Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

SUBSTANCES THAT MAY BE USED IN LISTED MEDICINES IN AUSTRALIA – CHANGES

12 December 2007

Substances that may be used in Listed medicines in Australia – log of changes

The following list reflect changes made to the document: ***Substances that may be used in Listed Medicines in Australia***

This list was updated on 12 December 2007.

Ingredient	Use[†]	Restrictions
Acetyl dipeptide-1 cetyl ester	E	Approved for topical use only. Concentration must not exceed 0.01%.
Acrylamide/sodium acryloyldimethyltaurate copolymer	E	Approved for topical use only. Concentration must not exceed 1.7%.
Alpha acids (humulone, cohumulone, adhumulone) of Humulus lupus	C	
Aluminium starch octenylsuccinate	E	Concentration must not exceed 7%.
Ammonium bicarbonate	A	This ingredient is only listable as an uncompounded BP substance.
Ammonium lactate	E	Approved for topical use only. Concentration must not exceed 0.1%.
Anacystis nidulans ferment	E	Approved for topical use only. Concentration must not exceed 0.0025%.
Anthocyanosides (of Vitis vinifera)	C	
Arginine ferulate	E	Approved for topical use only. Concentration must not exceed 0.0125%.
Ascorbyl tocopheryl maleate	E	Approved for topical use only. Concentration must not exceed 0.01%.
Brassica oleracea var. botrytis	A, E	Allyl isothiocyanate is a mandatory component of this ingredient when the plant part is seed (see separate entry).
Brassica oleracea var. capitata	A, E	Allyl isothiocyanate is a mandatory component of this ingredient when the plant part is seed (see separate entry).
Brassica oleracea var. gemmifera	A, E	Allyl isothiocyanate is a mandatory component of this ingredient when the plant part is seed (see separate entry).
Brassica oleracea var. Italia	A, E	Allyl isothiocyanate is a mandatory component of this ingredient when the plant part is seed (see separate entry).
Brassica oleracea var. viridis	A, E	Allyl isothiocyanate is a mandatory component of this ingredient when the plant part is seed (see separate entry).
Boron nitride	E	Approved for topical use only. Concentration must not exceed 0.5%.

Ingredient	Use†	Restrictions
Camellia oleifera	A, E	Camellia oleifera (seed oil) when used as a solvent is restricted to topical/suncreen preparations only.
Carthamus tinctorius	A, E	When Carthamus tinctorius is used as a solvent the resulting preparation is for topical use only.
Catechin (of Uncaria gambir)	C	
Cocamidopropyl betaine	E	Approved for topical use only. Concentration must not exceed 0.8% (buccal mucosa), 1% (dermal application) and 6% (wash-on/wash off products). Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropyl cocoamide; AA) should be controlled to below the level of detection.
Crithmum maritimum whole plant extract 1:9 in 50% propylene glycol : W ICID2004	E	Approved for topical use only. Concentration must not exceed 0.00341%.
Dipentaerythrityl tetrahydroxystearate/tetraisostearate	E	Approved for topical use only. Concentration must not exceed 5%.
Disodium oleamido PEG-2 sulfosuccinate	E	Approved for topical use only. Concentration must not exceed 1%.
Divinyldimethicone/dimethicone copolymer	E	Approved for topical use only. Concentration must not exceed 1.5%.
Ellagic acid (of Punica granatum)	C	
Fish oil, rich in in Omega-3 acids	A, E	If therapeutic indications are made against Vitamin A or Cholecalciferol (Vitamin D) then these are mandatory components of this ingredient (see separate entries). May be a native species – if exporting this product please contact the DEH.
Gallic acid (of Punica granatum)	C	
Glycerol	A, E	If used as a BP Uncompounded preparation – no restrictions, if used as an active as part of a formulation, restricted to topical only. If used as an excipent there are no restrictions.
Glyceryl isostearate	E	Approved for topical use only. Concentration must not exceed 3%.
Glyceryl oleate citrate	E	Approved for topical use only. Concentration must not exceed 4%.
Hexyldecanol	E	Approved for topical use only. Concentration must not exceed 3%.
Homosalate	A, E	Sunscreen ingredient permitted only in topical products. Concentration must not exceed 15%.
Hydrolysed algin	E	Approved for topical use only. Concentration must not exceed 0.02%.
Hydroxypropyl distarch phosphate	E	Approved for topical use only. Concentration must not exceed 2%. Synonym: Hydroxypropyl starch phosphate
Lauryl PEG/PPG-18/18 Methicone	E	Approved for topical use only. Concentration must not exceed 2%.

