
*AMENDMENTS TO
TGA APPROVED TERMINOLOGY FOR MEDICINES – July 1999*

AMENDMENTS AS AT 6 MARCH 2001

CHAPTER 1 – AUSTRALIAN APPROVED NAMES FOR THERAPEUTIC SUBSTANCES

1. CHEMICAL SUBSTANCES

1.4 AUSTRALIAN APPROVED NAMES – CHEMICAL LISTS

1.4.1 Chemical Substance Names List

APPROVED NAME	REFERENCE	COMMENT
Abacavir sulfate	USAN	
Acetyllevocarnitine hydrochloride	CAS 5080-50-2	
N-Acetyltryptophan	BPAP	
Acidopholus/grape ferment	ICID	PRV
Acrylamide	CAS 79-06-1	
Adenine sulfate dihydrate	USP	
(S)-S-Adenosylmethionine	CAS 78548-84-2	
DL-Alanine	CAS 3020-72-7	
Aluminium zirconium trichlorohydrate complex	ICID*	
Amisulpride	INN	
DL-Aspartic acid	CAS 617-45-8	
Atosiban	INN	
Atosiban acetate	INN*	
Balsalazide	BAN	
Balsalazide sodium	BAN	
Bicisate dihydrochloride	CAS 14344-58-2	
Bupivacaine hydrochloride anhydrous	BP*	
Bupropion	INN*	
Bupropion hydrochloride	INN*	
Buserelin	INN	
C6-14 Olefin polymers - hydrogenated	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
C12-16 Alcohols	ICID	PRV
Calcium ascorbate threonate complex	TGA 2000	
Calcium diglutamate	FAO	
Calcium hydroxycitrate	TGA99	
Calcium pyruvate anhydrous	CAS 17070-07-4	
Calteridol calcium	BAN	
Carboprost	INN	
Carboprost trometamol	BAN	
Ceramide 2	ICID	PRV
Ceteareth-15	ICID	PRV
Cetrorelix	INN	
Cetrorelix acetate	BAN	
Cetyl myristate	ICID	PRV
Cholesteryl/behenyl/octyldodecyl lauroyl glutamate	ICID	
Chromium citrate	TGA2001	
Chromium nitrate nonahydrate	MI	
Conjugated linoleic acid 75%	CG	
Cystine dihydrochloride	CAS 300925-07-6	
Desoxyribose	MI*	
Dexamethasone sodium metasulfobenzoate	CAS 16978-57-7	
Dexmedetomidine	INN	
Dexmedetomidine hydrochloride	INN*	
Dicaprylyl carbonate	ICID	PRV
Dienogest	INN	
Diethylhexyl-2,6-naphthalate	CAS 127474-91-3	
Diisopropyl adipate	ICID	PRV
Dimethiconol stearate	ICID	PRV
Dimethylsiloxane/methylvinylsiloxane cross linked elastomer	TGA 2000	
Dioxane	CAS 123-91-1	
Dipropylene glycol dibenzoate	ICID	PRV
Disodium dimethicone copolyol sulfosuccinate	ICID	PRV
DNA (from Saccharomyces cerevisiae) ICID 2000 - hydrolysed	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Eletriptan	USAN	
Epoprostenol	INN	
Epoprostenol sodium	BAN	
Ertapenem	USAN*	
Ertapenem sodium	USAN	
Esomeprazole	INN	
Esomeprazole magnesium trihydrate	INN*	
Ethyl butylacetylaminopropionate	ICID	PRV
Ethylene dioleamide	ICID	
Exemestane	INN	
Ferric nitrate	BPAP	
Ferucarbotran	BAN	
Fludeoxyglucose[18F]	BP*	Formerly 2-Deoxy-2-[18F]-fluoro-d-glucose. Change of name in BP reference.
Fomivirsen	INN	
Fomivirsen sodium	INN	
Fosphenytoin sodium	USAN	
Frusemide sodium	BP*	
Gadoteridol	INN	
Galantamine	INN	
Galantamine hydrobromide	USAN	
Ganirelix	INN	
Ganirelix acetate	INN*	
Gatifloxacin	INN	
Gatifloxacin sesquihydrate	BAN	
Gemifloxacin	INN	
Gemifloxacin mesilate sesquihydrate	USAN	
Glucosamine	INN	
Glucosamine sulfate-potassium chloride complex	TGA99	
Glucosamine sulfate-sodium chloride complex	TGA99	
DL-Glutamic acid	CAS 617-65-2	
Glycereth-26	ICID	PRV
Glycol montanate	ICID	

