Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 6 July 2018

Includes amendments up to: F2018L01003

This compilation is in 6 volumes

Volume 1: section 1–3, Schedule 1, Parts 1 and 2 (items 1–729)
Volume 2: Schedule 1, Part 2 (items 730–2137)
Volume 3: Schedule 1, Part 2 (items 2138—2814)
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Volume 6: Schedule 1, Part 2 (items 5014–5220)

Each volume has its own contents

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018* that shows the text of the law as amended and in force on 6 July 2018 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine

(section 4)

Part 2 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5014	UBIDECARENONE	A, E	When used as an excipient, the route of administration must be topical and the concentration in the medicine must not be more than 0.05%. Not to be included in medicines intended for use in the eye. When for internal use, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone. When for internal use in combination with Ubiquinol-10, the maximum recommended daily dose must not provide more than 300 milligrams of ubiquinol-10 and ubidecarenone combined. When for internal use, the following warning statement is required on the medicine label: - (WARF) 'Do not take while on warfarin therapy without

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medical advice'.
5015	UBIQUINOL-10	A, E	When used as an excipient, the route of administration must be topical and the concentration in the medicine must be no more than 0.05%. Not to be included in medicines intended for use in the eye. When for internal use, the maximum recommended daily dose must provide no more than 300 milligrams of ubiquinol-10. When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined. The medicine requires the following warning statement on the medicine label: - (WARF) 'Do not take while on warfarin therapy without medical advice.'
5016	ULEX EUROPAEUS	A, H	
5017	ULMUS AMERICANA	A, H	
5018	ULMUS CAMPESTRIS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5019	ULMUS GLABRA	A, H	
5020	ULMUS PARVIFOLIA	A, H	
5021	ULMUS PROCERA	A, H	
5022	ULMUS PUMILA	A, H	
5023	ULMUS RUBRA	A, H	
5024	ULTRALIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5025	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5026	ULVA LACTUCA	A, H	Iodine is a mandatory component of Ulva lactuca. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5027	UMBELLULARIA CALIFORNICA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5028	UNCARIA GAMBIR	A, H	
5029	UNCARIA RHYNCOPHYLLA	A, H	
5030	UNCARIA SINENSIS	A, H	
5031	UNCARIA TOMENTOSA	A, H	
5032	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5033	UNDECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5034	UNDECANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5035	UNDECENOIC ACID	E	
5036	UNDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5037	UNDECYLCRYLENE DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
5038	UNDECYLENAMIDE DEA	E	
5039	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5040	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
5041	UREA	A, E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10% (w/w).
5042	URTICA DIOICA	A, E, H	
5043	URTICA URENS	A, H	
5044	USNEA BARBATA	A, H	
5045	UVA URSI LEAF DRY	A, H	
5046	UVA URSI LEAF POWDER	A, E, H	
5047	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	E	Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate copolymer. The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 ppm. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5048	VACCARIA SEGATALIS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5049	VACCINIUM BRACTEATUM	A, H	
5050	VACCINIUM CORYMBOSUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5051	VACCINIUM MACROCARPON	A, E, H	
5052	VACCINIUM MYRTILLOIDES	A, H	
5053	VACCINIUM MYRTILLUS	A, E, H	
5054	VACCINIUM OXYCOCCUS	A, H	
5055	VACCINIUM VITIS-IDAEA	A, H	Arbutin is a mandatory component of Vaccinium vitis-idaea. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
5056	VALENCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5057	VALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5058	VALERIAN DRY	A, H	
5059	VALERIAN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5060	VALERIAN POWDER	A, H	
5061	VALERIANA EDULIS	A, H	
5062	VALERIANA OFFICINALIS	A, H	
5063	VALERIANA SORBIFOLIA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5064	VALERIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5065	VALINE	A, E	
5066	VANADIUM	H	
5067	VANILLA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5068	VANILLA DRY	A, E, H	
5069	VANILLA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5070	VANILLA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5071	VANILLA PLANIFOLIA	A, E, H	
5072	VANILLA POWDER	A, E, H	
5073	VANILLA TAHITENSIS	A, H	
5074	VANILLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5075	VANILLIN	E	
5076	VANILLIN ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5077	VANILLYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5078	VAT RED 1	E	Permitted for use only as a colour for topical use.
5079	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5080	VAT RED 5	E	Permitted for use only as a colour for topical use.
5081	VEGETABLE OIL	E	
5082	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women

