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

Note: See sections 5 and 6.

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
5071	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'.
5072	UBIQUINOL-10	A, E	When used as an excipient, the route of administration must be topical and the concentration in the medicine must be no more than 0.05%.
			Not to be included in medicines intended for use in the eye.
			When for internal use, the maximum recommended daily dose must provide no more

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

			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.'
5073	ULEX EUROPAEUS	A, H	
5074	ULMUS AMERICANA	A, H	
5075	ULMUS CAMPESTRIS	A, H	
5076	ULMUS GLABRA	A, H	
5077	ULMUS MINOR	A, H	
5078	ULMUS PARVIFOLIA	A, H	
5079	ULMUS PUMILA	A, H	
5080	ULMUS RUBRA	A, H	
5081	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%.
5082	ULTRAMARINE BLUE	Е	Permitted for use only as a colour for topical use.
5083	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%.

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

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5084	UMBELLULARIA CALIFORNICA	A A, H	
5085	UNCARIA GAMBIR	A, H	
5086	UNCARIA RHYNCOPHYLLA	A, H	
5087	UNCARIA SINENSIS	A, H	
5088	UNCARIA TOMENTOSA	A, H	
5089	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5090	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%.
5091	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
5002	LINDECENOIC ACID	Б	medicine must be no more than 5%.
5092 5093	UNDECENOIC ACID UNDECYL ALCOHOL	<u>Е</u> Е	Permitted for use only in
J073	CNDLCTE ALCOHOL	L	combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5094	UNDECYLCRYLENE DIMETICONE	E	Only for use in topical medicines for dermal

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

			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%.
5095	UNDECYLENAMIDE DEA	E	
5096	UNDECYLENOYL PEG-5 PARABEN	Е	Only for use in topical medicines for dermal application.
5097	URANIUM NITRATE	Н	Only for use as an active homoeopathic ingredient.
5098	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).
5099	URTICA DIOICA	A, E, H	
5100	URTICA URENS	A, H	
5101	USNEA BARBATA	A, H	
5102	UVA URSI LEAF DRY	A, H	
5103	UVA URSI LEAF POWDER	A, E, H	
5104	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%.
5105	VACCARIA SEGATALIS	А, Н	
5106	VACCINIUM BRACTEATUM	A, H	

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

5107	VACCINIUM CORYMBOSUM	E	Permitted for use only in
	THE STATE OF THE OFFI	2	combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5108	VACCINIUM MACROCARPON	A, E, H	
5109	VACCINIUM MYRTILLOIDES	A, H	
5110	VACCINIUM MYRTILLUS	A, E, H	
5111	VACCINIUM OXYCOCCUS	A, H	
5112	VACCINIUM VITIS-IDAEA	А, Н	Beta-arbutin is a mandatory component of Vaccinium vitisidaea.
			When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.
			When for dermal application exclusively to the face:
			a) the concentration of beta- arbutin in the medicine must not be more than 7%;
			b) hydroquinone is a mandatory component; and
			c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.
			When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5113	VALENCENE	Е	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%.

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

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5114	VALERALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5115	VALERIAN DRY	A, H	The following warning statement is required on the medicine label when the medicine is for oral use:
			(VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'
5116	VALERIAN OIL	Е	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%.
5117	VALERIAN POWDER	A, H	The following warning statement is required on the medicine label when the medicine is for oral use:
			(VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'
5118	VALERIANA EDULIS	A, H	
5119	VALERIANA OFFICINALIS	А, Н	The following warning statement is required on the medicine label when the medicine is for oral use:

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

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			(VALER) 'In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.'
5120	VALERIANA SORBIFOLIA	А, Н	
5121	VALERIC ACID	Е	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%.
5122	VALINE	A, E	
5123	VANADIUM	Н	
5124	VANILLA	Е	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%.
5125	VANILLA DRY	A, E, H	
5126	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%.
5127	VANILLA OLEORESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5128	VANILLA PLANIFOLIA	A, E, H	
5129	VANILLA POWDER	A, E, H	
5130	VANILLA TAHITENSIS	A, H	
5131	VANILLIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5132	VANILLIN	Е	
5133	VANILLIN ACETATE	Е	Vanillin acetate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.
			The total concentration of flavour proprietary excipient formulations containing vanillin acetate must not be more than 5% of the total medicine.
			The maximum recommended daily dose of the medicine must not provide more than 1.8 micrograms of vanillin acetate.
5134	VANILLIN ISOBUTYRATE	Е	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%.

