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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5051	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'.
5052	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

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.'
5053	ULEX EUROPAEUS	A, H	
5054	ULMUS AMERICANA	A, H	
5055	ULMUS CAMPESTRIS	A, H	
5056	ULMUS GLABRA	A, H	
5057	ULMUS PARVIFOLIA	A, H	
5058	ULMUS PROCERA	A, H	
5059	ULMUS PUMILA	A, H	
5060	ULMUS RUBRA	A, H	
5061	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5062	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5063	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%.
5064	UMBELLULARIA CALIFORNICA	A, H	
5065	UNCARIA GAMBIR	A, H	
5066	UNCARIA RHYNCOPHYLLA	A, H	
5067	UNCARIA SINENSIS	A, H	
5068	UNCARIA TOMENTOSA	A, H	
5069	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5070	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
5071	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%.
5072	UNDECENOIC ACID	E	
5073	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%.
5074	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%.
5075	UNDECYLENAMIDE DEA	E	
5076	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5077	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5078	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).
5079	URTICA DIOICA	A, E, H	
5080	URTICA URENS	A, H	
5081	USNEA BARBATA	A, H	
5082	UVA URSI LEAF DRY	A, H	
5083	UVA URSI LEAF POWDER	A, E, H	
5084	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%.
5085	VACCARIA SEGATALIS	A, H	
5086	VACCINIUM BRACTEATUM	A, H	

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5087	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%.
5088	VACCINIUM MACROCARPON	A, E, H	
5089	VACCINIUM MYRTILLOIDES	A, H	
5090	VACCINIUM MYRTILLUS	A, E, H	
5091	VACCINIUM OXYCOCCUS	A, H	
5092	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 %.
5093	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%.
5094	VALERALDEHYDE	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5095	VALERIAN DRY	A, H	
5096	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%.
5097	VALERIAN POWDER	A, H	
5098	VALERIANA EDULIS	A, H	
5099	VALERIANA OFFICINALIS	A, H	
5100	VALERIANA SORBIFOLIA	A, H	
5101	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%.
5102	VALINE	A, E	
5103	VANADIUM	H	
5104	VANILLA	E	Permitted for use only in combination with other

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
5105	VANILLA DRY	A, E, H	
5106	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%.
5107	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%.
5108	VANILLA PLANIFOLIA	A, E, H	
5109	VANILLA POWDER	A, E, H	
5110	VANILLA TAHITENSIS	A, H	
5111	VANILLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
5112	VANILLIN	E	
5113	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%.
5114	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%.
5115	VAT RED 1	E	Permitted for use only as a colour for topical use.
5116	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5117	VAT RED 5	E	Permitted for use only as a colour for topical use.
5118	VEGETABLE OIL	E	

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5119	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).'
5120	VEIN	H	Only for use as an active homoeopathic ingredient.
5121	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%.
5122	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%.
5123	VERATRUM ALBUM	A, H	Solanidine is a mandatory component of Veratrum album. The concentration of equivalent dry Veratrum album

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
5124	VERBASCUM DENSIFLORUM	A, H	
5125	VERBASCUM THAPSUS	A, H	
5126	VERBENA OFFICINALIS	A, H	
5127	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%.
5128	VERONICA CHAMAEDRYS	A, H	
5129	VERONICA OFFICINALIS	A, H	
5130	VERONICASTRUM VIRGINICUM	A, E, H	
5131	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%.
5132	VETIVER OIL	E	Permitted for use only in combination with other permitted ingredients as a

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
5133	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%.
5134	VIBURNUM OPULUS	A, E, H	
5135	VIBURNUM PRUNIFOLIUM	A, E, H	
5136	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 or 1mg/L or 0.1%.
5137	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5138	VIGNA RADIATA	A, H	
5139	VIGNA UMBELLATA	A, H	
5140	VINCA MAJOR	A, H	Vincamine is a mandatory component of Vinca major. The concentration of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
5141	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%
5142	VINCETOXICUM OFFICINALE	A, H	
5143	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%.
5144	VIOLA ODORATA	A, E, H	
5145	VIOLA TRICOLOR	A, H	
5146	VIOLA YEDOENSIS	A, H	
5147	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%.

