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

Note: See sections 5, 6 and 6A.

Item	Ingredient Name	Purpose	Specific requirements
5074	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 medical advice'.
5075	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:

Volume 6

			- (WARF) 'Do not take while on warfarin therapy without medical advice.'
5076	ULEX EUROPAEUS	A, H	
5077	ULMUS AMERICANA	A, H	
5078	ULMUS CAMPESTRIS	A, H	
5079	ULMUS GLABRA	A, H	
5080	ULMUS MINOR	A, H	
5081	ULMUS PARVIFOLIA	A, H	
5082	ULMUS PUMILA	A, H	
5083	ULMUS RUBRA	A, H	
5084	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%.
5085	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5086	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%.
5087	UMBELLULARIA CALIFORNICA	A, H	
5088	UNCARIA GAMBIR	A, H	
5089	UNCARIA RHYNCOPHYLLA	A, H	
5090	UNCARIA SINENSIS	A, H	
5091	UNCARIA TOMENTOSA	A, H	
5092	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5093	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%.
5094	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%.
5095	UNDECENOIC ACID	E	
5096	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%.
5097	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%.
5098	UNDECYLENAMIDE DEA	E	
5099	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5100	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5101	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).
5102	UROLITHIN A	A	Until 19 September 2027, urolithin A must only be used in a medicine where: (a) Timeline Nutrition Australia Pty Ltd (Client ID 84148) is the sponsor of the medicine (the primary sponsor); or

			(b) another person is the sponsor of the medicine (the secondary sponsor) and the TGA has been notified that the secondary sponsor has been authorised by the primary sponsor to use the ingredient in the medicine. The route of administration for medicines that contain urolithin A must be oral. The maximum recommended daily dose of a medicine must not exceed 1000 mg of urolithin A. Medicines that contain urolithin A must be indicated for use in adults only and not in pregnant or lactating women. The recommended duration for use for a medicine containing urolithin A must be four months or less.
5103	URTICA DIOICA	A, E, H	
5104	URTICA URENS	A, H	
5105	USNEA BARBATA	A, H	
5106	UVA URSI LEAF DRY	A, H	
5107	UVA URSI LEAF POWDER	A, E, H	
5108	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%.
5109	VACCARIA SEGATALIS	A, H	
5110	VACCINIUM BRACTEATUM	A, H	
5111	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%.
5112	VACCINIUM MACROCARPON	A, E, H	

5113	VACCINIUM MYRTILLOIDES	A, H	
5114	VACCINIUM MYRTILLUS	A, E, H	
5115	VACCINIUM OXYCOCCUS	A, H	
5116	VACCINIUM VITIS-IDAEA	A, H	Beta-arbutin is a mandatory component of Vaccinium vitis-idaea. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5117	VALENCENE	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%.
5118	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%.
5119	VALERIAN DRY	A, H	The following warning statement is required on the medicine label when the medicine is for oral use: (VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'

Volume 6

5120	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%.
5121	VALERIAN POWDER	A, H	The following warning statement is required on the medicine label when the medicine is for oral use: (VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'
5122	VALERIANA EDULIS	A, H	
5123	VALERIANA OFFICINALIS	A, H	The following warning statement is required on the medicine label when the medicine is for oral use: (VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'
5124	VALERIANA SORBIFOLIA	A, H	
5125	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%.
5126	VALINE	A, E	
5127	VANADIUM	H	
5128	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%.
5129	VANILLA DRY	A, E, H	

5130	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%.
5131	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%.
5132	VANILLA PLANIFOLIA	A, E, H	
5133	VANILLA POWDER	A, E, H	
5134	VANILLA TAHITENSIS	A, H	
5135	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%.
5136	VANILLIN	E	
5137	VANILLIN ACETATE	E	Vanillin acetate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing vanillin acetate must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 1.8 micrograms of vanillin acetate.
5138	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Volume 6

5139	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%.
5140	VAT RED 1	E	Permitted for use only as a colour for topical use.
5141	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5142	VAT RED 5	E	Permitted for use only as a colour for topical use.
5143	VEGETABLE OIL	E	
5144	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 (or words to that effect).'
5145	VEIN	H	Only for use as an active homoeopathic ingredient.
5146	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%.
5147	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%.

