TGA THERAPEUTIC GOODS ADMINISTRATION

NON-PRESCRIPTION MEDICINES BRANCH

Australian regulatory guidelines for OTC medicines

(ARGOM)

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Commonwealth Department of Health and Ageing

Sunscreens

Chapter added 24 September 2003

Introduction

Australia has the highest rate of melanoma in the world[1]. Many Australians use sunscreen every day of their lives, sometimes over large areas of their body surface. It is important therefore that sunscreens used in Australia are safe and effective and of good quality.

This chapter describes the regulatory requirements for sunscreens and their ingredients in Australia. It replaces all information on sunscreens contained in the TGA publication, *Listing drug products in the Australian Register of Therapeutic Goods for supply in Australia: Guidelines for applicants*[2].

Medicine or cosmetic?

Most sunscreens are regulated as medicines under the *Therapeutic Goods Act 1989*. Some products that contain an ingredient with sunscreening properties are regulated as cosmetics rather than as medicines where the primary purpose is not sunscreening. These cosmetic products are referred to as 'excluded' sunscreens and are not regulated under therapeutic goods legislation.

A table at the end of this chapter (*Summary of sunscreen regulation*) summarises the current regulation of the various categories of sunscreens. This information is based on the *Therapeutic Goods (Excluded Goods) Order No. 1 of 1998, Therapeutic Goods (Excluded Goods) Order No. 2 of 1998* and the *Therapeutic Goods Regulations 1990.*

The labelling of cosmetics is regulated by the Australian Competition and Consumer Commission (ACCC)[3]. The safety of ingredients used in cosmetics is regulated by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS)[4]

Regulatory requirements for sunscreens

Most sunscreens currently defined as medicines can be 'listed', some are exempt from registration or listing and some must be 'registered' in the Australian

[1] Marks R (2002) The changing incidence and mortality of melanoma in Australia. Recent Results Cancer Res. 160: 113-121, 2002
[2] www.tga.gov.au/docs/html/listguid.htm
[3] www.accc.gov.au
[4] www.tga.gov.au/chemicals/index.htm

Register of Therapeutic Goods (ARTG). General information on listing and registration is available on the TGA website[1].

Exempt sunscreens

These sunscreens do not require registration or listing in the Australian Register of Therapeutic Goods (ARTG) but are treated as medicines in all other respects. They must comply with all relevant parts of the legislation, for example:

- The Labelling Order (*Therapeutic Goods Order No. 69*)[2];
- The *Therapeutic Goods Advertising Code*[3].

Sunscreen products are 'exempt' if:

- The claimed SPF (established by testing according to AS/NZS 2604:1998[4]) is 3 or less; and
- The label claims comply with AS/NZS 2604:1998; and
- The product **does not** contain ingredients of human origin or from cattle, sheep, goats or mule deer that are derived from body parts listed in the Regulations (eg. adrenal glands, brain).

Exempt products can only contain active ingredients that are included in the list of *Sunscreening agents permitted as active ingredients in listed products* within the maximum concentrations stated in the list.

Reference: *Therapeutic Goods Regulations 1990*, Schedule 5, Part 8(g).

Listing of sunscreens

The majority of sunscreen products require listing in the ARTG. Products are eligible for listing where:

- The claimed SPF has been tested according to AS/NZS 2604:1998 and is 4 or greater; and
- The product does not make a 'prohibited' or 'restricted' representation as defined in Appendix 6 to the *Therapeutic Goods Advertising Code*[5] (note that *"prevention of skin cancer through the use of sunscreens"* is not a 'prohibited representation' for *some sunscreens*); and
- The labelling complies with AS/NZS 2604:1998, the *Labelling Order* and the *Therapeutic Goods Advertising Code*.

[1] www.tga.gov.au/docs/html/infokit.htm
[2] www.tga.gov.au/docs/html/tgo/tgo69.htm
[3] www.tgacc.com.au
[4] Australia/New Zealand Standard: Sunscreen products – evaluation and classification (available from Standards Australia www.standards.com.au)
[5] www.tgacc.com.au

Sunscreen products that are otherwise exempt will require listing where the product **does** contain ingredients of human origin or from cattle, sheep, goats or mule deer that are derived from parts listed in the *Therapeutic Goods Regulations 1990* (eg. adrenal glands, brain).