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

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5135	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%.
5136	VAT RED 1	Е	Permitted for use only as a colour for topical use.
5137	VAT RED 1 ALUMINIUM LAKE	Е	Permitted for use only as a colour for topical use.
5138	VAT RED 5	Е	Permitted for use only as a colour for topical use.
5139	VEGETABLE OIL	Е	
5140	VEGETABLE OIL	A	Only for use in oral medicines.
	PHYTOSTEROL ESTERS		The medicine requires the following warning statement on the medicine label:
			- (PREGNT) 'Not recommended for use by
			pregnant and lactating women (or words to that effect).'
5141	VEIN	Н	Only for use as an active homoeopathic ingredient.
5142	VERATRALDEHYDE	Е	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%.
5143	VERATROL	E	Permitted for use only in combination with other permitted ingredients as part of

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

			a fragrance proprietary excipient formulation.
			The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
5144	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%.
5145	VERBASCUM DENSIFLORUM	A, H	
5146	VERBASCUM THAPSUS	A, H	
5147	VERBENA OFFICINALIS	A, H	
5148	VERBENA OIL	Е	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%.
5149	VERONICA CHAMAEDRYS	A, H	
5150	VERONICA OFFICINALIS	A, H	
5151	VERONICASTRUM VIRGINICUM	A, E, H	
5152	VERTONAL	Е	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%.
5153	VETIVER OIL	Е	Permitted for use only in combination with other

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

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			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%.
5154	VETIVERYL ACETATE	Е	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%.
5155	VIBURNUM OPULUS	A, E, H	
5156	VIBURNUM PRUNIFOLIUM	A, E, H	
5157	VICIA FABA	A, H	Levodopa is a mandatory component of Vicia faba.
			The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
5158	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5159	VIGNA RADIATA	A, H	
5160	VIGNA UMBELLATA	A, H	
5161	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%.
5162	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%.

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

			The concentration of Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5163	VINCETOXICUM OFFICINALE	A, H	
5164	VINEGAR	Е	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%.
5165	VIOLA ODORATA	A, E, H	
5166	VIOLA TRICOLOR	A, H	
5167	VIOLA YEDOENSIS	A, H	
5168	VIOLET LEAF ABSOLUTE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5169	VIPER	Н	Only for use as an active homoeopathic ingredient.
5170	VISCUM ALBUM	A, E, H	
5171	VISCUM COLORATUM	A, H	
5172	VISCUM FLAVESCENS	A, H	
5173	VITELLARIA PARADOXA	A, E, H	
5174	VITEX AGNUS-CASTUS	A, E, H	When the ingredient is in a medicine that is for internal use, the following warning statement is required on the label:
			<ul> <li>- (VAC) 'Vitex agnus-castus may affect hormones and medicines such as oral</li> </ul>

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

			contraceptives. Consult your health professional before use' (or words to that effect).
5175	VITEX NEGUNDO	A, H	
5176	VITEX ROTUNDIFOLIA	A, H	
5177	VITEX TRIFOLIA	A, H	
5178	VITIS VINIFERA	A, E, H	
5179	VITREOSCILLA CONCENTRATE	Е	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 0.1%.
5180	VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER	Е	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%.
5181	WAHLENBERGIA GRACILIS	А, Н	
5182	WALNUT	Е	
5183	WALNUT OIL	Е	
5184	WHEAT	Е	Gluten is a mandatory component of Wheat when the route of administration is other than topical and mucosal.
5185	WHEAT BRAN	Е	Gluten is a mandatory component of Wheat bran when the route of administration is other than topical and mucosal.
5186	WHEAT DEXTRIN	A, E	Gluten is a mandatory component of wheat dextrin. Only for use when the dosage form is capsule, tablet or pill.
5187	WHEAT GERM	Е	Gluten is a mandatory component of Wheat germ

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

			when the route of administration is other than topical and mucosal.
5188	WHEAT GERM GLYCERIDES	Е	Gluten is a mandatory component of wheat germ glycerides when the route of administration is other than topical and mucosal.
5189	WHEAT LEAF	Е	
5190	WHEAT STARCH	Е	When the route of administration is other than topical or mucosal, gluten is a mandatory component of whear starch.
5191	WHEATGERM OIL	A, E, H	
5192	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of administration is oral.
5193	WHEY PROTEIN	Е	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5194	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%.
5195	WHITE BEESWAX	Е	
5196	WHITE HOREHOUND HERB DRY	A, H	
5197	WHITE HOREHOUND HERB POWDER	A, H	
5198	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

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

			Volume
			substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5199	WHOLE DRY MILK	E	
5200	WIKSTROEMIA VIRIDIFLORA	A, H	
5201	WILD CARROT HERB DRY	A, E, H	
5202	WILD CARROT HERB POWDER	A, H	
5203	WILD CHERRY BARK DRY	A, H	
5204	WILD CHERRY BARK POWDER	A, H	
5205	WILD LETTUCE LEAF DRY	A, H	
5206	WILD LETTUCE LEAF POWDER	A, H	
5207	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:
			<ul> <li>the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> </ul>
			- direct suction through the delivery device results in delivery of no more than one dosage unit; and
			<ul> <li>actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul>

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

#### Volume 6

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'.

