Worldwide Regulations for Sunscreens and Anti-Ageing Products

EU
ASEAN
China
Japan
Republic of Korea
Taiwan
India
Australia/New Zealand
Mercosur
Russia
USA
Canada

Debra Redbourn
dR Cosmetic Regulations
EU Sunscreen Recommendation 2006

Minimum efficacy

- Lowest SPF 6
- 1/3 UVA
- Critical wavelength at least 370nm

Harmonised labelling

4 Protection categories with specific SPF numbers

Precautions and usage instructions - suggestions

Test methods - preference to in vitro test methods for ethical reasons

Referred to an SPF + UVA test method – but ultimately wanted harmonised standards
EU Test Methods

Cosmetics Europe (formerly Colipa) Position

**ISO 24444 *in vivo* SPF** 2010 – EU reference test method
Supersedes the International SPF Test Method 2006

**ISO 24443 *in vitro* UVA** 2012- EU reference method

Products tested to International and Colipa methods do not need to be retested, both remain valid methods, move towards ISO methods

**ISO 24442 *in vivo* UVA** 2011 replaces persistent pigment darkening published by the Japanese industry in 1995 and specified in the EU Recommendation 2006 can be also used to test products.

Preference to *in vitro* UVA
Claims

Commission Regulation Common Criteria for Claims 655/2013/EU and accompanying guidance

Not aiming to define and specify words

Claims should conform to these six criteria:

- Legal compliance
- Truthfulness
- Evidence support
- Honesty
- Fairness
- Allow consumers to make informed decisions

The acceptability of the claim shall be based on the perception of the average end user.

Cosmetics Europe Guiding principles on responsible advertising and marketing communication
ASEAN Cosmetics Directive

Sunscreen labelling guideline for primary sunscreens

Introduced in 2009 for all primary sunscreens.

Can use any recognised test method; International SPF test method, FDA, AS/NZ 2604, preference ISO test methods

UVA labelling not specified; 'UVA protection', 'broad spectrum', UVA logo – all acceptable

ASEAN Cosmetics Directive Annexe VII requires the warning 'Do not stay too long in the sun, even while using a sunscreen product' for every UV filter when used in primary sunscreens.
China

**Classification:** Special use cosmetics

**Registration:** State Food Drug Administration (SFDA) reviews safety and efficacy; SPF and PA

**UV filters:** same as EU

**Labelling:** SPF (max 30+)

**UVA:** PA+, PA++, PA+++  
PA++++ not yet accepted
Japan

JCIA self-regulating standards:

SPF testing and labelling
ISO 24444 was adopted October 2011
No changes regarding labelling: Minimum SPF 2  maximum 50+
No requirement to label protection category

UVA testing and Labelling:
PA must accompany SPF labelling
ISO 24442 in vivo was adopted January 2013
New labelling to indicate higher level of protection PA+++++

Fair Trade Commission requires 2 cautions:
• Reapply every 2-3 hours
• Reapply after wiping the skin with a towel
Republic of Korea

Classification: Functional cosmetics

Registration: Ministry of Food and Drug Safety (MFDS formerly KFDA) reviews safety and efficacy; SPF and PA

MFDS Guideline on nanomaterials

UV filters: similar to EU (6 not permitted and 3 at lower %)

Labelling: SPF (max 50)

Protection category is not required

UVA: PA+, PA++, PA+++ 

Discussions ongoing on PA++++
Anti-ageing claims

Japan
‘Anti-aging’ and ‘prevent wrinkles’ claims are prohibited

‘prevent fine lines caused by dryness of skin’ - allowed provided it is substantiated by carrying evaluation tests.

South Korea Labeling and Advertising Guidelines
issued November 2013, went into effect March 1, 2014

Anti-ageing products can be general cosmetic products or functional cosmetics depending on the claims.

Functional cosmetics are designed to;
- a) develop natural looking tanning or protect the skin from UV rays
- b) minimize wrinkles
- c) whiten skin tone

Local expertise essential
Taiwan

**Classification:** Medicated cosmetics

**Registration:** yes GMP certification required. Takes up to 3 months

**UV filters:** Same as EU but some differences in concentrations

**Labelling:** SPF

PA++++

**Testing:** ISO 24442 in vivo

India

Classification: Cosmetics

Registration: yes

UV filters: Same as EU
IS 4707 (Part 2):2009 Classification of Cosmetic Raw Materials and adjuncts

BIS (Bureau of Indian standards):
No specific standard for sunscreens, but looking at introducing and BIS keen to incorporate ISO standards (usually aligns with EU + ISO rather than USA).

