

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

(section 4)

Part 1 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5018	UBIDECARENONE	A, E	<p>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%.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 300 milligrams of ubidecarenone.</p> <p>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.</p> <p>When for internal use, the following warning statement is required on the medicine label:</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (WARF) 'Do not take while on warfarin therapy without medical advice'.
5019	UBIQUINOL-10	A, E	<p>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%.</p> <p>Not to be included in medicines intended for use in the eye.</p> <p>When for internal use, the maximum recommended daily dose must provide no more than 300 milligrams of ubiquinol-10.</p> <p>When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (WARF) 'Do not take while on warfarin therapy without medical advice.'</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5020	ULEX EUROPAEUS	A, H	
5021	ULMUS AMERICANA	A, H	
5022	ULMUS CAMPESTRIS	A, H	
5023	ULMUS GLABRA	A, H	
5024	ULMUS PARVIFOLIA	A, H	
5025	ULMUS PROCERA	A, H	
5026	ULMUS PUMILA	A, H	
5027	ULMUS RUBRA	A, H	
5028	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%.
5029	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5030	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

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye. The concentration in the medicine must be no more than 0.1%.
5031	UMBELLULARIA CALIFORNICA	A, H	
5032	UNCARIA GAMBIR	A, H	
5033	UNCARIA RHYNCOPHYLLA	A, H	
5034	UNCARIA SINENSIS	A, H	
5035	UNCARIA TOMENTOSA	A, H	
5036	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5037	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%.

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5038	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%.
5039	UNDECENOIC ACID	E	
5040	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%.
5041	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

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			10%.
5042	UNDECYLENAMIDE DEA	E	
5043	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5044	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5045	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).
5046	URTICA DIOICA	A, E, H	
5047	URTICA URENS	A, H	
5048	USNEA BARBATA	A, H	
5049	UVA URSI LEAF DRY	A, H	
5050	UVA URSI LEAF POWDER	A, E, H	
5051	VA/BUTYL MALEATE/ISOBORNYL ACRYLATE COPOLYMER	E	Vinyl acetate is a mandatory component of VA/butyl maleate/isobornyl acrylate

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>copolymer.</p> <p>The concentration of vinyl acetate in the medicine must be no more than 0.01% or 100 ppm.</p> <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
5052	VACCARIA SEGATALIS	A, H	
5053	VACCINIUM BRACTEATUM	A, H	
5054	VACCINIUM CORYMBOSUM	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
5055	VACCINIUM MACROCARPON	A, E, H	
5056	VACCINIUM MYRTILLOIDES	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5057	VACCINIUM MYRTILLUS	A, E, H	
5058	VACCINIUM OXYCOCCUS	A, H	
5059	VACCINIUM VITIS-IDAEA	A, H	<p>Arbutin is a mandatory component of Vaccinium vitis-idaea.</p> <p>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.</p> <p>When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.</p>
5060	VALENCENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
5061	VALERALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p>

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%.
5062	VALERIAN DRY	A, H	
5063	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%.
5064	VALERIAN POWDER	A, H	
5065	VALERIANA EDULIS	A, H	
5066	VALERIANA OFFICINALIS	A, H	
5067	VALERIANA SORBIFOLIA	A, H	
5068	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5069	VALINE	A, E	
5070	VANADIUM	H	
5071	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%.
5072	VANILLA DRY	A, E, H	
5073	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%.
5074	VANILLA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5075	VANILLA PLANIFOLIA	A, E, H	
5076	VANILLA POWDER	A, E, H	
5077	VANILLA TAHITENSIS	A, H	
5078	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%.
5079	VANILLIN	E	
5080	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

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
5081	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%.
5082	VAT RED 1	E	Permitted for use only as a colour for topical use.
5083	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5084	VAT RED 5	E	Permitted for use only as a colour for topical use.
5085	VEGETABLE OIL	E	
5086	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
5087	VEIN	H	Only for use as an active homoeopathic ingredient.
5088	VERATRALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
5089	VERATROL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5090	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%.
5091	VERBASCUM DENSIFLORUM	A, H	
5092	VERBASCUM THAPSUS	A, H	
5093	VERBENA OFFICINALIS	A, H	
5094	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%.
5095	VERONICA CHAMAEDRYIS	A, H	
5096	VERONICA OFFICINALIS	A, H	
5097	VERONICASTRUM VIRGINICUM	A, E, H	
5098	VERTONAL	E	Permitted for use only in combination with other permitted ingredients as part of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>a fragrance proprietary excipient formulation.</p> <p>When included in a medicine for use on the lips the concentration of vertonal must be no more than 0.2%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
5099	VETIVER OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
5100	VETIVERYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
5101	VIBURNUM OPULUS	A, E, H	
5102	VIBURNUM PRUNIFOLIUM	A, E, H	
5103	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%.
5104	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5105	VIGNA RADIATA	A, H	
5106	VIGNA UMBELLATA	A, H	
5107	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%.
5108	VINCA MINOR	A, H	Vincamine and vincristine are mandatory components of