Ingredient	Use†	Restrictions
Maltol	E	
Oleic acid	E, C	
Palmitoyl oligopeptide	E	Approved for topical use only. Concentration must not exceed 0.002%.
Palmitoyl tetrapeptide-3	E	Approved for topical use only. Concentration must not exceed 0.001%.
PEG/PPG-18/18 dimethicone	E	Approved for topical use only. Concentration must not exceed 3%.
PEG-8 cetyl dimethicone	E	Approved for topical use only. Concentration must not exceed 0.0005%.
Pentasodium ethylenediamine tetramethylene phosphonate	E	Approved for topical use only. Concentration must not exceed 0.1%.
Polycaprolactone	E	Approved for topical use only. Concentration must not exceed 0.1%.
Polyglyceryl-3 polydimethylsiloxyethyl dimethicone	E	Polyglyceryl-3 polydimethylsiloxyethyl dimethicone is for dermal use only. The concentration of Polyglyceryl-3 polydimethylsiloxyethyl dimethicone is not to exceed 3%.
Polyglyceryl-6 polyricinoleate	E	Approved for topical use only. Concentration must not exceed 1%.
Potassium aspartate dihydrate	A, E	Potassium is a mandatory component of this ingredient. If used as an active AND intended as a mineral supplementation, the equivalent quantity of potassium is required on the product label.
Potassium aspartate monohydrate	A, E	Potassium is a mandatory component of this ingredient. If used as an active AND intended as a mineral supplementation, the equivalent quantity of potassium is required on the product label.
Proanthocyanidins calculated as procyanidine B1 (of Vaccinium macrocarpon)	C	
Punicalagins (of Punica granatum)	C	
Serenoa repens	A, E	Serenoa repens is the correct AAN and replaces the name Serenoa serrulata.
Sitosterol and sitosterol glycosides – calculated as sitosterol (of Prunus Africana)	C	
Sodium dehydroacetate	E	Approved only in topical preparations for localised effect. Requires the label statement SDACET.
Sodium DNA	E	Approved for topical use only. Concentration must not exceed 0.1%.
Sodium RNA	E	Approved for topical use only. Concentration must not exceed 0.1%.
Sodium hydroxyethyl acrylate/acryloyldimethyl taurate copolymer	E	Approved for topical use only. The concentration of Sodium hydroxyethyl acrylate/acryloyldimethyl taurate copolymer is not to exceed 1.5%.
Sorbitan palmitate	E	Approved for topical use only. Replaces Soritan monopalmitate.
Soy protein-hydrolysed	E	Approved for topical use only. Concentration must not exceed 0.5%.
Stannic oxide	E	Approved for topical use only. Concentration must not exceed 0.005%.
Stearyl dimethicone	E	Approved only in topical preparations for localised effect. Concentration must not exceed 4.5%. Requires the label statements EYE and EYE2.

Ingredient	Use†	Restrictions
Titanium dioxide	A, E	Not to be used in topical products intended for use in the eye. Concentration in topical products must not exceed 25%. For Sunscreen products only.
Torreya grandis	A, E ,H	REMOVED FROM THE LIST
Tribehenin	E	Approved for topical use only. Concentration must not exceed 6%.
Trimethoxycaprylyl silane	E	Approved for topical use only. Concentration must not exceed 0.25%.
Wool fat	A, E	If derived from Bovine, Deer, Goat, or Sheep from BSE High Risk Countries, this ingredient requires pre-clearance from TGAL. For Uncompounded BP Substances.
Wool fat - hydrous	A, E	If derived from Bovine, Deer, Goat, or Sheep from BSE High Risk Countries, this ingredient requires pre-clearance from TGAL. For Uncompounded BP Substances.

† **Ingredient Use**: A = active; E = excipient; C = component.

ABBREVIATIONS:

BP	British Pharmacopoeia
BSE	Bovine Spongiform Encephalopathy
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
CRC	Child Resistant Closure
DEH	Department of the Environment and Heritage: http://www.deh.gov.au/biodiversity/trade-use/index.html
MDD	Maximum Daily Dose
MRDD	Maximum Recommended Daily Dose
PRV	Provisional Ingredient – For further information on conditions related to PRVs, refer to the Australian Regulatory Guidelines for OTC Medicines: http://www.tga.gov.au/docs/html/argom.htm
RDD	Recommended Daily Dose
RFI	Restricted Flow Insert
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGAL	Therapeutic Goods Administration Laboratories