5208 WITHANIA SOMNIFERA A, E, H

The medicine requires the following warning statement on the label:

- (WITHANIA) 'If you are pregnant, or considering becoming pregnant, do not take without consulting a health professional' (or words to that effect)

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

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			unless:  (a) the plant part is root;  (b) the plant preparation is an
			extract; (c) the extraction solvents are only water, ethanol or methanol; and
			(d) the maximum recommended daily dose of the medicine contains no more than the equivalent quantity of 12 g dry root.
5209	WOLFIPORIA COCOS	A, E, H	
5210	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.
5211	WOOL FAT	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5212	XANTHAN GUM	E	
5213	XANTHIUM SIBIRICUM	A, H	The requirements specified in paragraphs (a) to (h) below apply to a medicine that contains the ingredient that is: - listed in the Register on or
			after 1 March 2025; or
			- released for supply on or after 1 March 2026.
			(a) Carboxyatractyloside and atractyloside are mandatory components of Xanthium sibiricum.
			(b) The concentration of carboxyatractyloside must not be more than 0.35% of Xanthium sibiricum.

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

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- (c) The concentration of atractyloside must not be more than 0.3% of Xanthium sibiricum.
- (d) The route of administration for medicines that contain Xanthium sibiricum must be limited to oral.
- (e) The plant part must be limited to fruit that is dried, cooked and had the spines removed.
- (f) The plant preparation must be limited to dry, powder, and extraction preparations with water as the only solvent.
- (g) The maximum recommended daily dose of the medicine must not provide more than 10 g of Xanthium sibiricum.
- (h) The medicine must not be directed for use in children, those who are pregnant, likely to become pregnant, or lactating.

#### 5214 XANTHIUM STRUMARIUM A, H

The requirements specified in paragraphs (a) to (h) below apply to a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2025; or
- released for supply on or after 1 March 2026.
- (a) Carboxyatractyloside and atractyloside are mandatory components of Xanthium strumarium.
- (b) The concentration of carboxyatractyloside must not be more than 0.35% of Xanthium strumarium.
- (c) The concentration of atractyloside must not be more than 0.3% of Xanthium strumarium.

(d) The route of administration
for medicines that contain
Xanthium strumarium must be
limited to oral.

- (e) The plant part must be limited to fruit that is dried, cooked and had the spines removed.
- (f) The plant preparation must be limited to dry, powder, and extraction preparations with water as the only solvent.
- (g) The maximum recommended daily dose of the medicine must not provide more than 10 g of Xanthium strumarium.
- (h) The medicine must not be directed for use in children, those who are pregnant, likely to become pregnant, or lactating.

5215	XANTHOMONA CAMPESTRIS	A, H	
5216	XEROPHYLLUM ASPHODELOIDES	A, H	
5217	XYLENE	Е	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%.
5218	XYLITOL	E	
5219	XYLOSE	Е	
5220	YAM	E	
5221	YARROW HERB DRY	A, H	
5222	YARROW HERB POWDER	A, H	
5223	YEAST AUTOLYSATE	Е	
5224	YEAST DRIED	A, E, H	
5225	YELLOW 2G	Е	Permitted for use only as a colour for topical use.

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

5226	YELLOW BEESWAX	Е	
5227	YELLOW MERCURIC OXIDE	Н	Only for use as an active homoeopathic ingredient.
5228	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.
5229	YLANG YLANG OIL	A, E, H	
5230	YUCCA BACCATA	A, H	
5231	YUCCA ELATA	A, H	
5232	YUCCA FILAMENTOSA	A, H	
5233	YUCCA GLORIOSA	A, H	
5234	Z-BETA-DAMASCONE	E	<ul> <li>Z – beta damascone must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</li> <li>The total concentration of flavour proprietary excipient formulations containing Z – beta damascone must not be more than 5% of the total medicine.</li> </ul>
5235	ZANTHOXYLUM AMERICANUM	A, H	
5236	ZANTHOXYLUM BUNGEANUM	A, E, H	
5237	ZANTHOXYLUM CLAVA- HERCULIS	А, Н	
5238	ZANTHOXYLUM NITIDUM	A, H	
5239	ZANTHOXYLUM PIPERITUM	A, H	
5240	ZANTHOXYLUM SIMULANS	A, H	
5241	ZEA MAYS	A, E, H	
5242	ZEAXANTHIN	A, E	

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

5243	ZEIN	E	
5244	ZINC	Н	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)'.
5245	ZINC AMINO ACID CHELATE	A, E, H	When used internally, zinc is a mandatory component of zinc amino acid chelate.  The concentration of zinc in zinc amino acid chelate must be no more than 30%.  When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'  OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5246	ZINC ASCORBATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate.