Applications for listing of sunscreen products that contain material of human or animal origin as above must include a pre-clearance certificate issued by the TGA Laboratories Branch (TGAL).

Listed sunscreen products can only contain active ingredients that are included in the list of *Sunscreening agents permitted as active ingredients in listed products* within the maximum concentrations stated in the list.

Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.

Sunscreen products that make claims other than sunscreening (eg. 'antioxidant' claims or claims relating to reduction of UV induced immune suppression) and / or contain active ingredients that are not included in the list of *Sunscreening agents permitted as active ingredients in listed products* are not 'sunscreen preparations' and must be registered as an OTC medicine rather than listed in the ARTG (see below for details of registration).

All other sunscreen products (ie. those that are neither exempt nor listable) must be registered in the ARTG.

Information on the listing process can be found on the TGA website[1].

Reference: *Therapeutic Goods Regulations 1990*, Schedule 4, Item 7.

Registration of sunscreens

'Registration' is the default category for sunscreens that are not 'exempt' or 'listable'. These products are evaluated by the TGA for quality, safety and efficacy under the provisions of Section 25 of the *Therapeutic Goods Act 1989*.

Products in this category include:

- Products that are to be included in the *Schedule of Pharmaceutical Benefits*;
- Products that contain a sunscreen active ingredient that is not included in the list of *Sunscreening agents permitted as active ingredients in listed products;*
- Products that make therapeutic claims other than sunscreening;
- Products that are not otherwise 'exempt' or 'listable'.

[1] www.tga.gov.au/docs/html/infokit.htm

Labelling of sunscreens

The labelling of sunscreen products must comply with:

- The Labelling Order (*Therapeutic Goods Order No. 69*) [1];
- The *Therapeutic Goods Advertising Code*[2];
- Australia/New Zealand Standard *AS/NZS 2604:1998* [3].

Note that AS/NZS 2604:1998 has particular requirements for the labelling of sunscreens:

- Specifications for the declaration of the SPF;
- Limitations on *"broad spectrum"* claims;
- Limitations on the use of *"water resistant"* claims.

The following claims are permitted for broad spectrum sunscreen preparations with a sun protection factor of '30 plus':

- may assist in preventing some skin cancers;
- may reduce the risk of some skin cancers;

provided that the product label highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear. Reference: *Gazette notice: Advertising sunscreens, 13 September 2002*[4].

A broad-spectrum sunscreening preparation may make the claim *"can aid in the prevention of premature skin ageing"* or words to that effect.
["30+" deleted after "broad spectrum" 13 February 2004]

The labels of sunscreen products should include statements to the effect of the following:

- Advise consumers to apply generous amounts of sunscreen over all exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling.

- Highlight the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear.

- Advise consumers to keep the product out of the eyes.

[1] www.tga.gov.au/docs/html/tgo/tgo69.htm
[2] www.tgacc.com.au
[3] Australia/New Zealand Standard: Sunscreen products – evaluation and classification (available from Standards Australia www.standards.com.au)
[4] www.tga.gov.au/docs/html/reg7csun.htm

The first and second requirements above do not apply to secondary sunscreens (those sunscreen products that are represented on the label as protecting the skin from harmful effects of the sun's rays while fulfilling another primary function). None of the above labelling requirements apply to lip preparations.

Stability testing of sunscreens

Guidelines for the stability testing of sunscreen products have been compiled by industry peak bodies and agreed by the TGA. Sponsors of all sunscreen products are expected to have performed stability testing on each product to at least the standard set out in these guidelines. The claimed shelf life and storage conditions for each product should be derived from the results of the stability testing on that product.

The stability testing guidelines for listed sunscreens can be found on the Australian Self Medication Industry (ASMI) website[1]. The stability testing guidelines for registered sunscreens can be found in Chapter 4E, *Stability testing*.

Microbial content and preservative efficacy of sunscreens

Sunscreen products in all categories (exempt, listed or registered) are expected to comply with the TGAL guidelines for microbiological testing for 'products for topical application' in Chapter 4F, *Microbiological testing*, and to comply with the preservative efficacy test in the current edition of the *British Pharmacopoeia.*

Manufacturers of sunscreens

Manufacturers of listed or registered sunscreens must be licensed or approved by the TGA. Information on licensing/approval is available on the TGA website[2].

