organic sunscreens, among which the density variation is small, but becomes significant when both organic and inorganic sunscreens are considered. As can be seen in Table 1, a typical sunscreen containing ZnO is denser than a typical organic sunscreen by a factor of 1.21, meaning that the sunscreen layer laid on the skin in *in vivo* SPF tests is 1.21 times thicker for the latter than for the former. Fairly small as it may appear, the 21% difference in layer thickness can have strong influence on SPF. In the ideal case where the layer thickness is uniform and Beer's law holds, the SPF will increase exponentially with increasing layer thickness; see Fig. 1. As an example, the SPF of a sunscreen will decrease (increase) from 30 to 14.7 (61.3) if the application rate is decreased (increased) by 21%. This means that when an organic sunscreen with SPF 30 is applied to the skin by a consumer, it will be only as effective as a ZnO sunscreen with SPF 15; similarly, a ZnO sunscreen with SPF 30 is expected

[*] This is reflected in Cancer Council of Australia's recommendation regarding the application rate: "Apply sunscreen liberally – at least a teaspoon for each limb, front and back of the body and half a teaspoon for the face, neck and ears." (http://www.cancer.org.au/cancersmartlifestyle/SunSmart/Preventingskincancer.htm).

to be comparable in the effectiveness of UV protection in real usage to an organic sunscreen with SPF 60. In real systems, the exponential dependence of the SPF on layer thickness may not always be observed, but it is beyond doubt that a higher (lower) application rate results in a higher (lower) SPF.

Table 1. Compositions and densities of typical organic and inorganic sunscreens.

Sunscreen	Organic	Inorganic
wt% active	12	20
Density of active (g/cm^3)	0.95	5.606
wt% emollients	38	30
Density of emollients (g/cm^3)	0.95	0.95
%water	50	50
Density of sunscreen (g/cm^3)	0.974	1.174

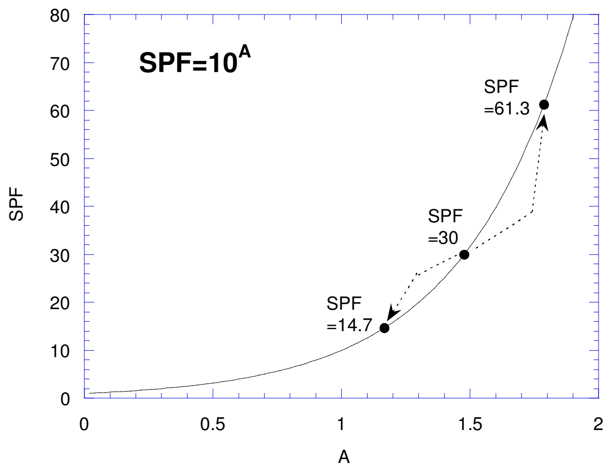

Fig. 1. Dependence of SPF on absorbance (*A*), which is proportional to layer thickness. The arrows show changes in SPF resulting from changes in sunscreen layer thickness by 21%.

From the above considerations, it is clear that the current *in vivo* testing procedure does not consistently yield SPF values that properly represent the sunscreens' effectiveness of UV protection in real usage.

It is suggested that the procedure be changed so that the application rate is prescribed by volume per unit area, e.g. 2 $\mu l/cm^2$ (which corresponds to 2 mg/cm^2 for a density of 1 g/cm^3); this would solve the problems described above.