5148	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 more than 10mg/Kg or 10mg/L or 0.001%.
5149	VERBASCUM DENSIFLORUM	A, H	
5150	VERBASCUM THAPSUS	A, H	
5151	VERBENA OFFICINALIS	A, H	
5152	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%.
5153	VERONICA CHAMAEDRYS	A, H	
5154	VERONICA OFFICINALIS	A, H	
5155	VERONICASTRUM VIRGINICUM	A, E, H	
5156	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 1%.
5157	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%.
5158	VETIVERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Volume 6

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5159	VIBURNUM OPULUS	A, E, H	
5160	VIBURNUM PRUNIFOLIUM	A, E, H	
5161	VICIA FABA	A, H	Levodopa is a mandatory component of Vicia faba. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5162	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5163	VIGNA RADIATA	A, H	
5164	VIGNA UMBELLATA	A, H	
5165	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%.
5166	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%
5167	VINCETOXICUM OFFICINALE	A, H	
5168	VINEGAR	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%.
5169	VIOLA ODORATA	A, E, H	
5170	VIOLA TRICOLOR	A, H	
5171	VIOLA YEDOENSIS	A, H	
5172	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 than 1%.
5173	VIPER	H	Only for use as an active homoeopathic ingredient.
5174	VISCUM ALBUM	A, E, H	
5175	VISCUM COLORATUM	A, H	
5176	VISCUM FLAVESCENS	A, H	
5177	VITELLARIA PARADOXA	A, E, H	
5178	VITEX AGNUS-CASTUS	A, E, H	When the ingredient is in a medicine that is for internal use, the following warning statement is required on the label: - (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).
5179	VITEX NEGUNDO	A, H	
5180	VITEX ROTUNDIFOLIA	A, H	
5181	VITEX TRIFOLIA	A, H	
5182	VITIS VINIFERA	A, E, H	
5183	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5184	VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must not be more than 2.00%.
5185	WAHLENBERGIA GRACILIS	A, H	
5186	WALNUT	E	
5187	WALNUT OIL	E	
5188	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.

Volume 6

5189	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5190	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin. Only for use when the dosage form is capsule, tablet or pill.
5191	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than topical and mucosal.
5192	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5193	WHEAT LEAF	E	
5194	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.
5195	WHEATGERM OIL	A, E, H	
5196	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5197	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5198	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%.
5199	WHITE BEESWAX	E	
5200	WHITE HOREHOUND HERB DRY	A, H	
5201	WHITE HOREHOUND HERB POWDER	A, H	

5202	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 time.
5203	WHOLE DRY MILK	E	
5204	WIKSTROEMIA VIRIDIFLORA	A, H	
5205	WILD CARROT HERB DRY	A, E, H	
5206	WILD CARROT HERB POWDER	A, H	
5207	WILD CHERRY BARK DRY	A, H	Amygdalin and hydrocyanic acid are mandatory components of wild cherry bark dry. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
5208	WILD CHERRY BARK POWDER	A, H	Amygdalin and hydrocyanic acid are mandatory components of wild cherry bark powder. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
5209	WILD LETTUCE LEAF DRY	A, H	
5210	WILD LETTUCE LEAF POWDER	A, H	
5211	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 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. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) 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); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
5212	WITHANIA SOMNIFERA	A, E, H	The medicine requires the following warning statement on the label: - (WITHANIA) 'If you are pregnant, or considering becoming pregnant, do not

			take without consulting a health professional' (or words to that effect) unless: (a) the plant part is root; (b) the plant preparation is an extract; (c) the extraction solvents are only water, ethanol or methanol; and (d) the maximum recommended daily dose of the medicine contains no more than the equivalent quantity of 12 g dry root.
5213	WOLFIPORIA COCOS	A, E, H	
5214	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5215	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.
5216	XANTHAN GUM	E	
5217	XANTHIUM SIBIRICUM	A, H	The requirements specified in paragraphs (a) to (h) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. (a) Carboxyatractyloside and atractyloside are mandatory components of Xanthium sibiricum. (b) The concentration of carboxyatractyloside must not be more than 0.35% of Xanthium sibiricum. (c) The concentration of atractyloside must not be more than 0.3% of Xanthium sibiricum. (d) The route of administration for medicines that contain Xanthium sibiricum must be limited to oral. (e) The plant part must be limited to fruit that is dried, cooked and had the spines removed.

