

Mr Terry Slater
National Manager
TGA
PO Box 100
WODEN, ACT, 2606

Dear Mr Slater,

I wish to draw your attention to the 'Review of the Regulation of Products at the interface between cosmetic and therapeutic goods', March 18, 2005

(www.nicnas.gov.au/obligations/reform/files/CosmeticsReview2005.doc)

In particular, relating to the regulation of Sunscreen-containing products (4.3, pp 55 – 69) and the recommendation for Moisturisers that contain a sunscreen where the Sun Protection Factor (SPF) is equal or greater to 4 (page 68).

Moisturisers claiming a SPF rating equal or greater to four are termed 'secondary sunscreens' by definition in the current Australian/ New Zealand Standard 2604 : 1998. As such, they are a 'suntan product represented on the label as protecting the skin from certain harmful effects of the sun's rays while fulfilling another primary function', that of moisturizing the skin.

Universally, the public has been educated that the Sun Protection Factor is an indicator of the efficacy of sunscreen products against sunburn. Claim of such a SPF rating is consistent with the product having a therapeutic function. In Australia, this ensures quality control of the product that can legally be enforced by the Therapeutic Goods Administration. In particular, it ensures high standards regarding evidence of SPF testing, verification of the claimed SPF value, regulation of the testing procedures, appropriate safety measures in formulation of the product and active ingredients as well as control of maximum allowable concentrations, appropriate stability testing and expiry dating, correct marketing and labeling in compliance with AS/NZ 2604:1998, assurance of Good Manufacturing Practice and the associated requirements in equipment and process. The consumer can have every confidence in the product.

Australia has the highest incidence of skin cancer in the world. Each year 1300 Australians die from melanoma and 382,000 Australians are diagnosed with skin cancer. Consequently, as a consumer advocate and Consumers' Federation representative for over 10 years on numerous Standards Australia technical committees related to sun protection products, I fully endorse Australian Standards leading the world in sun protective regulations. The unique demographic and climatic conditions, plus our lifestyle, exposes Australians to more risk from the effects of the sun than elsewhere in the world and every effort must be made to maintain the highest level of standardization of products which claim sun protective properties. Barriers to trade are universally undesirable but the health of the Australian consumer is of prime importance and cannot be compromised. Even our closest neighbour, New Zealand, must not be allowed to lower such public health measures.

It has been proposed in a recent TGA review that Moisturisers containing a sunscreen with a SPF not exceeding 20, should be deregulated and not classified as therapeutic products.

(www.tga.gov.au/consult/2005/cosmeticrepdr.htm)

There is strong opposition to this recommendation in the best health interests of the Australian public.

Furthermore, the proposed maximum SPF 20 level for product compliance is of extreme concern. One of the vital factors influencing SPF protection is the amount of product required to deliver the claimed protection when applied to the skin. The application of a moisturizing product possibly would not be in sufficient quantity to achieve the SPF level stated on the product.

It was also recommended that 'any representation about anti-ageing can only be made if the product is defined as "broad spectrum"'. The Consumers' Federation of Australia would oppose, in the interest of public safety, any secondary sunscreen being labeled as Broad Spectrum.

The recommendations if adopted would allow unapproved agents anywhere in the world to manufacture cosmetics, in particular moisturizers, with claimed SPF values up to 20 without manufacturing regulations and regulated quality control of the product and for these cosmetics to be imported into Australia. This Draft compromises the exceptional high standard of regulated sun protection currently afforded to the Australian public. They deserve better.

Yours sincerely,

Robyn Easton, BSc (Hons),

**Consumers' Federation of Australia representative on Standards Australia
Technical committees including :-**

CS/042 –Sunscreen Agents

CS/053 –Sunglasses & Fashion Spectacles

CS/064 –Solaria

TX/021 -Sun Protective Clothing

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