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			(or words to that effect).'
5083	VEIN	H	Only for use as an active homoeopathic ingredient.
5084	VERATRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5085	VERATROL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
5086	VERATRUM ALBUM	A, H	Solanidine is a mandatory component of Veratrum album. The concentration of equivalent dry Veratrum album in the medicine must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 10mg/Kg or 10mg/L or 0.001%.
5087	VERBASCUM DENSIFLORUM	A, H	
5088	VERBASCUM THAPSUS	A, H	
5089	VERBENA OFFICINALIS	A, H	
5090	VERBENA OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5091	VERONICA CHAMAEDRYS	A, H	
5092	VERONICA OFFICINALIS	A, H	
5093	VERONICASTRUM VIRGINICUM	A, E, H	
5094	VERTONAL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. When included in a medicine for use on the lips the concentration of vertonal must be no more than 0.2%. The total fragrance proprietary excipient formulation in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
5095	VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5096	VETIVERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5097	VIBURNUM OPULUS	A, E, H	
5098	VIBURNUM PRUNIFOLIUM	A, E, H	
5099	VICIA FABA	A, H	Levodopa (of Vicia faba) is a mandatory component of Vicia faba. The concentration of Levodopa (of Vicia faba) from all ingredients in the medicine must be no more than 1mg/kg

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			or 1mg/L or 0.1%.
5100	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5101	VIGNA RADIATA	A, H	
5102	VIGNA UMBELLATA	A, H	
5103	VINCA MAJOR	A, H	Vincamine is a mandatory component of Vinca major. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
5104	VINCA MINOR	A, H	Vincamine and vincristine are mandatory components of Vinca minor. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5105	VINCETOXICUM OFFICINALE	A, H	
5106	VINEGAR	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5107	VIOLA ODORATA	A, E, H	
5108	VIOLA TRICOLOR	A, H	
5109	VIOLA YEDOENSIS	A, H	
5110	VIOLET LEAF ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5111	VIOLET LEAVES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5112	VIPER	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5113	VISCUM ALBUM	A, E, H	
5114	VISCUM COLORATUM	A, H	
5115	VISCUM FLAVESCENS	A, H	
5116	VITELLARIA PARADOXA	A, E, H	
5117	VITEX AGNUS-CASTUS	A, E, H	
5118	VITEX NEGUNDO	A, H	
5119	VITEX ROTUNDIFOLIA	A, H	
5120	VITEX TRIFOLIA	A, H	
5121	VITIS VINIFERA	A, E, H	
5122	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5123	WAHLENBERGIA GRACILIS	A, H	
5124	WALNUT	E	
5125	WALNUT OIL	E	
5126	WATER MELON	E	
5127	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal. When the route of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5128	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5129	WHEAT DEXTRIN	A, E	Only for use when the dosage form is capsule, tablet or pill. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to that effect.
5130	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5131	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of Wheat germ glycerides when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5132	WHEAT LEAF	E	
5133	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
5134	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
5135	WHEATGERM OIL	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5136	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5137	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5138	WHEY PROTEIN CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5139	WHITE BEESWAX	E	
5140	WHITE HOREHOUND HERB DRY	A, H	
5141	WHITE HOREHOUND HERB POWDER	A, H	
5142	WHITE SOFT PARAFFIN	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to

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			time.
5143	WHOLE DRY MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
5144	WIKSTROEMIA VIRIDIFLORA	A, H	
5145	WILD CARROT HERB DRY	A, E, H	
5146	WILD CARROT HERB POWDER	A, H	
5147	WILD CHERRY BARK DRY	A, H	
5148	WILD CHERRY BARK POWDER	A, H	
5149	WILD LETTUCE LEAF DRY	A, H	
5150	WILD LETTUCE LEAF POWDER	A, H	
5151	WINTERGREEN OIL	A, E, H	Methyl salicylate is a mandatory component of wintergreen oil. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid

