

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

Volume 6

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

Note: See sections 5 and 6.

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<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5029	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: - (WARF) 'Do not take while on warfarin therapy without medical advice'.</p>
5030	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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			than 0.05%.
			Not to be included in medicines intended for use in the eye.
			When for internal use, the maximum recommended daily dose must provide no more than 300 milligrams of ubiquinol-10.
			When used in combination with ubidecarenone, the maximum recommended daily dose must provide no more than 300 mg of ubiquinol-10 and ubidecarenone combined.
			The medicine requires the following warning statement on the medicine label:
			- (WARF) 'Do not take while on warfarin therapy without medical advice.'
5031	ULEX EUROPAEUS	A, H	
5032	ULMUS AMERICANA	A, H	
5033	ULMUS CAMPESTRIS	A, H	
5034	ULMUS GLABRA	A, H	
5035	ULMUS PARVIFOLIA	A, H	
5036	ULMUS PROCERA	A, H	
5037	ULMUS PUMILA	A, H	
5038	ULMUS RUBRA	A, H	
5039	ULTRALIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
5040	ULTRAMARINE BLUE	E	Permitted for use only as a colour for topical use.
5041	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%.
5042	UMBELLULARIA CALIFORNICA	A, H	
5043	UNCARIA GAMBIR	A, H	
5044	UNCARIA RHYNCOPHYLLA	A, H	
5045	UNCARIA SINENSIS	A, H	
5046	UNCARIA TOMENTOSA	A, H	
5047	UNDARIA PINNATIFIDA	A, H	Whole dried Undaria pinnatifida must not contain the holdfast. Only for use in oral medicines.
5048	UNDECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<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>
5049	UNDECANOIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
5050	UNDECENOIC ACID	E	
5051	UNDECYL ALCOHOL	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>
5052	UNDECYLCRYLENE DIMETICONE	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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 10%.
5053	UNDECYLENAMIDE DEA	E	
5054	UNDECYLENOYL PEG-5 PARABEN	E	Only for use in topical medicines for dermal application.
5055	URANIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
5056	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).
5057	URTICA DIOICA	A, E, H	
5058	URTICA URENS	A, H	
5059	USNEA BARBATA	A, H	
5060	UVA URSI LEAF DRY	A, H	
5061	UVA URSI LEAF POWDER	A, E, H	
5062	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

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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%.
5063	VACCARIA SEGATALIS	A, H	
5064	VACCINIUM BRACTEATUM	A, H	
5065	VACCINIUM CORYMBOSUM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5066	VACCINIUM MACROCARPON	A, E, H	
5067	VACCINIUM MYRTILLOIDES	A, H	
5068	VACCINIUM MYRTILLUS	A, E, H	
5069	VACCINIUM OXYCOCCUS	A, H	
5070	VACCINIUM VITIS-IDAEA	A, H	Arbutin is a mandatory component of Vaccinium vitis-idaea. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5071	VALENCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5072	VALERALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5073	VALERIAN DRY	A, H	
5074	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%.
5075	VALERIAN POWDER	A, H	
5076	VALERIANA EDULIS	A, H	
5077	VALERIANA OFFICINALIS	A, H	
5078	VALERIANA SORBIFOLIA	A, H	

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5079	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%.
5080	VALINE	A, E	
5081	VANADIUM	H	
5082	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%.
5083	VANILLA DRY	A, E, H	
5084	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%.
5085	VANILLA OLEORESIN	E	Permitted for use only in combination with other