APPROVED NAME	REFERENCE	COMMENT
Glycylglutamine monohydrate	CAS 13115-71-4	
Glycyltyrosine dihydrate	CAS 658-79-7	
Guanine hydrochloride monohydrate	USP	
Hydroxocobalamin acetate	BP	
Hydroxocobalamin chloride	BP	
Hydroxocobalamin sulfate	BP	
Hydroxycitric acid	CAS 6205-14-7	
Hypromellose acetate succinate	TGA 2000	
Ibandronic acid	INN	
Ibuprofen lysine	CAS	
Ibutilide	INN	
Icodextrin	INN	
Ipriflavone	INN	
DL-Isoleucine	CAS 443-79-8	
Lactic-glycolic copolymer	CAS 343436-01-5	
Lanreotide	INN	
Lanreotide acetate	USAN	
Lecithin liquid - soy phosphatidylserine-enriched soy	CG 2000	
Lecithin powder - soy phosphatidylserine-enriched soy	CG 2000	
Lercanidipine	INN	
Lercanidipine hydrochloride	BAN	
DL-Leucine	MI	
Levetiracetam	INN	
Levocarnitine	INN	
Levocarnitine fumarate	CAS 90471-79-7	
Levocarnitine hydrochloride	CAS 6645-46-1	
Levocarnitine magnesium citrate	CAS 134620-06-7	
Linezolid	INN	
R-alpha Lipoic acid	CAS 62-46-4	
R,S-alpha Lipoic acid	CAS 1077-28-7	
Lopinavir	INN	
Lovastatin	INN	
Lycopene	CG	

APPROVED NAME	REFERENCE	COMMENT
Magnesium diglutamate	FAO	
Magnesium silicate dihydrate	TGA99	
Magnesium sulfate heptahydrate	BP*	
Magnesium sulfate dihydrate	BP*	
Maize syrup - high fructose	TGA 2001	
Menthoxypropanediol	ICID	
Modafinil	INN	
Monoammonium glutamate	FCC*	
Myreth-4	ICID	
Nonoxinol 100	BAN*	
Nordihydroguaiaretic acid	ICID	PRV
Octafluoropropane	CAS 76-19-7	
Oseltamivir	INN	
Oseltamivir phosphate	CAS 204255-11-8	
Oxaliplatin	INN	
Oxcarbazepine	INN	
Oxitriptan	INN	
Paroxetine mesilate	INN*	
PEG-4 Oliviate	ICID	PRV
PEG-20 glyceryl stearate	ICID	
PEG-150 Pentaerythrityl tetrastearate	ICID	PRV
Pigment green 18 CI77288	CI	PRV
Pioglitazone	INN	
Pioglitazone hydrochloride	USAN	
Polifeprosan	INN	
Polycarbophil	INN	
Polyglyceryl-2 triisostearate	ICID	PRV
Potassium ascorbate dihydrate	CAS	
Potassium carbomer	ICID	PRV
Potassium cocoyl hydrolysed soy protein	ICID	PRV
Potassium hydroxycitrate	TGA99	
PPG-10 cetyl ether	ICID	PRV
PPG-15 stearyl ether benzoate	ICID	PRV
PPG-51/SMDI copolymer	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Propionyllevocarnitine	CAS 119793-66-7	
Propionyllevocarnitine hydrochloride	CAS 119793-66-7	
Propylene glycol caprylate	ICID	PRV
D-Pulegone	CAS 89-82-7	
Rabeprazole	INN	
Rabeprazole sodium	BAN	
Rapacuronium bromide	INN	
Ribose	BPAP	
Risedronate sodium	USAN	
Risedronic acid	INN	
RNA (from <i>Saccharomyces cerevisiae</i>) ICID 2000 - hydrolysed	ICID	PRV
Saccharide isomerate	ICID	PRV
Saccharomyces/calcium ferment	ICID	PRV
Saccharomyces/manganese ferment	ICID	PRV
Safrole	CAS 94-59-7	
DL-Serine	MI	
Sodium hydroxycitrate	TGA99	
Sodium hypoxanthine	TGA 2000	
Sodium ibandronate	BAN	
Sodium myreth sulfate	ICID	PRV
Sodium selenite pentahydrate	MI12	
Sodium xanthine	CAS 1196-43-6	
Sorbitan	CAS 27299-12-3	
Sorbitan olivate	ICID	PRV
Sorbitan palmitate	ICID	PRV
Stearoyl macroglycerides	BP	
Sugar cane wax alcohols	CG 2000	
Sulpiride	INN	
Tazarotene	INN	
Technetium[99mTc] biccisate	BAN	
Tegafur	INN	
Tegaserod	INN	
Tegaserod maleate	INN*	
Tetrahydrodiferuloylmethane	ICID	PRV

