



Why SunSense sunscreen packs don't claim SPF 100

SunSense background

SunSense sunscreens have been developed by Ego Pharmaceuticals to withstand harsh Australian conditions. Ultraviolet radiation from the sun is a known carcinogen and causes the majority of skin ageing. SunSense sunscreens have a higher Sun Protection Factor (SPF) than is claimed on the label. We formulate our sunscreens to have high SPF whilst not compromising the feel of the product upon application. Ego is bound by the Australian/New Zealand Standard AS/NZS:2604:1998¹ and the Australian Therapeutic Goods Administration as to what SPF can be advertised on our labels when sold in Australia.

Many SunSense sunscreens are capable of claiming SPF 100. This would be a breach of the regulations set down by the different regulatory bodies that Ego adheres to. Therefore Ego will only claim the maximum SPF allowed under the regulatory guidelines.

What is SPF?

SPF (Sun Protection Factor) is a measure of protection of the skin from erythematous UV radiation.

How is the SPF of a sunscreen measured?

SPF is calculated by measuring the amount of time required to produce the first sign of reddening on unprotected skin and comparing it to the time it takes to produce the first sign of reddening on skin protected with sunscreen.

For example:

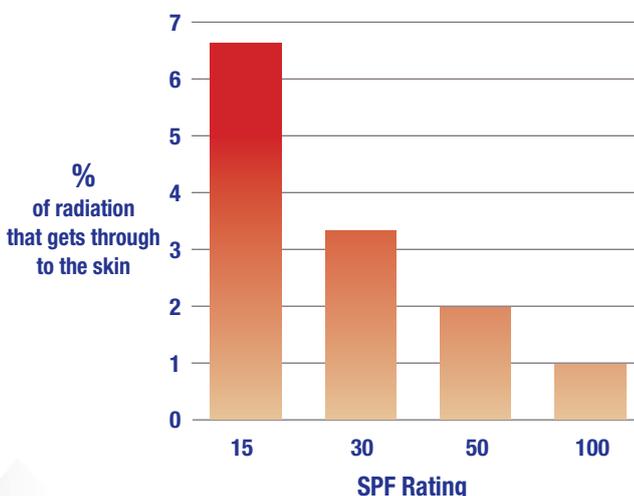
If the unprotected skin reddens in 10 minutes and the protected skin reddens in 500 minutes, then the SPF is:

$$SPF = 500 \text{ minutes} \div 10 \text{ minutes} = SPF 50$$

This is an example only. The time it takes skin to show the first signs of reddening will vary from person to person. Reddening of the skin is one of the first **visible** signs of skin damage. Skin can be damaged by the sun before you see visible damage.

The time it takes your skin to sunburn will vary from person to person. SPF is only one element of sun protection and should not be considered alone but also with water resistance, amount of sunscreen applied, sweating, film uniformity and activities which may rub the sunscreen away.

Erythematous radiation that gets through to the skin



AUSTRALIA

Therapeutic Goods Administration (TGA)²

The Therapeutic Goods Administration regulates medicines in Australia. Sunscreens with an SPF of over 15 in Australia are classified as medicines and as such are subject to the same strict regulations as medicines. These include meeting testing standards and having supporting test results proving all claims as specified by the Australian/New Zealand Standard: Sunscreen Products - Evaluation and Classification, AS/NZS 2604:1998.

All SunSense sunscreens are SPF 30 or above.

Test methods required for registration with the TGA:

- *In vivo* SPF testing on human skin using UVA and UVB
- Water Resistance – (if claimed) resultant SPF level after period of time, post emersion.
- *In vitro* Broad Spectrum testing for UVA protection
- Preservative Efficacy
- Stability testing of formula in commercial pack to justify shelf life and storage temperature.

Test results and certificates are held onsite by Ego Pharmaceuticals, Australia.

The TGA audits companies who make medicines regularly to ensure Good Manufacturing Practices (GMP) are in place and correct processes are followed.

Ego Pharmaceuticals is audited by the TGA every 2-3 years and has always passed.

The maximum SPF that can be claimed on the label under the **Australian/New Zealand Standard: Sunscreen Products - Evaluation and Classification AS/NZS 2604:1998 in Australia is SPF 30+.**

EUROPE

EU Recommendations and Colipa

For markets outside of Australia, Ego abides by the EU recommendations for sunscreens.

Europe has an industry body - **Colipa**³, the European Cosmetics Association. Colipa publishes regulatory framework for cosmetics and toiletries within Europe.

Retailers within Europe help enforce compliance to the Colipa framework. This is done by mandating product compliance before they are able to be ranged into stores.

SunSense sunscreens in Europe are cosmetics and therefore fall under the requirements of the EU recommendations. The SPF advertised on SunSense labels have been assigned in accordance with the EU Commission Recommendation (2006/647/EC).