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>Vinca minor.</p> <p>The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.</p> <p>The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%</p>
5109	VINCETOXICUM OFFICINALE	A, H	
5110	VINEGAR	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
5111	VIOLA ODORATA	A, E, H	
5112	VIOLA TRICOLOR	A, H	
5113	VIOLA YEDOENSIS	A, H	
5114	VIOLET LEAF ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
5115	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%.
5116	VIPER	H	Only for use as an active homoeopathic ingredient.
5117	VISCUM ALBUM	A, E, H	
5118	VISCUM COLORATUM	A, H	
5119	VISCUM FLAVESCENS	A, H	
5120	VITELLARIA PARADOXA	A, E, H	
5121	VITEX AGNUS-CASTUS	A, E, H	
5122	VITEX NEGUNDO	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5123	VITEX ROTUNDIFOLIA	A, H	
5124	VITEX TRIFOLIA	A, H	
5125	VITIS VINIFERA	A, E, H	
5126	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5127	WAHLENBERGIA GRACILIS	A, H	
5128	WALNUT	E	
5129	WALNUT OIL	E	
5130	WATER MELON	E	
5131	WHEAT	E	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5132	WHEAT BRAN	E	<p>Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
5133	WHEAT DEXTRIN	A, E	<p>Only for use when the dosage form is capsule, tablet or pill.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
5134	WHEAT GERM	E	<p>Gluten is a mandatory component of Wheat germ</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
5135	WHEAT GERM GLYCERIDES	E	<p>Gluten is a mandatory component of Wheat germ glycerides when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
5136	WHEAT LEAF	E	
5137	WHEAT SPROUT	E	Gluten is a mandatory

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>component of Wheat sprout when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
5138	WHEAT STARCH	E	<p>When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).</p>
5139	WHEATGERM OIL	A, E, H	

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5140	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5141	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5142	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%.
5143	WHITE BEESWAX	E	
5144	WHITE HOREHOUND HERB DRY	A, H	
5145	WHITE HOREHOUND HERB POWDER	A, H	
5146	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

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5147	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).
5148	WIKSTROEMIA VIRIDIFLORA	A, H	
5149	WILD CARROT HERB DRY	A, E, H	
5150	WILD CARROT HERB POWDER	A, H	
5151	WILD CHERRY BARK DRY	A, H	
5152	WILD CHERRY BARK POWDER	A, H	
5153	WILD LETTUCE LEAF DRY	A, H	
5154	WILD LETTUCE LEAF POWDER	A, H	
5155	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> - 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. <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);</p> <p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).</p> <p>a) The following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight'. (or words to that effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
5156	WITHANIA SOMNIFERA	A, E, H	
5157	WOLFIPORIA COCOS	A, E, H	When the ingredient is included in a medicine that is listed in the Register before 1 July 2018 and supplied before 1 January 2020, the medicine label may refer to the ingredient name as 'Poria cocos' instead of 'Wolfiporia cocos'.
5158	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5159	WOOL FAT	A, E	When used as an active ingredient, can only be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
5160	XANTHAN GUM	E	
5161	XANTHIUM SIBIRICUM	A, H	
5162	XANTHIUM STRUMARIUM	A, H	
5163	XANTHOMONA CAMPESTRIS	A, H	
5164	XEROPHYLLUM ASPHODELOIDES	A, H	
5165	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%.
5166	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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]'
5167	XYLOSE	E	
5168	YAM	E	
5169	YARROW HERB DRY	A, H	
5170	YARROW HERB POWDER	A, H	
5171	YEAST AUTOLYSATE	E	
5172	YEAST DRIED	A, E, H	
5173	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5174	YELLOW BEESWAX	E	
5175	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5176	YELLOW SOFT PARAFFIN	A, E	Only for use in topical medicines for dermal