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			preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5%, and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight'. (or words to that effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to this effect).
5152	WITHANIA SOMNIFERA	A, E, H	
5153	WOLFIPORIA COCOS	A, E, H	When the ingredient is included in a medicine that is listed in the Register before 1 July 2018 and supplied before 1 January 2020, the medicine label may refer to the ingredient name as 'Poria cocos' instead of 'Wolfiporia cocos'.
5154	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5155	WOOL FAT	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5156	XANTHAN GUM	E	
5157	XANTHIUM SIBIRICUM	A, H	
5158	XANTHIUM STRUMARIUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5159	XANTHOMONA CAMPESTRIS	A, H	
5160	XEROPHYLLUM ASPHODELOIDES	A, H	
5161	XYLENE	E	The residual solvent limit for xylene is 21.7 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.217%.
5162	XYLITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that effect]'.
5163	XYLOSE	E	
5164	YAM	E	
5165	YARROW HERB DRY	A, H	
5166	YARROW HERB POWDER	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5167	YEAST AUTOLYSATE	E	
5168	YEAST DRIED	A, E, H	
5169	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5170	YELLOW BEESWAX	E	
5171	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5172	YELLOW SOFT PARAFFIN	A, E	Only for use in topical medicines for dermal application. When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5173	YLANG YLANG OIL	A, E, H	
5174	YUCCA BACCATA	A, H	
5175	YUCCA ELATA	A, H	
5176	YUCCA FILAMENTOSA	A, H	
5177	YUCCA GLORIOSA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5178	YUCCA WHIPPLEI	A, H	
5179	ZANTHOXYLUM AMERICANUM	A, H	
5180	ZANTHOXYLUM BUNGEANUM	A, E, H	
5181	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5182	ZANTHOXYLUM NITIDUM	A, H	
5183	ZANTHOXYLUM PIPERITUM	A, H	
5184	ZANTHOXYLUM SIMULANS	A, H	
5185	ZEA MAYS	A, E, H	
5186	ZEAXANTHIN	A, E	
5187	ZEIN	E	
5188	ZINC	H	Only for use as an active homoeopathic ingredient. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			long period (or words to that effect)'.
5189	ZINC AMINO ACID CHELATE	A, E, H	When used internally, zinc is a mandatory component of zinc amino acid chelate. The concentration of zinc in zinc amino acid chelate must be no more than 30%. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5190	ZINC ASCORBATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5191	ZINC ASCORBATE MONOHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			long period (or words to that effect)'.
5192	ZINC CHLORIDE	A, E, H	The concentration of zinc chloride in the medicine must be no more than 5%. When used internally, zinc is a mandatory component of zinc chloride. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5193	ZINC CITRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate. When for internal use, the maximum recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5194	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5195	ZINC CITRATE TRIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate trihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5196	ZINC DIASPARTATE	A	When used internally, zinc is a mandatory component of zinc diaspartate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5197	ZINC GLUCONATE	A, E, H	When used internally, zinc is a mandatory component of zinc gluconate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			effect).'
5198	ZINC GLYCINATE	A	When used internally, zinc is a mandatory component of Zinc glycinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5199	ZINC GLYCINATE MONOHYDRATE	A	When used internally, zinc is a mandatory component of Zinc glycinate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.
5200	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye. The concentration of zinc lactate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5201	ZINC LACTATE DIHYDRATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye. The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%. The concentration of Zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%. Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old. Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5202	ZINC LYSINATE	A	When used internally, zinc is a mandatory component of Zinc lysinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5203	ZINC METHIONINE SULFATE	A	For topical use, the concentration of zinc methionine sulfate must be no more than 5%. When used internally, zinc is a mandatory component of zinc methionine sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5204	ZINC MYRISTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5205	ZINC OXIDE	A, E, H	When used internally, zinc is a mandatory component of zinc oxide. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dangerous if taken in large amounts or for a long period.' OR -'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).' When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			words to this effect).
5206	ZINC PARA-PHENOLSULFONATE	E	The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%. When used internally, zinc is a mandatory component of zinc para-phenolsulfate. The percentage of zinc from zinc para-phenolsulfonate should be calculated based on the molecular weight of zinc para-phenolsulfonate. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period' (or words to that effect).
5207	ZINC STEARATE	E	When used internally, zinc is a mandatory component of zinc stearate. The percentage of zinc from zinc stearate should be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			calculated based on the molecular weight of zinc stearate.
5208	ZINC SUCCINATE	A, E, H	When used internally, zinc is a mandatory component of zinc succinate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' or - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5209	ZINC SULFATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5210	ZINC SULFATE HEPTAHYDRATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate heptahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5211	ZINC SULFATE HEXAHYDRATE	A, E, H	For topical use, the concentration of zinc sulfate must be no more than 5%. For internal use, zinc is a mandatory component of zinc sulfate hexahydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5212	ZINC SULFATE MONOHYDRATE	A, E, H	When the route of administration is topical the concentration of zinc sulfate in the medicine must be no more than 5%. When the medicine is for internal use, zinc is a mandatory component of zinc sulfate monohydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5213	ZINC VALERATE	H	Only for use as an active homoeopathic ingredient. For internal use, zinc is a mandatory component of zinc valerate. The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.
5214	ZINGERONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5215	ZINGIBER OFFICINALE	A, E, H	When for oral use AND the extract ratio is equal to or more than 25:1 AND the equivalent dry weight per dosage unit is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			equal to or more than 2g, the medicine requires the following warning statement on the medicine label: - (GINGER) 'Individuals taking anticoagulants should seek medical advice before taking this medicine.' AND 'Individuals at risk of bleeding problems should seek advice from their healthcare practitioner prior to taking this medicine'.
5216	ZIZIPHUS JUJUBA	A, H	
5217	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5218	ZIZYPHUS SATIVA	A, H	
5219	ZOSTERA MARINA	A, H	
5220	ZUCCHINI	E	