Labelling: SPF
UVA protection and PA++ acceptable and most widely used
Water resistant, Sunblock, Broad spectrum are also on packs
Australia / New Zealand

Sunscreen Standard AS/NZS 2604 : 2012

1) Australia – Primary sunscreens – therapeutic goods - TGA
Australian Regulatory Guidelines for Sunscreens (ARGS) Version 1 Nov 2012
All new products must meet AS/NZS 2604 : 2012
Old products can stay on the market indefinitely

2) Australia – Secondary sunscreens – cosmetics - NICNAS
Skin Care: SPF ≤ 15, not water-resistant, <300ml
Makeup SPF 4 - 50+
NICNAS adopted 2012 sunscreen standard 1 Aug 2013 with 5 year transition

3) New Zealand – cosmetics
Adoption not mandated
Australia
Sunscreens Standard AS/NZS 2604 : 2012

ISO 24444 in vivo SPF
ISO 24443 in vitro UVA for broad spectrum

**Protection Categories & Labelled SPF**

Increased SPF from 30+ to 50+

Introduced specific SPF numbers

<table>
<thead>
<tr>
<th></th>
<th><strong>Australia</strong></th>
<th><strong>EU</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>4, 6, 8, 10</td>
<td>6, 10</td>
</tr>
<tr>
<td>Medium</td>
<td>15, 20, 25</td>
<td>15, 20, 25</td>
</tr>
<tr>
<td>High</td>
<td>30, 40, 50</td>
<td>30, 50</td>
</tr>
<tr>
<td>Very High</td>
<td>50+</td>
<td>50+</td>
</tr>
</tbody>
</table>

‘Broad spectrum’ compulsory on primary and secondary sunscreens
Only exception secondary sunscreens colour cosmetics with SPF <30
Secondary Sunscreens

New high **broad spectrum performance:**
- Some products needed to be reformulated
- Some products marketed in other international markets cannot be marketed in Australia

**Free radical claims are therapeutic and require registration:**
'against ageing free radicals'
'help fight the ageing effects of free radicals'
'help protect skin cells from free radical damage'
High regulatory costs for therapeutic goods

- Listing is done electronically by an Australian sponsor
- Companies assessed for GMP compliance with Pharmaceutical Inspection Co-operation Scheme (PICs)
- All excipients must be listed in TGA’s Approved Terminology for Medicines
- TGA fees
- Separate labels

Industry has requested and is in discussions with TGA:
1. Immediate reform increase SPF from 15 to SPF 30 for cosmetic secondary sunscreen skincare
2. All secondary sunscreens are regulated as cosmetics.
3. All sunscreens regulated as cosmetics
Australia

Diethylamino hydroxybenzoyl hexyl benzoate (Uvinul A Plus)

**Primary sunscreens** – permitted

Approved by TGA at up to 10%

Listed in Australian regulatory guidelines for sunscreens

**Secondary sunscreens** - not permitted

NICNAS has:

- Listed it in their NICNAS Guidelines at up to 10%
- Not listed on AICS (Australian Inventory of Chemicals)

Administrative Appeals Tribunal (AAT) case – NICNAS has concerns risk to the environment and want a limit of 1 tonne pa per importer

Will not be listed on AICS until the AAT case is resolved

Diethylhexyl butamido triazine

**Primary and secondary sunscreens** - not permitted.
MERCOSUR Technical Regulation on Sun Protection Products in Cosmetics 2012

Implemented nationally in Argentina, Brazil, Paraguay, Uruguay & Venezuela

Broadly follows EC Recommendation 2006

Minimum level accepted of UVA is 1/3 of UVB

Applies to primary sun protection products and multifunctional products

Products must be registered

Multifunctional products should:

• have a minimum SPF2 and FPUVA 2

• labeled with the warning: ‘This product is not a sunscreen’
**Mercosur**

**Protection Categories & Labelled FPS**

<table>
<thead>
<tr>
<th>Protection Category Designation</th>
<th>Mercosur</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>6 – 14.9</td>
<td>6, 10</td>
</tr>
<tr>
<td>Medium</td>
<td>15 – 29.9</td>
<td>15, 20, 25</td>
</tr>
<tr>
<td>High</td>
<td>30 – 50</td>
<td>30, 50</td>
</tr>
<tr>
<td>Very High</td>
<td>&gt;50 &lt;100</td>
<td>50+</td>
</tr>
</tbody>
</table>