Manufacturers of sunscreens are required to comply with the Australian Code of GMP for Therapeutic Goods – Sunscreen Products[3].

Sunscreening agents permitted as active ingredients in listed or exempt products

The only active ingredients permitted in exempt or listed sunscreens are those included in the table of *Sunscreening agents permitted as active ingredients in listed or exempt products*, within the maximum concentrations stated in the list. This list replaces the list included in the TGA publication, *Listing drug products*

[1] www.asmi.com.au/Stability%20G%20for%20Sunscreen.pdf
[2] www.tga.gov.au/manuf/index.htm
[3] www.tga.gov.au/docs/html/gmpsunsc.htm

in the Australian Register of Therapeutic Goods for supply in Australia: Guidelines for applicants[1] (pp 35 – 37).

Sponsors wanting to market a product containing an active ingredient not on the list must submit data to establish the safety of the ingredient under its proposed conditions of use (see below).

New active ingredients in sunscreens

Guidelines for the approval of new substances are given in Chapter 6B, *New substances*. This section (below) describes the specific requirements that apply to new sunscreen active ingredients and should be read in conjunction with Chapter 6B.

Data requirements

The table (below) gives specific references to the relevant guidelines for the types of data that are usually required for a new sunscreen active ingredient. All EU guidelines referenced below have been adopted by the TGA.

The intention in specifying these guidelines is not to impose them as absolute requirements but to assist sponsors in assessing the type and depth of information needed to support an application. If a particular guideline is not applicable or other data are available that adequately address the same criteria, alternative approaches based on adequate scientific justification will be considered.

Type of data	European guidelines reference
Photostability – UV absorption spectra	*Photostability testing of new active substances and medicinal products* (pp 157-166 of Rules 1998 (3A) – 3AQ18a) www.tga.gov.au/docs/pdf/euguide/vol3a/3aq18aen.pdf
Acute toxicity (oral and dermal)	*Single dose toxicity* (pp 3-8 of Rules 1998 (3B) – 3BS1a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs1aen.pdf
Local tolerance - skin irritation - phototoxicity - eye irritation	*Note for guidance on non-clinical local tolerance testing of medicinal products* (CPMP/SWP/2145/00) www.tga.gov.au/docs/pdf/euguide/swp/214500en.pdf
Allergenicity - skin sensitisation - photosensitisation	*Note for guidance on non-clinical local tolerance testing of medicinal products* (CPMP/SWP/2145/00) www.tga.gov.au/docs/pdf/euguide/swp/214500en.pdf

[1] www.tga.gov.au/docs/html/listguid.htm

Type of data	European guidelines reference
Toxicokinetics [a] - oral & dermal bioavailability (exposure) - ADME studies	*Repeated dose tissue distribution studies* (pp 21-24 of Rules 1998 (3B) – 3BS3a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs3aen.pdf *The assessment of systemic exposure in toxicity studies* (pp 89-101 of Rules 1998 (3B) – 3BS10a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs10aen.pdf *Pharmacokinetics and metabolic studies in the safety evaluation of new medicinal products in animals* (pp 103-106 of Rules 1998 (3B) – 3BS11a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs11aen.pdf
Repeat dose toxicity (oral & dermal) – 3 to 6 months data	*Note for guidance on repeated dose toxicity* (CPMP/SWP/1042/99) www.tga.gov.au/docs/pdf/euguide/swp/104299en.pdf **See also:** *Note for guidance on duration of chronic toxicity testing in animals (rodent and non-rodent toxicity testing)* (CPMP/SWP/300/95) www.tga.gov.au/docs/pdf/euguide/ich/030095entga.pdf
Genotoxicity [b] photomutagenicity	*Testing of medicinal products for their mutagenic potential* (pp 45-50 of Rules 1998 (3B) – 3BS5a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs5aen.pdf *Genotoxicity: Specific aspects of regulatory genotoxicity tests for pharmaceuticals* (pp 51-62 of Rules 1998 (3B) – 3BS6a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs6aen.pdf *Note for guidance on genotoxicity: A standard battery for genotoxicity testing of pharmaceuticals* (CPMP/ICH/174/95) www.tga.gov.au/docs/pdf/euguide/ich/017495en.pdf
Reproductive toxicity [c, e]	*Detection of toxicity to reproduction for medicinal products including toxicity to male fertility* (pp 25-44 of Rules 1998 (3B) – 3BS4a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs4aen.pdf
Carcinogenicity [d] photocarcinogenicity	*Carcinogenic potential* (pp 63-67 of Rules 1998 (3B) – 3BS7a) www.tga.gov.au/docs/pdf/euguide/vol3b/3bs7aen.pdf
Interaction potential	Since sunscreen formulations usually contain more than one active ingredient, data on the potential for interaction of the new substance with other UV filters will usually need to be provided.