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5148	VIPER	H	Only for use as an active homoeopathic ingredient.
5149	VISCUM ALBUM	A, E, H	
5150	VISCUM COLORATUM	A, H	
5151	VISCUM FLAVESCENS	A, H	
5152	VITELLARIA PARADOXA	A, E, H	
5153	VITEX AGNUS-CASTUS	A, E, H	When the ingredient is in a medicine that is for internal use and is listed in the Register on or after 2 March 2020, or that is supplied after 2 March 2021, 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).
5154	VITEX NEGUNDO	A, H	
5155	VITEX ROTUNDIFOLIA	A, H	
5156	VITEX TRIFOLIA	A, H	
5157	VITIS VINIFERA	A, E, H	
5158	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.1%.
5159	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%.
5160	WAHLENBERGIA GRACILIS	A, H	
5161	WALNUT	E	
5162	WALNUT OIL	E	
5163	WATER MELON	E	
5164	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.
5165	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5166	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin. Only for use when the dosage form is capsule, tablet or pill.
5167	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			topical and mucosal.
5168	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5169	WHEAT LEAF	E	
5170	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal.
5171	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.
5172	WHEATGERM OIL	A, E, H	
5173	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5174	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5175	WHEY PROTEIN CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5176	WHITE BEESWAX	E	
5177	WHITE HOREHOUND HERB DRY	A, H	
5178	WHITE HOREHOUND HERB POWDER	A, H	
5179	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.
5180	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).
5181	WIKSTROEMIA VIRIDIFLORA	A, H	
5182	WILD CARROT HERB DRY	A, E, H	
5183	WILD CARROT HERB POWDER	A, H	
5184	WILD CHERRY BARK DRY	A, H	
5185	WILD CHERRY BARK POWDER	A, H	
5186	WILD LETTUCE LEAF DRY	A, H	

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5187	WILD LETTUCE LEAF POWDER	A, H	
5188	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
5189	WITHANIA SOMNIFERA	A, E, H	The requirements specified in paragraph (a) below apply in relation to a medicine that contains the ingredient that:

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) 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: (i) the plant part is root; (ii) the plant preparation is an extract; (iii) the extraction solvents are only water, ethanol or methanol; and (iv) the maximum recommended daily dose of the medicine contains no more than the equivalent quantity of 12 g dry root.
5190	WOLFIPORIA COCOS	A, E, H	
5191	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5192	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			British Pharmacopoeia, as in force or existing from time to time.
5193	XANTHAN GUM	E	
5194	XANTHIUM SIBIRICUM	A, H	
5195	XANTHIUM STRUMARIUM	A, H	
5196	XANTHOMONA CAMPESTRIS	A, H	
5197	XEROPHYLLUM ASPHODELOIDES	A, H	
5198	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%.
5199	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]'.
5200	XYLOSE	E	
5201	YAM	E	

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5202	YARROW HERB DRY	A, H	
5203	YARROW HERB POWDER	A, H	
5204	YEAST AUTOLYSATE	E	
5205	YEAST DRIED	A, E, H	
5206	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5207	YELLOW BEESWAX	E	
5208	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5209	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.
5210	YLANG YLANG OIL	A, E, H	
5211	YUCCA BACCATA	A, H	
5212	YUCCA ELATA	A, H	
5213	YUCCA FILAMENTOSA	A, H	
5214	YUCCA GLORIOSA	A, H	
5215	YUCCA WHIPPLEI	A, H	
5216	ZANTHOXYLUM AMERICANUM	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5217	ZANTHOXYLUM BUNGEANUM	A, E, H	
5218	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5219	ZANTHOXYLUM NITIDUM	A, H	
5220	ZANTHOXYLUM PIPERITUM	A, H	
5221	ZANTHOXYLUM SIMULANS	A, H	
5222	ZEA MAYS	A, E, H	
5223	ZEAXANTHIN	A, E	
5224	ZEIN	E	
5225	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)'.
5226	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5227	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).'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5228	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)'.
5229	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5230	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).'
5231	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5232	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).'
5233	ZINC DIASPARTATE	A	When used internally, zinc is a

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5234	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5235	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).'
5236	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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)'.
5237	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 label: - (CHILD3) 'Use in children under 12 years is not recommended'.
5238	ZINC LACTATE DIHYDRATE	E	Only for use in topical and dental medicines and not to be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
5239	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5240	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 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).'
5241	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must be no more than 0.1%.
5242	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).
5243	ZINC PARA-PHENOLSULFONATE	E	The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%. When used internally, zinc is a

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
5244	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.
5245	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5246	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. 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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			taken in large amounts or for a long period (or words to that effect).'
5247	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).'
5248	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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

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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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.
5251	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%.
5252	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
5253	ZIZIPHUS JUJUBA	A, H	
5254	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5255	ZIZYPHUS SATIVA	A, H	
5256	ZOSTERA MARINA	A, H	
5257	ZUCCHINI	E	

Volume 6

Schedule 2—Repeals

Note: See section 7.

Therapeutic Goods (Permissible Ingredients) Determination (No.1) 2020

1 The whole of the instrument

Repeal the instrument.