FPUVA (minimum UVA protection FPUVA 2)

‘Broad protection’ is NOT accepted

Sunblock, 100% protection and no need to reapply claims not permitted

Warnings and instructions – hybrid between EU & USA
Russia

**Classification:** Cosmetics
'Special Products' - Whitening & Self Tan products

**Registration:** yes
**GOST R Declaration of Conformity** – documentation must include test results

**UV filters:** Very similar to EU
Russia Customs Union Technical Regulations Appendix V - UV filters

**Labelling and Testing:**
No separate Sunscreen directive/guideline
Tends to align with EU
USA Sunscreen Drug Products

Final Rule 2011 – Labeling and Effectiveness Testing

Still to be resolved:

Whether will permit SPFs above 50 in future?
Will sprays continue to be allowed?
What about wipes, powders, body washes?
‘New’ UV actives for which TEA applications made?
Combinations of existing UV filters?
Increasing concentration of Avobenzone from 3% to 5%?

When resolved will publish final monograph.
Sunscrenn manufacturers; BASF, L’Oreal, Beiersdorf, Ashland
Health organisations; Skin Cancer Foundation, Melanoma Research Foundation

**Sunscreen Innovation Act:**

- Hope to be signed into law this year
- Will accelerate FDA’s review of sunscreen Time & Extent Applications (TEA)
- Will amend the Food Drug & Cosmetic Act to introduce a transparent review within a set timeframe (11 months for new applications proposed)

Time & Extent Applications (TEA) made for 8 UV filters between 2002 – 2009 – still waiting for FDA approval

Only actives and combinations in 1999 Final Rule permitted
USA - no difference between primary and secondary sunscreens

Final Rule 2011 removed delay in implementing 1999 Drug Facts Final Rule
New Skin cancer/Skin Aging Alert for products with an SPF <15 or are not labelled as ‘Broad spectrum’. 

MISUNDERSTANDING: Cannot make a broad spectrum claim if SPF <15.
USA – OTC drug products

- Register establishment electronically, including contract manufacturers
- List products electronically – NOT pre-market approval
- Foreign companies must identify a US agent
- Current Good Manufacturing Practice (CGMP) - FDA audit facilities
- Warning letters + import detention notices published on FDA’s website
# Import Refusal Report

## Refusal Details as Recorded in OASIS by FDA for Refusal AEK-9750053-8/3/11

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer FEI</td>
<td>3007420424</td>
</tr>
<tr>
<td>Manufacturer Name</td>
<td>Trilogy</td>
</tr>
<tr>
<td>Manufacturer Address line 1</td>
<td>132 134 Old Hutt Road</td>
</tr>
<tr>
<td>Manufacturer Address line 2</td>
<td></td>
</tr>
<tr>
<td>Manufacturer's City</td>
<td>Wellington</td>
</tr>
<tr>
<td>Manufacturer Province/State</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Country/Area</td>
<td>New Zealand</td>
</tr>
<tr>
<td>Product Code</td>
<td>53LD03</td>
</tr>
<tr>
<td>Importer's Product Description</td>
<td>SKIN DEFENCE DAY CREAM WITH SPF15</td>
</tr>
<tr>
<td>Refusal Date</td>
<td>07-May-2009</td>
</tr>
<tr>
<td>FDA District</td>
<td>LOS-DO</td>
</tr>
<tr>
<td>Entry/doc/line/sfx</td>
<td>AEK-9750053-8/3/11</td>
</tr>
<tr>
<td>FDA Sample Analysis</td>
<td>No</td>
</tr>
<tr>
<td>FDA Record of Private Lab Sample Analysis</td>
<td>No</td>
</tr>
</tbody>
</table>

**Charge(s)**

<table>
<thead>
<tr>
<th>Violation Code</th>
<th>Section</th>
<th>Charge Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT LISTED</td>
<td>502(o), 801(a)(3); MISBRANDING</td>
<td>It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).</td>
</tr>
</tbody>
</table>
FDA Warning Letters

September and October 2012:

**Lancome**
- See significant deep wrinkle reduction in UV damaged skin, clinically proven.
- ... has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality.

**Greek Island Laboratories**
- Organic Plant Stem Cells ... reactivate your body’s own dormant and weak skin stem cells, pushing them to regenerate.
- Helps promote the development of collagen.