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

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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).'

#### 5247 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)'.

#### 5248 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.

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

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			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5249	ZINC 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).'
5250	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate.
			When for internal use, the maximum recommended daily

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

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			dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5251	ZINC CITRATE TRIHYDRATE	А, Е, Н	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:
			<ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'</li> <li>OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</li> </ul>
5252	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

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

			Volume
			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).'
5253	ZINC GLUCONATE	A, E, H	When used internally, zinc is a mandatory component of zinc gluconate.  When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.  When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'  OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5254	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

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

			following warning statement
			on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5255	ZINC GLYCINATE MONOHYDRATE	A	When used internally, zinc is a mandatory component of Zinc glycinate monohydrate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect)'.
5256	ZINC LACTATE	E	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.
			The concentration of zinc lactate in a medicine intended for topical use should not be more than 2%.
			The concentration of zinc lactate in a medicine for 'dental' use in toothpaste medicines must not be more than 2.5%.
			Zinc lactate is not to be included in dental/toothpaste

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

Volume	6
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			Volun
			medicines intended for use by children less than 12 years old.
			Medicines containing zinc lactate for dental use require the following warning statement (or words to the same effect) on the medicine label:
			- (CHILD3) 'Use in children under 12 years is not recommended'.
5257	ZINC LACTATE DIHYDRATE	Е	Only for use in topical and dental medicines and not to be included in medicines intended for use in the eye.
			The concentration of zinc lactate dihydrate in a medicine intended for topical use should not be more than 2%.
			The concentration of zinc lactate dihydrate in a medicine for 'dental' use in toothpaste medicines must not be more than 2.5%.
			Zinc lactate dihydrate is not to be included in dental/toothpaste medicines intended for use by children less than 12 years old.
			Medicines containing zinc lactate dihydrate for dental use require the following warning statement (or words to the same effect) on the medicine label:
			- (CHILD3) 'Use in children under 12 years is not recommended'.
5258	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.

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

Volume 6			
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5259	ZINC 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).'

5260 ZINC MYRISTATE Е Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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

			Volui
			The concentration in the medicine must be no more than 0.1%.
5261	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:
			<ul> <li>- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR</li> </ul>
			-'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:
			<ul> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> </ul>
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
5262 ZINC PARA- PHENOLSULFONATE		Е	Only permitted for use in topical medicines for dermal use.
			The concentration of zinc paraphenolsulfonate in the medicine must not exceed 5%.
5263	ZINC STEARATE	Е	When used internally, zinc is a mandatory component of zinc stearate.
			The percentage of zinc from zinc stearate should be calculated based on the

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

#### Volume 6

molecular weight of zinc stearate.

When for internal use, the maximum recommended daily dose must not provide more than 50 milligrams of zinc.

When for internal use and the maximum recommended daily dose is more than 25 milligrams but not more than 50 milligrams of zinc, the medicine requires the following warning statement (or words to the same effect) on the medicine label:

- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period'; or
- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period'.

5264 ZINC SUCCINATE A, E, H

When used internally, zinc is a mandatory component of zinc succinate.

When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.

When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:

- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'
- '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

5265	ZINC SULFATE	A, E	For topical use, the concentration of zinc sulfate must be no more than 5%.
			For internal use, zinc is a mandatory component of zinc sulfate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			- (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5266	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

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

			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5267	ZINC SULFATE HEXAHYDRATE	A, E, H	For topical use, the concentration of zinc sulfate must be no more than 5%.
			For internal use, zinc is a mandatory component of zinc sulfate hexahydrate.
			When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.
			When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:
			<ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR</li> </ul>
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5268	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

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

			more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.'  OR  - 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5269	ZINC VALERATE	Н	Only for use as an active homoeopathic ingredient.  When for internal use, zinc is a mandatory component of zinc valerate.
			The percentage of zinc from zinc valerate should be calculated based on the molecular weight of zinc valerate.
			When for internal use, the maximum recommended daily dose must not provide more than 50 milligrams of zinc.
			When for internal use and the maximum recommended daily dose is more than 25 milligrams but not more than 50 milligrams of zinc, the medicine requires the following warning statement (or words to the same effect) on the medicine label:
			<ul> <li>(ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period'; or</li> </ul>
			'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period'.
5270	ZINGERONE	Е	Permitted for use only in combination with other

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

			permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5271	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'.
5272	ZIZIPHUS JUJUBA	А, Н	
5273	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5274	ZIZYPHUS SATIVA	A, H	
5275	ZOSTERA MARINA	A, H	