APPROVED NAME	REFERENCE	COMMENT
Thujone	MI	
Thymine	BPAP	
DL-alpha Tocopherol phosphate disodium	CAS 60934-46-5	
D-alpha Tocopheryl polyethylene glycol 1000 succinate	USP*	
Tocotrienols complex - palm	CG	
Travoprost	INN	
Tributyl citrate	USP	
Triisocetyl citrate	ICID	
DL-Tryptophan	FCC	
Tyrosine disodium	CAS 69847-45-6	
Unoprostone	INN	
Unoprostone isopropyl	INN*	
Uracil	USAN	
Urea[13C]	TGA99	
DL-Valine	MI	
Vanadyl sulfate	MI12	
Vanadyl sulfate dihydrate	MI12*	
Verteporfin	INN	
Wheat amino acids	ICID	PRV
Yeast - hydrolysed	ICID	PRV
Zinc picolinate monohydrate	CAS17949-65-4*	
Zoledronic acid	INN	

1.4.2 Label-AANs – Chemical List

LABEL- AAN	APPROVED NAME(S)	TYPE OF LABEL-AAN
Alcohol	Ethanol Ethanol - absolute	Excipient Group for Schedule 1 Medicines Labelling Order
Benzoates	Benzoic acid Calcium benzoate Potassium benzoate Sodium benzoate	Excipient Group for Schedule 1 Medicines Labelling Order

LABEL- AAN	APPROVED NAME(S)	TYPE OF LABEL-AAN
Hydroxybenzoates	Ethyl hydroxybenzoate Methyl hydroxybenzoate Propyl hydroxybenzoate Sodium ethyl hydroxybenzoate Sodium methyl hydroxybenzoate	Excipient Group for Schedule 1 Medicines Labelling Order
Sodium salts	Sodium chloride Sodium bicarbonate	Excipient Group for Schedule 1 Medicines Labelling Order
Sorbates	Sorbic acid Potassium sorbate	Excipient Group for Schedule 1 Medicines Labelling Order
Sugars	Glucose Honey Honey - purified Invert sugar Lactose Maltose Sucrose	Excipient Group for Schedule 1 Medicines Labelling Order
Sulfites	Sulfur dioxide Potassium metabisulfite Sodium metabisulfite Sodium sulfite	Excipient Group for Schedule 1 Medicines Labelling Order

1.5 AMENDMENTS AND SYNONYMS

1.5.1 Monograph Changes

APPROVED NAME	OLD REFERENCE	NEW REFERENCE
Calcium saccharate	USP	INN
Ipratropium bromide	BAN	BP
Oestrone sulfate – sodium	MAR	USAN
Camphor	BP	BP88

1.5.2 Synonyms for Chemical Substance Names

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Acetaldehyde-diethylacetal (CAS 105-57-7)	Acetal
Acetate PA	Allyl phenoxyacetate