**Avon**
- Start rebuilding collagen in just 48 hours.
- Stimulate elastin to help improve elasticity and resilience.

**Bioque Technologies**
- Argireline provides all the muscle-relaxing properties of BOTOX®...
- ... repairs the structural damage that actually causes those wrinkles.
Canada

Classification:

**Drug** – organic UV filters (with TiO$_2$/ZnO)

**Natural Health product** – solely TiO$_2$/ZnO

Sunscreen Monograph July 2013 - aligns closely with US FDA Final Rule

Includes sprays (aerosols + non-aerosols) and powders - but not wipes

Covers all products that make sunscreen claims including secondary sunscreens. **Health Canada is considering reclassifying as cosmetics.**

Registration: yes

Label on front of pack:

Drug Identification Number (**DIN**)  
Natural Product Number (**NPN**)
Canada

**UV filters:** Same as USA. Reduced conc. 5 UV filters to align with FDA Final Rule 1999

**Labelling:** SPF Max 50+
UVA labelling optional
‘Broad spectrum’ allowed if critical wavelength ≥ 370 nm
‘Skin cancer/Skin Aging Alert’ for products with an SPF <15 or if do NOT have a critical wavelength ≥ 370 nm
UVA logo acceptable
Canada – uses

Claims not permitted:
... will repair or reverse any skin damage
Allows you to stay longer in the sun
Provides “X” times your natural protection against sunburn
Sunscreens with insect repellents

Claims outside Monograph that require support data:
Sustained action/long-lasting (longer than 2 hours)
Prevention of photoaging and/or related damage (i.e. age spots, wrinkles, etc.)
UVC protection claims

Source: Appendix 1 of Monograph
Canada Guidelines for Cosmetic Advertising and Labelling Claims

February 2006 and Interim June 2010
Acceptable and unacceptable claims on each product category

**Anti-Aging/Anti-Wrinkle - examples**

<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Unacceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduces the appearance of age spots</td>
<td>Collagen, elastin, skin enzyme synthesis/replenishment/stimulation/production unacceptable</td>
</tr>
<tr>
<td>Reverses the signs/look of aging (visibility)</td>
<td>De-pigments</td>
</tr>
<tr>
<td>Rejuvenates skin (qualified)</td>
<td>Rejuvenates skin (unqualified)</td>
</tr>
<tr>
<td>Skin brightening</td>
<td>Repairs (damaged) skin</td>
</tr>
</tbody>
</table>

Update expected imminently in a different format
Drug Establishment Licence (DEL)

A DEL is required for all facilities dealing with drugs.

A Quality Control Unit of a registered drug establishment must inspect all imported drugs on arrival in Canada. This includes testing locally the level of actives i.e. UV filters in each consignment.

A distributor without testing facilities cannot get a DEL, so must import through a third party who will receive, inspect and release the drugs.

To import a company must have a Pharmaceutical Quality Agreement with another provider in Canada. This makes it possible to import through a third party, who will receive, inspect and release goods, which can then be moved to a company's warehouse (which does not a licensed establishment).

Obtaining a DEL is onerous and prohibitively expensive.
Comparison of UVA Labelling

**USA** – Broad Spectrum

**Australia** – Broad Spectrum

**EU** – UVA

**Japan** - PA+, PA++, PA+++, PA++++

**Korea** - PA+, PA++, PA+++

**Mercosur** – FPUVA  [Broad protection is NOT accepted]

**ASEAN** – not specified. Accepts; 'UVA protection', ‘broad spectrum', UVA

**India** – not specified

**Russia** – not specified

**Canada** – not specified; UVA and Broad spectrum acceptable
Regulatory Reforms

USA
Sunscreen Innovation Act - signed into law this year?
Publish final monograph - timing?

Canada reclassify secondary sunscreens as cosmetics?

Australia
1. increase SPF from 15 to SPF 30 for secondary skincare sunscreens?
2. Regulate all secondary sunscreens as cosmetics?
3. Regulate all sunscreens as cosmetics?
Thank you

PCPC – International department
CTPA
CAPA - Argentina cosmetic trade association
KCIA – Republic of South Korea cosmetic trade association
JCIA – Japanese cosmetic trade association
Energiser
Estee Lauder
Avon
Oriflame
JPH SunCare Technologies
Engel, Hellyer & Partners Pty