Volume 6

			(f) The plant preparation must be limited to dry, powder, and extraction preparations with water as the only solvent. (g) The maximum recommended daily dose of the medicine must not provide more than 10 g of Xanthium sibiricum. (h) The medicine must not be directed for use in children, those who are pregnant, likely to become pregnant, or lactating.
5218	XANTHIUM STRUMARIUM	A, H	The requirements specified in paragraphs (a) to (h) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. (a) Carboxyatractyloside and atractyloside are mandatory components of Xanthium strumarium. (b) The concentration of carboxyatractyloside must not be more than 0.35% of Xanthium strumarium. (c) The concentration of atractyloside must not be more than 0.3% of Xanthium strumarium. (d) The route of administration for medicines that contain Xanthium strumarium must be limited to oral. (e) The plant part must be limited to fruit that is dried, cooked and had the spines removed. (f) The plant preparation must be limited to dry, powder, and extraction preparations with water as the only solvent. (g) The maximum recommended daily dose of the medicine must not provide more than 10 g of Xanthium strumarium. (h) The medicine must not be directed for use in children, those who are pregnant, likely to become pregnant, or lactating.
5219	XANTHOMONA CAMPESTRIS	A, H	
5220	XEROPHYLLUM ASPHODELOIDES	A, H	

5221	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%.
5222	XYLITOL	E	
5223	XYLOSE	E	
5224	YAM	E	
5225	YARROW HERB DRY	A, H	
5226	YARROW HERB POWDER	A, H	
5227	YEAST AUTOLYSATE	E	
5228	YEAST DRIED	A, E, H	
5229	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5230	YELLOW BEESWAX	E	
5231	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5232	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.
5233	YLANG YLANG OIL	A, E, H	
5234	YUCCA BACCATA	A, H	
5235	YUCCA ELATA	A, H	
5236	YUCCA FILAMENTOSA	A, H	
5237	YUCCA GLORIOSA	A, H	
5238	Z-BETA-DAMASCONE	E	Z – beta damascone must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing Z – beta damascone must not be more than 5% of the total medicine.

Volume 6

5239	ZANTHOXYLUM AMERICANUM	A, H	
5240	ZANTHOXYLUM BUNGEANUM	A, E, H	
5241	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5242	ZANTHOXYLUM NITIDUM	A, H	
5243	ZANTHOXYLUM PIPERITUM	A, H	
5244	ZANTHOXYLUM SIMULANS	A, H	
5245	ZEA MAYS	A, E, H	
5246	ZEAXANTHIN	A, E	
5247	ZEIN	E	
5248	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 long period (or words to that effect)'.
5249	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).'
5250	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. 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).'
5251	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 long period (or words to that effect)'.
5252	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:

Volume 6

			Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5253	ZINC CITRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate. 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).'
5254	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 which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5255	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).'
5256	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 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).'
5257	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 effect).'
5258	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.

Volume 6

			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).'
5259	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 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)'.
5260	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 not be more than 2%. The concentration of zinc lactate in a medicine for 'dental' use in toothpaste medicines must not be 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 (or words to the same effect) on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.

5261	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 not be more than 2%. The concentration of zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must not be 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 dihydrate for dental use require the following warning statement (or words to the same effect) on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5262	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).'
5263	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.

Volume 6

			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).'
5264	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%.
5265	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 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, the following warning statements are required on the 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).
5266	ZINC PARA-PHENOLSULFONATE	E	Only permitted for use in topical medicines for dermal use. The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%.

5267	ZINC STEARATE	E	When used internally, zinc is a mandatory component of zinc stearate. The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate. When for internal use, the maximum recommended daily dose must not provide more than 50 milligrams of zinc. When for internal use and the maximum recommended daily dose is more than 25 milligrams but not more than 50 milligrams of zinc, the medicine requires the following warning statement (or words to the same effect) 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’.
5268	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).'
5269	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 sulfate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.

Volume 6

			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).'
5270	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. 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).'
5271	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 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).'
5272	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.' OR - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5273	ZINC VALERATE	H	Only for use as an active homoeopathic ingredient. When 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. When for internal use, the maximum recommended daily dose must not provide more than 50 milligrams of zinc. When for internal use and the maximum recommended daily dose is more than 25 milligrams but not more than 50 milligrams of zinc, the medicine requires the following warning statement (or words to the same effect) on the medicine label: - (ZINC) ‘WARNING: May be dangerous if taken in large amounts or for a long period’; or

Volume 6

			'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period'.
5274	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%.
5275	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 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'.
5276	ZIZIPHUS JUJUBA	A, H	
5277	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5278	ZIZYPHUS SATIVA	A, H	
5279	ZOSTERA MARINA	A, H	