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted
am = amended
amdt = amendment
c = clause(s)
C[x] = Compilation No. x
Ch = Chapter(s)
def = definition(s)
Dict = Dictionary
disallowed = disallowed by Parliament
Div = Division(s)
ed = editorial change
exp = expires/expired or ceases/ceased to have effect
F = Federal Register of Legislation
gaz = gazette
LA = *Legislation Act 2003*
LIA = *Legislative Instruments Act 2003*
(md) = misdescribed amendment can be given effect
(md not incorp) = misdescribed amendment cannot be given effect
mod = modified/modification
No. = Number(s)
o = order(s)
Ord = Ordinance
orig = original
par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
pres = present
prev = previous
(prev…) = previously
Pt = Part(s)
r = regulation(s)/rule(s)
reloc = relocated
renum = renumbered
rep = repealed
rs = repealed and substituted
s = section(s)/subsection(s)
Sch = Schedule(s)
Sdiv = Subdivision(s)
SLI = Select Legislative Instrument
SR = Statutory Rules
Sub-Ch = Sub-Chapter(s)
SubPt = Subpart(s)
underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018	18 June 2018 (F2018L00781)	19 June 2018 (s 2)	
Therapeutic Goods (Permissible Ingredients) Amendment Determination No. 2 of 2018	5 July 2018 (F2018L01003)	6 July 2018 (s 2(1) item 1)	—

Endnote 4—Amendment history

Provision affected	How affected
Schedule 1	
Part 2 – Table 1,	
Item 332	am F2018L01003
Item 645	am F2018L01003
Item 1308	am F2018L01003
Item 2817	am F2018L01003
Item 2936	am F2018L01003
Item 3564	am F2018L01003
Item 4192	am F2018L01003
Item 4193	am F2018L01003
Item 4272	am F2018L01003
Item 5007	am F2018L01003
Item 5055	am F2018L01003