



*Submission:*

**Proposed revisions to Chapter 10 ‘Sunscreens’ in the Australian Regulatory Guidelines for OTC Medicines**

**Ref: X.5      SPF testing and reproducibility of results**

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The proposed calculation of the SPF according to the US FDA method is theoretically supported.

However, with a view to perspective:

SPF 24

Range: 21 – 28

Retest range: 19 – 32

With a 10’ MED (approximate for Type I skin at noon in Sydney)

SPF 24 = 240 mins

Range: 210 – 280 mins

Actual Range: 190 mins – 320 mins (3 hrs 10 mins – 5 hrs 20 mins)

Reapplication is encouraged, at least every 2 hrs. This does not return the skin condition to a zero point of accumulated dose.

People tend not to know their MED time, which may vary considerably through a summer season for an individual (from 6’ – 12’ for example, depending on a range of factors influencing susceptibility).

At the University of Sydney we exposed ten (10) people to mid-summer sunlight at noon and ranked their susceptibility according to their MED time. We then exposed the same people to a solar simulator used in sunscreen testing and ranked their susceptibility in the same way. There was no correlation between their susceptibility to natural sunlight and solar simulated UV (only 5% of the total sunlight spectrum).(1)

Not only are people unaware of their MED time, they are also discouraged from “doing the (SPF) numbers” with a view to maxing out on sun protection.

Sunscreens in use are applied at a rate half or less than half the rate applied in laboratory SPF testing. The relationship in practice between the amount applied and SPF appears to be approximately linear.

**Taken together these facts do not support a notion of a “true SPF in use”. The SPF is a function of a host of interactions, biological, chemical, photochemical, physical and behavioral. The SPF is not a characteristic of a sunscreen product apart from this interactive context.**



**This interactive context also applies to the laboratory derived SPF in one important respect of the method of application to the skin. In contrast, a plate of 3 mm window glass will confer a measurable or “true” SPF as its protection does not depend on its interaction with the skin surface. (The protection conferred by clothing is also affected by its distance from the skin because weave structure acts like a grating, which magnifies UV transmitted through it (2).)**

**Put another way: the “true SPF” of a sunscreen product applied to the skin can only fall within a range of values.**

Based on twenty years of experience testing sunscreens, conformance to a Standard does not by itself ensure reproducibility.

Therefore it would be reasonable to allow a product shown to be stable as both a conformation and composition of phases and ingredients to make a claim on the basis of a set of data conforming to an international Standard or Guideline which supports that claim (eg. SPF 31 = SPF 30+) and allow the claim to stand if subsequent testing to the same Standard returned an SPF of no less than SPF 25 (or 20%).

[An additional requirement for a retested product which returned an SPF lower by more than 10% might be that the UVA Ratio remained the same (+/- 0.06)

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(1) Gavin E. Greenoak\*, Jules M. Martin, Golda Gruszka  
**Minimal Erythema (Sunburning) Doses (MED) of Sydney Summer (January 1990 and 1997) Sunlight at Solar Noon on Fair Skinned Human Subjects.**  
Cosmetics, Aerosols & Toiletries in Australia - Vol 10, No 5

(2) Menzies, S.W., Lukins, P.B., Greenoak, G.E., Walker, P.J., Pailthorpe, M.T., Martin, J.M., David, S.K. and Georgouras, K.E. **A comparative study of fabric protection against ultraviolet-induced erythema determined by spectrophotometric and human skin measurements.** (1991) *Photodermatol. Photoimmunol. Photomed* **8**, 157-163