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Acetic acid, ethyl ester	Ethyl acetate
Acid Yellow 17 CI18965	Yellow 2G CI18965
Alcohol C-6	Hexan-1-ol
Alcohol C-7	1-Heptanol
Alcohol C-9	n-Nonyl alcohol
Alcohol C-10	Decan-1-ol
Alcohol C-12	1-Dodecanol
Aldehyde C-6	Caproic aldehyde
Aldehyde C-7	Heptanal
Aldehyde C-8	Caprylic aldehyde
Aldehyde C-9	Nonanal
Aldehyde C-10	Decanal
Aldehyde C-11 undecyclic	Undecanal
Aldehyde C-11 undecylenic	10-Decanal
Aldehyde C-12 lauric	Lauryl aldehyde
Aldehyde C-12 MNA	2-Methylundecanal
Aldehyde C-14 (true)	Myristic aldehyde
Aldehyde C-14 So-called	gamma-Undecalactone
Aldehyde C-16 So-called	Ethyl methylphenylglycidate
Aldehyde C-18 So-called	gamma-Nonalactone
Aldehyde C-18 true	Octadecanal
Amfebutamone	Bupropion
Amfebutamone hydrochloride	Bupropion hydrochloride
Basic violet 10 CI45170	Rhodamine B CI45170
Benzodioxole-5-carbohyaldehyde	Piperonal
Benzoic acid, sodium salt	Sodium Benzoate
BHT	Butylated hydroxytoluene
Carbomer ETD 2050	Carbomer 2050
Carbomer Ultrez 10	Carbomer U-10
4-Chloro-3-methyl phenol	Chlorocresol
2-Deoxy-2-[18F]-fluroro-d-glucose	Fludeoxyglucose[18F]
Dimethyl siloxane reaction products with Silica	Simethicone
Dimethylcyclosiloxane	Cyclomethicone
Disodium adenosine triphosphate	Adenosine disodium phosphate

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
3-Ethoxy-4-hydroxy-benzaldehyde	Ethyl vanillin
Formic acid, ethyl ester	Ethyl formate
D-Glucosamine sulfate-potassium chloride complex	Glucosamine sulfate-potassium chloride complex
D-Glucosamine sulfate-sodium chloride complex	Glucosamine sulfate-sodium chloride complex
Glucose syrup dried	Glucose - liquid
Glucose syrup solids	Glucose - liquid
cis-3-Hexenol	cis-3-Hexen-1-ol
4-Hydroxy-3-methoxy-benzaldehyde	Vanillin
3-Hydroxy-2-methyl-4H-pyran-4-one	Maltol
3-Hydroxy-1,2,3-Propanetricarboxylic acid	See Citric acid
5-Hydroxytryptophan	Oxitriptan
l-5-Hydroxytryptophan	Oxitriptan
Isopentanal	Isovaleraldehyde
Lauryl alcohol	1-Dodecanol
Lutein	Xanthophyll
3-Methylbutyl acetate	Isoamyl acetate
Montanglycol	Glycol montanate
Ornithine hydrochloride	Ornithine monohydrochloride
Parachlorometacresol	Chlorocresol
Polyvinylpyrrolidone	Povidone
Ponceau 4R	Brilliant scarlet 4R CI16255
PVP	Povidone
Sodium carboxymethylcellulose	Carmellose sodium
Tocophersolan	Tocofersolan
D-alpha-Tocopheryl polyethylene glycol 1000 succinate	Tocofersolan
Tribasic calcium phosphate	Calcium phosphate
Trimethyl hexadecyl ammonium chloride	Cetrimonium chloride
Tromethamine	Trometamol

1.5.3 Other Changes to Entries

The following entries have had additions, deletions or changes made to the statements shown in the Comments field since the publication of the July 1999 edition. Current entries are shown.