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
5177	YLANG YLANG OIL	A, E, H	
5178	YUCCA BACCATA	A, H	
5179	YUCCA ELATA	A, H	
5180	YUCCA FILAMENTOSA	A, H	
5181	YUCCA GLORIOSA	A, H	
5182	YUCCA WHIPPLEI	A, H	
5183	ZANTHOXYLUM AMERICANUM	A, H	
5184	ZANTHOXYLUM BUNGEANUM	A, E, H	
5185	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5186	ZANTHOXYLUM NITIDUM	A, H	
5187	ZANTHOXYLUM PIPERITUM	A, H	
5188	ZANTHOXYLUM SIMULANS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5189	ZEA MAYS	A, E, H	
5190	ZEAXANTHIN	A, E	
5191	ZEIN	E	
5192	ZINC	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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)'.</p>
5193	ZINC AMINO ACID CHELATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc amino acid chelate.</p> <p>The concentration of zinc in zinc amino acid chelate must</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>be no more than 30%.</p> <p>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:</p> <p>- (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).'</p>
5194	ZINC ASCORBATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc ascorbate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5195	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).'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5196	ZINC CHLORIDE	A, E, H	<p>The concentration of zinc chloride in the medicine must be no more than 5%.</p> <p>When used internally, zinc is a mandatory component of zinc chloride.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5197	ZINC CITRATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc citrate.</p> <p>When for internal use, the</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5198	ZINC CITRATE DIHYDRATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc citrate dihydrate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>on the medicine label:</p> <p>- (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).'</p>
5199	ZINC CITRATE TRIHYDRATE	A, E, H	<p>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.</p> <p>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:</p> <p>- (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).'</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5200	ZINC DIASPARTATE	A	<p>When used internally, zinc is a mandatory component of zinc diaspertate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5201	ZINC GLUCONATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc gluconate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>When for internal use and the maximum recommended daily</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:</p> <p>- (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).'</p>
5202	ZINC GLYCINATE	A	<p>When used internally, zinc is a mandatory component of Zinc glycinate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			taken in large amounts or for a long period (or words to that effect).'
5203	ZINC GLYCINATE MONOHYDRATE	A	<p>When used internally, zinc is a mandatory component of Zinc glycinate monohydrate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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)'.</p>
5204	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>The concentration of zinc lactate in a medicine intended for topical use should be no more than 2%.</p> <p>The concentration of Zinc lactate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.</p> <p>Zinc lactate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.</p> <p>Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'.</p>
5205	ZINC LACTATE DIHYDRATE	E	<p>Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.</p> <p>The concentration of Zinc lactate dihydrate in a medicine intended for topical use should be no more than 2%.</p> <p>The concentration of Zinc</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must be no more than 2.5%.</p> <p>Zinc lactate dihydrate is not to be included in dental / toothpaste medicines intended for use by children less than 12 years old.</p> <p>Medicines containing Zinc lactate for dental use require the following warning statement on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'.</p>
5206	ZINC LYSINATE	A	<p>When used internally, zinc is a mandatory component of Zinc lysinate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>on the medicine label:</p> <p>- (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).'</p>
5207	ZINC METHIONINE SULFATE	A	<p>For topical use, the concentration of zinc methionine sulfate must be no more than 5%.</p> <p>When used internally, zinc is a mandatory component of zinc methionine sulfate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5208	ZINC MYRISTATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
5209	ZINC OXIDE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc oxide.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'</p> <p>OR</p> <p>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>long period (or words to that effect).'</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5210	ZINC PARA-PHENOLSULFONATE	E	<p>The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%.</p> <p>When used internally, zinc is a mandatory component of zinc para-phenolsulfate.</p> <p>The percentage of zinc from zinc para-phenolsulfonate should be calculated based on the molecular weight of zinc para-phenolsulfonate.</p> <p>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:</p> <p>- (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).</p>
5211	ZINC STEARATE	E	<p>When used internally, zinc is a mandatory component of zinc stearate.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate.
5212	ZINC SUCCINATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc succinate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' or</p> <p>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</p>
5213	ZINC SULFATE	A, E	For topical use, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>concentration of zinc sulfate must be no more than 5%.</p> <p>For internal use, zinc is a mandatory component of zinc sulfate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5214	ZINC SULFATE HEPTAHYDRATE	A, E	<p>For topical use, the concentration of zinc sulfate must be no more than 5%.</p> <p>For internal use, zinc is a</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>mandatory component of zinc sulfate heptahydrate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5215	ZINC SULFATE HEXAHYDRATE	A, E, H	<p>For topical use, the concentration of zinc sulfate must be no more than 5%.</p> <p>For internal use, zinc is a mandatory component of zinc sulfate hexahydrate.</p> <p>When for internal use, the</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>maximum recommended daily dose must be no more than 50mg of zinc.</p> <p>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:</p> <p>- (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).'</p>
5216	ZINC SULFATE MONOHYDRATE	A, E, H	<p>When the route of administration is topical the concentration of zinc sulfate in the medicine must be no more than 5%.</p> <p>When the medicine is for internal use, zinc is a mandatory component of zinc sulfate monohydrate.</p> <p>When for internal use, the maximum recommended daily dose must be no more than</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>50mg of zinc.</p> <p>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:</p> <p>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'</p> <p>OR</p> <p>- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</p>
5217	ZINC VALERATE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>For internal use, zinc is a mandatory component of zinc valerate.</p> <p>The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5218	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%.
5219	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'.
5220	ZIZIPHUS JUJUBA	A, H	
5221	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	

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

Table 1 **Part 1**

Volume 6

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5222	ZIZYPHUS SATIVA	A, H	
5223	ZOSTERA MARINA	A, H	
5224	ZUCCHINI	E	