The maximum SPF that can be claimed under the **EU Commission Recommendation (2006/647/EC) is SPF 50+.**

USA

US Food and Drug Administration (FDA)⁴

In the USA, sunscreens are regulated as medicines by the FDA. Strict regulations restrict claims and ingredients that are approved for use in sunscreens.

The new sunscreen monograph published by the FDA has the maximum SPF that a sunscreen can claim at **SPF50+.**



Information for consumers

The following statement will appear on our leaflets for consumers in order to better educate consumers as to why our SPF ratings may be lower than those of our competitors.

The SPF advertised on the sunscreen label has been assigned in accordance with the EU Commission Recommendation (2006/647/EC). The actual SPF of the sunscreens have been determined by Ego Pharmaceuticals using the in vivo testing method published by the Australian/New Zealand Standard: Sunscreen Products - Evaluation and Classification AS/NZS 2604:1998. Test results and certificates are held onsite by Ego Pharmaceuticals, Australia.

Common Misunderstandings

SPF 100 advertised on pack will be two times more effective than SunSense SPF 50.

Yes, SPF ratings are mathematically calculated. But SunSense sunscreens are formulated to be higher than what is advertised on the label. We strongly adhere to the regulations set down for the export markets and on our packaging only advertise a maximum of SPF50+. Our sunscreens are industry quality, have effective ingredients for reflecting and dispersing UVA and UVB rays and are formulated by a pharmaceutical company. The comparison on efficacy needs to be more in depth than just what is stated on the label.

Applying sunscreen once a day is enough

Studies show that consumers tend to apply one third to one half of the sunscreen that they should to obtain the SPF protection on the sunscreen label. SunSense sunscreens are designed to assist the consumer in getting an even coverage, but even then, areas can be missed. Additionally through activities, sunscreens can be rubbed or washed off, leaving the skin exposed to the sun. Application of a sunscreen should be done according to the label of a product that complies with recognised recommendations. Regular re-application is essential. It is uncommon for any product to claim 'once a day application' as this is in breach of EU recommendations. It is difficult for any product to be able to maintain proper protection for that period of time. The protection at the end of the day is likely to be substantially less than that of the SPF on the label.

Sun block is better.

Sunscreens are a way of filtering UV radiation. Unfortunately, some companies have been promoting sunscreen products that block the sun's rays. The actives within sunscreens are designed to absorb, reflect or scatter UV rays, so they act as filters. Sunscreens are not able to block UV radiation completely. As such a product is being misleading by claiming or inferring that it 'blocks' the sun's rays. Even sunscreens that have Titanium dioxide or Zinc Oxide will not block all of the sun.

Ego avoids use of the term 'block' as it may give consumers a false over-confidence in a sunscreen.

References:

1. AS/NZS 2604:1998. Australian/New Zealand Standard: Sunscreen products – Evaluation and Classification
2. TGA. <http://www.tga.gov.au/docs/html/gmpsunsc.htm>. Cited 20/10/10
3. Colipa. <http://www.colipa.eu/about-colipa-the-european-cosmetic-cosmetics-association.html>. Cited 20/10/10
4. FDA. <http://www.fda.gov>. Cited 20/10/10
5. Sunsmart. http://www.sunsmart.com.au/ultraviolet_radiation/the_health_risks/sunburn/. Cited on 28 Jul 2010.

'Ego' and 'SunSense' are trademarks of Ego Pharmaceuticals Pty Ltd in Australia and other countries. ©2010 Ego.



Sunscreens cause more harm than good.

Ultraviolet radiation from the sun is a known carcinogen. Without protection, skin will age quicker and get damaged.

Any concerns that consumers have regarding sunscreen ingredients should be weighed out against the fact that quality high SPF sunscreens help protect the skin against sun damage. All SunSense sunscreens are listed by the TGA on the Australian Register of Therapeutic Goods.

I won't get enough Vitamin D if I use a sunscreen.

Application of a sunscreen is inexact and as such, some degree of UV filters through.

Therefore applying sunscreen before spending time in the sun still allows for Vitamin D to be produced, whilst ensuring the skin is protected. Vitamin D is linked to bone density levels. If concerned, the use of an oral Vitamin D supplement will aid in topping up consumer's levels.

It's OK to get sunburned every now and again.

Sun damage of the skin is cumulative.¹ Each time the skin is sunburned, additional damage can occur.

Sun damage leads to premature wrinkling and pigmentation. This quite often doesn't show visibly for many years, with history of severe sunburn linked with the development of melanoma⁵.

Glossary:

In vivo SPF testing - on human subjects SPF - Sun Protection Factor

TGA - Therapeutic Goods Administration - Australia

AS/NZS - Australian/New Zealand Standard

EU - European Union

FDA - Food and Drug Administration - United States of America

Colipa - the European trade association for the cosmetic, toiletry and perfumery industry.

Erythral radiation - Erythral radiation is composed of 85% UVB radiation plus 15% UVA radiation.