a) An *in vivo* determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.
b) Genotoxicity testing in bacterial and mammalian cell lines, photomutagenicity test in bacteria, photomutagenicity in a chromosomal aberration test and an *in vivo* chromosome aberration assay.
c) For assessment of developmental and fertility effects
d) *In vivo* carcinogenicity and photocarcinogenicity bioassay or a justification for not providing these studies (see below).
e) Endocrine disruption potential needs to be addressed. This could be examined during the repeat-dose toxicity and/or reproductive toxicity studies.

Relevant human studies are acceptable in the assessment of potential skin irritation and sensitisation using the repeat insult patch test or other relevant validated tests.

Justification for not providing particular studies

In circumstances where particular tests specified in the table above are not feasible or appropriate, sponsors should submit a justification, based on sound scientific argument, for not including these tests in the dossier.

In the case of *in vivo* carcinogenicity bioassays, a justification for not including long-term studies could be based around issues such as:

- the expected pattern of use (identify possible low exposure);
- results of mutagenicity studies;
- lack of similarity to other molecules with known carcinogenic activity;
- low persistence in the skin ;
- low *in vivo* absorption;
- lack of photosensitisation or phototoxic potential;
- proven photostability;
- lack of possible adverse effects on the skin (change to epidermis/dermis);
- length of submitted repeat dose toxicity studies.

Related studies

Other studies that are not currently referenced in EC guidelines may be useful in supporting particular applications. Reference to these studies is included only as a guide. They will not be relevant in all cases, nor should they be seen as a complete list of relevant studies.

The following studies may be useful in providing information on the potential of a substance to cause tumours in people:

- Studies using a transgenic mouse model to test exposure to the substance (the transgenic mouse is heterozygous for the p53 suppressor gene and tumours develop in a relatively short time frame (6 months) in this strain of mouse)[1];

- *In vitro* human dermal cell cultures exposed to the substance[2];

- *In vitro* human dermal tumour cell cultures exposed to the substance[5].

The following references may be useful in justifying the use of ingredients with a potential for skin corrosion/irritation:

- Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products; M K Robinson *et al*; Food and Chemical Toxicology, 40(5), pp 573-592, 2002.

- OECD/OCDE, Draft TG431, March 2002, OECD Guidelines for the testing of chemicals; *in vitro* skin corrosion: human skin model test.

Chemistry requirements

In addition to the requirements stated in Chapter 4B, *Formulation*, sponsors should provide data to establish the UV absorption range of the substance together with data addressing the potential for physical interaction with other commonly used sunscreening agents.

New excipients in sunscreens

Where a sunscreen contains an excipient ingredient which is not in any product currently included in the Australian Register of Therapeutic Goods (ARTG) for supply in Australia, the excipient must be cleared for use by the TGA.

The following information is required:

1. Identification of the excipient as a substance included in the CTFA International Cosmetic Ingredient Dictionary (the page number and reference should be quoted); and
2. Assurance that it does not appear in Annex II to the EEC Directive 76/768 List of substances which must not form part of the composition of cosmetic products; and
3. Assurance that the excipient has been approved by the appropriate regulatory agency in Sweden, Canada, USA, UK or The Netherlands; or (less desirably)

[1] Reference: *Novel systems for the study of human diseases*; OECD Proceedings; OECD Online Bookshop Code 931998021P1 (Page 400)
[2] Methodology for these studies can be obtained from the scientific literature

4. Assurance by the applicant that there have been market-place sales of comparable products containing the excipient in one of those five countries for at least two years; and
5. Acute oral toxicity: LD_{50} – animal or alternative method; and
6. Irritation study – skin; animal or alternative method; and
7. Sensitisation study – skin; animal or alternative method.

