Volume 6

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**
5043	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'.
5044	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

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.'
5045	ULEX EUROPAEUS	A, H	
5046	ULMUS AMERICANA	A, H	
5047	ULMUS CAMPESTRIS	A, H	
5048	ULMUS GLABRA	A, H	
5049	ULMUS PARVIFOLIA	A, H	
5050	ULMUS PROCERA	A, H	
5051	ULMUS PUMILA	A, H	
5052	ULMUS RUBRA	A, H	
5053	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%.

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**
5054	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5055	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%.
5056	UMBELLULARIA CALIFORNICA	A, H	
5057	UNCARIA GAMBIR	A, H	
5058	UNCARIA RHYNCOPHYLLA	A, H	
5059	UNCARIA SINENSIS	A, H	
5060	UNCARIA TOMENTOSA	A, H	
5061	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5062	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5063	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%.
5064	UNDECENOIC ACID	E	
5065	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%.
5066	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%.
5067	UNDECYLENAMIDE DEA	E	
5068	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.

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**
5069	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5070	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).
5071	URTICA DIOICA	A, E, H	
5072	URTICA URENS	A, H	
5073	USNEA BARBATA	A, H	
5074	UVA URSI LEAF DRY	A, H	
5075	UVA URSI LEAF POWDER	A, E, H	
5076	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%.
5077	VACCARIA SEGATALIS	A, H	
5078	VACCINIUM BRACTEATUM	A, H	
5079	VACCINIUM CORYMBOSUM	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
5080	VACCINIUM MACROCARPON	A, E, H	
5081	VACCINIUM MYRTILLOIDES	A, H	
5082	VACCINIUM MYRTILLUS	A, E, H	
5083	VACCINIUM OXYCOCCUS	A, H	
5084	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 %.
5085	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%.
5086	VALERALDEHYDE	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. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5087	VALERIAN DRY	A, H	
5088	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%.
5089	VALERIAN POWDER	A, H	
5090	VALERIANA EDULIS	A, H	
5091	VALERIANA OFFICINALIS	A, H	
5092	VALERIANA SORBIFOLIA	A, H	
5093	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%.
5094	VALINE	A, E	
5095	VANADIUM	H	
5096	VANILLA	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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	VANILLA DRY	A, E, H	
5098	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%.
5099	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%.
5100	VANILLA PLANIFOLIA	A, E, H	
5101	VANILLA POWDER	A, E, H	
5102	VANILLA TAHITENSIS	A, H	
5103	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

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**
			5%.
5104	VANILLIN	E	
5105	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%.
5106	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%.
5107	VAT RED 1	E	Permitted for use only as a colour for topical use.
5108	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5109	VAT RED 5	E	Permitted for use only as a colour for topical use.
5110	VEGETABLE OIL	E	
5111	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the

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: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
5112	VEIN	H	Only for use as an active homoeopathic ingredient.
5113	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%.
5114	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%.
5115	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

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**
			or 0.001%.
5116	VERBASCUM DENSIFLORUM	A, H	
5117	VERBASCUM THAPSUS	A, H	
5118	VERBENA OFFICINALIS	A, H	
5119	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%.
5120	VERONICA CHAMAEDRYS	A, H	
5121	VERONICA OFFICINALIS	A, H	
5122	VERONICASTRUM VIRGINICUM	A, E, H	
5123	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%.
5124	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

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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5125	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%.
5126	VIBURNUM OPULUS	A, E, H	
5127	VIBURNUM PRUNIFOLIUM	A, E, H	
5128	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%.
5129	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5130	VIGNA RADIATA	A, H	
5131	VIGNA UMBELLATA	A, H	
5132	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