APPROVED NAME	REFERENCE	COMMENT
Butyl ester of PVM/MA copolymer	ICID	PRV
Camphor	BP88	Includes natural (D) and synthetic (DL) forms.
Farnesol	MI	PRV
Lanosterol	ICID	PRV
Palmitoyl hydroxypropyltrimonium amylopectin/glycerin crosspolymer	ICID	PRV
Polyglyceryl-2 dipolyhydroxystearate	ICID	

1.6 DEVICE INGREDIENT CHEMICAL NAMES

1.6.2 Approved Device Ingredient Substance Names List

APPROVED NAME	REFERENCE	CAS NUMBER
Acid green 28	CI	
Acid red 1 CI18050	CI	
Acid violet 48	CI	CAS 12220-51-8
Alcohols, C6-C10 ethoxylated propoxylated	CAS 1569-01-3	CAS 1569-01-3
4-Benzyl-2-chlorophenol	CAS 31089-49-3	CAS 31089-49-3
2-Benzyl-4,6-dichlorophenol	CAS 19578-81-5	CAS 19578-81-5
4-Benzyl-2,6-dichlorophenol	CAS 38932-58-0	CAS 38932-58-
2-Benzyl phenol	CAS 28994-41-4	CAS 28994-41-4
4-Benzyl phenol	CAS 101-53-1	CAS 101-53-1
Butoxyethyl acetate	ICID	CAS 112-07-2
C6-12 Pareth-6	CAS 68439-45-2	CAS 68439-45-2
C11-15 Pareth-9	ICID	CAS 68131-40-8 (generic)
C12-15 Pareth-7	ICID	CAS 68131-39-5 (generic)

APPROVED NAME	REFERENCE	CAS NUMBER
C12-15 Pareth-12	ICID	CAS 68131-39-5 (generic)
C12-16 Pareth-7	CAS 68551-12-2	CAS 68551-12-2 (generic)
C12-16 Pareth-9	CAS 68551-12-2	CAS 68551-12-2 (generic)
Cupric nitrate trihydrate	MI	
Decamethylcyclopentasiloxane	MI	CAS 541-02-6
Decyldimethylisononylammonium chloride	CAS 138698-36-9	CAS 138698-36-9
Dimethyldioctylammonium chloride	CAS 5538-94-3	CAS 5538-94-3
Disodium cocoamphodipropionate	ICID	CAS 68604-71-7
Dodecamethylcyclohexasiloxane	MI	CAS 540-97-6
Ethylenediamine - ethoxylated propoxylated	CAS 26316-40-5	CAS 262316-40-5
Octamethylcyclotetrasiloxane	MI	CAS 556-67-2
PEG-9 Stearate	ICID	
para-tert-Pentylphenol	MI	CAS 80-46-6
ortho-Phthalaldehyde	CAS 643-79-8	CAS 643-79-8
Pigment violet 23 CI51319	CI	CAS 6358-30-1
PPG-4 C9-11 pareth-7	ICID*	
PPG-6 C12-18 Pareth-11	ICID	CAS 69227-21-0
Propylene glycol monopropyl ether	CAS 1569-01-3	CAS 1569-01-3
Quaternium-24	ICID	CAS 32426-11-2

1.6.3 Synonyms for Device Ingredient Chemical Names List

Applicants should note that synonyms ARE NOT approved names and should NOT BE USED in applications or on labels where approved terminology is required.

The following synonyms are provided for the assistance of applicants.

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Basic violet 10 CI45170	Rhodamine B CI45170
Basic violet 10 acetate	Rhodamine B acetate
C6-C12 Ethoxylated alcohol	C6-12 Pareth-6
4-Chloro-3-methyl phenol	Chlorocresol
2-Chloro-4-(phenylmethyl)-phenol	4-Benzyl-2-chlorophenol

SYNONYM (NOT TO BE USED)	APPROVED NAME (TO BE USED)
Dioctyl dimethyl ammonium chloride	Dimethyldioctylammonium chloride
Ethylene glycol monobutyl ether acetate	Butoxyethyl acetate
3-[(Ethylphenylamino)methyl]benzenesulfonic acid	alpha-N-Ethylanilintoluene-3-sulphonic acid
Myristyldimethylamine oxide	Myristamine oxide
Nonylphenol polyethylene glycol ether	Nonoxinol (Chain length to be specified)
Octyl decyl dimethyl ammonium chloride	Quaternium-24
Parachlorometacresol	Chlorocresol
Pareth-25-9	C12-15 Pareth-9
Sodium cocoamphodipropionate	Disodium cocoamphodipropionate
Trimethyl hexadexyl ammonium chloride	Cetrimonium chloride