The following additional studies may be requested in individual cases where concerns become evident at the time of evaluation.

8. Eye irritation study; and
9. *In vitro* mutagenicity (Ames) test; and
10. *In vitro* percutaneous absorption test.

All of the above information can be submitted prior to listing together with the *New substance application form*[1] (available from the TGA website). If the substance is cleared it will be given an 'Australian Approved Name' (AAN) and will thereafter be able to be used in other topical non-prescription medicines (subject to any conditions or limitations) without the need for further evaluation. The sponsor will be advised of the AAN and will then be able to submit an application to list/register the sunscreen product.

Alternative sources of data on the safety of the excipient will be considered. For instance, if the excipient has been cleared by NICNAS or by the US Cosmetic Ingredient Review (CIR) group the review document may be sufficient in itself. Copies of CIR reviews are available on the Internet[2]. Copies of NICNAS reviews may be available from the supplier of the excipient.

Alternatively, the information in the first four points above can be submitted as part of a 'Listing' application for a sunscreen together with an assurance that the data specified in points 5 to 7 will be provided to the TGA within 6 months of the date of listing of the product. The new excipient will be given a 'provisional AAN' (known as a 'PRV') and the product listed with a condition that the data must be provided within 6 months of listing. Failure to submit the specified data within this time may result in cancellation of the product from the ARTG and recall.

The data will be evaluated by the TGA and, if cleared, the excipient will be given an AAN and will thereafter be able to be used in other topical non-prescription medicines (subject to any conditions or limitations) without the need for further evaluation. If there are concerns about the safety of the excipient or if the data provided by the sponsor are incomplete or otherwise unacceptable, the product may be cancelled from the register and/or recalled.

[1] www.tga.gov.au/docs/html/substanc.htm
[2] www.cir-safety.org

Fees will apply to the evaluation of the data and the listing of the product as specified in the *Summary of fees and charges*[1].

Summary of sunscreen regulation

Product category	Sub-category	Currently regulated by TGA as:
Listable sunscreens	Sunscreens or moisturisers making SPF claims (or equivalent) where SPF is 4 or greater and claims are limited to sunscreening. Sunscreens that are otherwise exempt but contain certain ingredients of animal origin (see note below).	Listing in the ARTG.
Registrable sunscreens	Sunscreens that are included in the Schedule of Pharmaceutical Benefits. Sunscreens that make therapeutic claims other than sunscreening.	Registration in the ARTG.
Exempt sunscreens	Sunscreens or moisturisers making SPF claims (or equivalent) where SPF is 3 or less, claims are limited to sunscreening and the product does not contain certain ingredients of animal origin (see note below).	Exempt from listing or registration in ARTG, exempt from being made by a licensed manufacturer. Note: these sunscreens are still regulated as 'medicines' and must comply with the Labelling Order.

[1] www.tga.gov.au/docs/html/feesach.htm

Product category	Sub-category	Currently regulated by TGA as:
Excluded sunscreens	Tinted, unmedicated lip preparations (includes lipstick) without therapeutic claims (other than sunscreening) with or without SPF or equivalent declared on label. Other cosmetics (including moisturisers) without therapeutic claims (other than sunscreening) and without SPF claims or equivalent on the label.	Regulated by NICNAS / ACCC as a cosmetic

Note: The preceding table is a summary of legislative provisions. For complete details the following documents should be referred to:

- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods (Excluded Goods) Order No 1 of 1998*[1]
- *Therapeutic Goods (Excluded Goods) Order No 2 of 1998*[2]

[1] www.tga.gov.au/docs/html/tgeg9801.htm
[2] www.tga.gov.au/docs/html/tgeg9802.htm