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**
			or 10 mg/L or 0.001%.
5133	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%
5134	VINCETOXICUM OFFICINALE	A, H	
5135	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%.
5136	VIOLA ODORATA	A, E, H	
5137	VIOLA TRICOLOR	A, H	
5138	VIOLA YEDOENSIS	A, H	
5139	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
5140	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%.
5141	VIPER	H	Only for use as an active homoeopathic ingredient.
5142	VISCUM ALBUM	A, E, H	
5143	VISCUM COLORATUM	A, H	
5144	VISCUM FLAVESCENS	A, H	
5145	VITELLARIA PARADOXA	A, E, H	
5146	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).
5147	VITEX NEGUNDO	A, H	
5148	VITEX ROTUNDIFOLIA	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**
5149	VITEX TRIFOLIA	A, H	
5150	VITIS VINIFERA	A, E, H	
5151	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5152	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%.
5153	WAHLENBERGIA GRACILIS	A, H	
5154	WALNUT	E	
5155	WALNUT OIL	E	
5156	WATER MELON	E	
5157	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.
5158	WHEAT BRAN	E	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5159	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			Only for use when the dosage form is capsule, tablet or pill.
5160	WHEAT GERM	E	Gluten is a mandatory component of Wheat germ when the route of administration is other than topical and mucosal.
5161	WHEAT GERM GLYCERIDES	E	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5162	WHEAT LEAF	E	
5163	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout when the route of administration is other than topical and mucosal.
5164	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.
5165	WHEATGERM OIL	A, E, H	
5166	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5167	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			administration is oral.
5168	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%.
5169	WHITE BEESWAX	E	
5170	WHITE HOREHOUND HERB DRY	A, H	
5171	WHITE HOREHOUND HERB POWDER	A, H	
5172	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.
5173	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).
5174	WIKSTROEMIA VIRIDIFLORA	A, H	
5175	WILD CARROT HERB DRY	A, E, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5176	WILD CARROT HERB POWDER	A, H	
5177	WILD CHERRY BARK DRY	A, H	
5178	WILD CHERRY BARK POWDER	A, H	
5179	WILD LETTUCE LEAF DRY	A, H	
5180	WILD LETTUCE LEAF POWDER	A, H	
5181	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

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**
			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'.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5182	WITHANIA SOMNIFERA	A, E, H	The requirements specified in paragraph (a) below apply in relation to a medicine that contains the ingredient that: - 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.
5183	WOLFIPORIA COCOS	A, E, H	
5184	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5185	WOOL FAT	A, E	When used as an active ingredient, can only be

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**
			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.
5186	XANTHAN GUM	E	
5187	XANTHIUM SIBIRICUM	A, H	
5188	XANTHIUM STRUMARIUM	A, H	
5189	XANTHOMONA CAMPESTRIS	A, H	
5190	XEROPHYLLUM ASPHODELOIDES	A, H	
5191	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%.
5192	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			effect]'.
5193	XYLOSE	E	
5194	YAM	E	
5195	YARROW HERB DRY	A, H	
5196	YARROW HERB POWDER	A, H	
5197	YEAST AUTOLYSATE	E	
5198	YEAST DRIED	A, E, H	
5199	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5200	YELLOW BEESWAX	E	
5201	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5202	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.
5203	YLANG YLANG OIL	A, E, H	
5204	YUCCA BACCATA	A, H	
5205	YUCCA ELATA	A, H	
5206	YUCCA FILAMENTOSA	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**
5207	YUCCA GLORIOSA	A, H	
5208	YUCCA WHIPPLEI	A, H	
5209	ZANTHOXYLUM AMERICANUM	A, H	
5210	ZANTHOXYLUM BUNGEANUM	A, E, H	
5211	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5212	ZANTHOXYLUM NITIDUM	A, H	
5213	ZANTHOXYLUM PIPERITUM	A, H	
5214	ZANTHOXYLUM SIMULANS	A, H	
5215	ZEA MAYS	A, E, H	
5216	ZEAXANTHIN	A, E	
5217	ZEIN	E	
5218	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)'.
5219	ZINC AMINO ACID CHELATE	A, E, H	When used internally, zinc is a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5220	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

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**
			taken in large amounts or for a long period (or words to that effect).'
5221	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)'.
5222	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5223	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).'
5224	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate.

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**
			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).'
5225	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			effect).'
5226	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).'
5227	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:

Volume 6

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

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

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**
5231	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'.
5232	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

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

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**
5234	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%.
5235	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).

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
5236	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).
5237	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.
5238	ZINC SUCCINATE	A, E, H	When used internally, zinc is a mandatory component of zinc

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**
			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).'
5239	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

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 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).'
5241	ZINC SULFATE HEXAHYDRATE	A, E, H	For topical use, the concentration of zinc sulfate 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**
			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).'
5242	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).'
5243	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.
5244	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%.
5245	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

Volume 6

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
5246	ZIZIPHUS JUJUBA	A, H	
5247	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5248	ZIZYPHUS SATIVA	A, H	
5249	ZOSTERA MARINA	A, H	
5250	ZUCCHINI	E	

Schedule 2—Repeals

Note: See section 7.

Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2019

1 The whole of the instrument

Repeal the instrument.