Sunscreening agents permitted as active ingredients in listed products

Table updated 18 August 2006

Australian Approved Name (AAN)	EC & USA/FDA name	Synonyms/ abbreviations/ trade names	Maximum concentration
Aminobenzoic acid	4-Aminobenzoic acid		15%
Isoamyl methoxycinnamate	Isopentenyl-4-methoxycinnamate (Isoamyl 4-methoxycinnamate)		10%
Benzophenone		Phenylketone	To be determined
Benzophenone-2	Benzophenone-2	Bis(2,4-Dihydroxyphenyl) Methanone	To be determined
Butyl methoxy dibenzoylmethane	1-(4 tert butylphenyl)-3(4-methoxyphenyl)propane-1,3-dione	Avobenzone, BMDM, 4-tert-butyl-4-methoxy dibenzoylmethane	5%
Cinoxate	Cinoxate		6%
Dioxybenzone	Dioxybenzone	Benzophenone 8	3%
	Ethoxylated ethyl 4-aminobenzoic acid	PEG25 PABA	10%
Padimate O	2-Ethylhexyl 4-dimethylaminobenzoate	Octyl dimethyl PABA	8%
Octyl methoxycinnamate	Octyl methoxycinnamate	Ethylhexyl Methoxycinnamate	10%
Octyl salicylate	2-Ethylhexyl Salicylate		5%
Homosalate	Homosalate	Homomethyl salicylate	15%
Isopropylbenzyl salicylate	4-1sopropylbenzyl Salicylate		To be determined
Menthyl anthranilate	Menthyl Anthranilate	Methyl 2-aminobenzoate	5%
4 Methylbenzylidene camphor	3-(4-Methylbenzylidene)-d-1 camphor		4%
Octocrylene	2-cyano-3,3-diphenyl acrylic acid, 2-ethyl hexyl ester	2-Ethylhexyl-2-cyano-3,3 diphenylacrylate	10%
Octyl triazone	2,4,6-Trianalino-(p-Carbo-2'-ethylhexyl-1'oxy)1,3,5-Triazine		5%
	alpha-(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid and its salts		6% (as acid)
Oxybenzone	Oxybenzone	Benzophenone 3	10%
Phenylbenzimidazole sulfonic acid	2-Phenylbenzimidazole-5-sulfonic acid and its potassium, sodium and triethanolamine salts		4%

Australian Approved Name (AAN)	EC & USA/FDA name	Synonyms/ abbreviations/ trade names	Maximum concentration
	N,N,N-Trimethyl-4-(oxoborn-3-ylidenemethyl)anilinium methyl sulfate		6%
	Salicylic acid salts (potassium, sodium and triethanolamine)		To be determined
Sulisobenzone [2]		Benzophenone 4	10%
	Sulisobenzone sodium	Benzophenone 5	10%
Ecamsule	Terephthalylidene dicamphor sulfonic acid		10%
Titanium dioxide	Titanium dioxide		25%
Triethanolamine salicylate	Trolamine salicylate		12%
Zinc oxide [1]	Zinc oxide		No limit [1]
Bemotrizinol [3]	Bemotrizinol	Tinosorb S	10%
Methylene bis-benzotriazolyl tetramethylbutyl phenol [4]	2,2'-Methylene-bis-6-(2H-benzotriazol-2yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol	Tinosorb M	10%
Drometrizole trisiloxane [5]	phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6[2-methyl-3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy] disiloxanyl]propyl	Mexoryl XL	15%
Disodium phenyl dibenzimidazole tetrasulfonate [6]	2,2'-(1,4-Phenylene) bis-(1-H-benzimidazole-4,6-disulfonic acid, monosodium salt)	Bisimidazylate, Neoheliopan AP	10%
Polysilicone-15[7]	Dimethicodiethylbenzalmalonate	Parsol SLX	10%

1. Maximum concentration for zinc oxide amended 12 December 2003
2. 'Benzophenone-4' deleted from column 1 and 'Sulisobenzone' moved from column 2 to column 1, 25 June 2004
3. 'Bemotrizinol' added 22 November 2004
4. 'Methylene bis-benzotriazolyl tetramethylbutyl phenol' added 22 November 2004
5. 'Drometrizole trisiloxane' added 6 December 2004
6. 'Disodium phenyl dibenzimidazole tetrasulfonate' added 31 August 2005
7. Polysilicone-15 added 18 August 2006

Shading indicates that the sunscreen agent is currently under review – new products containing any of these ingredients will not be listed until the review has been completed

Note: Sponsors wanting to market a product containing an active ingredient not on this list must submit data to establish the safety of the ingredient under its proposed conditions of use (See *New active ingredients in sunscreens*).