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5086	VANILLA PLANIFOLIA	A, E, H	
5087	VANILLA POWDER	A, E, H	
5088	VANILLA TAHITENSIS	A, H	
5089	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%.
5090	VANILLIN	E	
5091	VANILLIN ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5092	VANILLYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5093	VAT RED 1	E	Permitted for use only as a colour for topical use.
5094	VAT RED 1 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
5095	VAT RED 5	E	Permitted for use only as a colour for topical use.
5096	VEGETABLE OIL	E	
5097	VEGETABLE OIL PHYTOSTEROL ESTERS	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
5098	VEIN	H	Only for use as an active homoeopathic ingredient.
5099	VERATRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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	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>
5101	VERATRUM ALBUM	A, H	<p>Solanidine is a mandatory component of Veratrum album.</p> <p>The concentration of equivalent dry Veratrum album in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.</p>
5102	VERBASCUM DENSIFLORUM	A, H	
5103	VERBASCUM THAPSUS	A, H	
5104	VERBENA OFFICINALIS	A, H	
5105	VERBENA OIL	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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5106	VERONICA CHAMAEDRYS	A, H	
5107	VERONICA OFFICINALIS	A, H	
5108	VERONICASTRUM VIRGINICUM	A, E, H	
5109	VERTONAL	E	<p>Permitted for use only in combination with other permitted ingredients as part of 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>
5110	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>
5111	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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			fragrance concentration in a medicine must be no more than 1%.
5112	VIBURNUM OPULUS	A, E, H	
5113	VIBURNUM PRUNIFOLIUM	A, E, H	
5114	VICIA FABAE	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%.
5115	VIGNA ANGULARIS VAR. ANGULARIS	A, H	
5116	VIGNA RADIATA	A, H	
5117	VIGNA UMBELLATA	A, H	
5118	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%.
5119	VINCA MINOR	A, H	Vincamine and vincristine are mandatory components of Vinca minor. The concentration of vincamine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%. The concentration of

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			Vincristine in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%
5120	VINCETOXICUM OFFICINALE	A, H	
5121	VINEGAR	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
5122	VIOLA ODORATA	A, E, H	
5123	VIOLA TRICOLOR	A, H	
5124	VIOLA YEDOENSIS	A, H	
5125	VIOLET LEAF ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
5126	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

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 5%.
5127	VIPER	H	Only for use as an active homoeopathic ingredient.
5128	VISCUM ALBUM	A, E, H	
5129	VISCUM COLORATUM	A, H	
5130	VISCUM FLAVESCENS	A, H	
5131	VITELLARIA PARADOXA	A, E, H	
5132	VITEX AGNUS-CASTUS	A, E, H	
5133	VITEX NEGUNDO	A, H	
5134	VITEX ROTUNDIFOLIA	A, H	
5135	VITEX TRIFOLIA	A, H	
5136	VITIS VINIFERA	A, E, H	
5137	VITREOSCILLA CONCENTRATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
5138	VP/ACRYLATES/LAURYL METHACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must not be more than 2.00%.
5139	WAHLENBERGIA GRACILIS	A, H	

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5140	WALNUT	E	
5141	WALNUT OIL	E	
5142	WATER MELON	E	
5143	WHEAT	E	<p>Gluten is a mandatory component of Wheat 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>
5144	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>
5145	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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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>
5146	WHEAT GERM	E	<p>Gluten is a mandatory component of Wheat germ 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>
5147	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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5148	WHEAT LEAF	E	
5149	WHEAT SPROUT	E	Gluten is a mandatory component of Wheat sprout 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.
5150	WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of wheat starch. 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).
5151	WHEATGERM OIL	A, E, H	
5152	WHEY POWDER	E	Lactose is a mandatory component of Whey powder when the route of

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			administration is oral.
5153	WHEY PROTEIN	E	Lactose is a mandatory component of Whey protein when the route of administration is oral.
5154	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%.
5155	WHITE BEESWAX	E	
5156	WHITE HOREHOUND HERB DRY	A, H	
5157	WHITE HOREHOUND HERB POWDER	A, H	
5158	WHITE SOFT PARAFFIN	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
5159	WHOLE DRY MILK	E	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
5160	WIKSTROEMIA VIRIDIFLORA	A, H	
5161	WILD CARROT HERB DRY	A, E, H	
5162	WILD CARROT HERB POWDER	A, H	
5163	WILD CHERRY BARK DRY	A, H	
5164	WILD CHERRY BARK POWDER	A, H	
5165	WILD LETTUCE LEAF DRY	A, H	
5166	WILD LETTUCE LEAF POWDER	A, H	
5167	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:

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> <li>- on or after 1 July 2018, the medicine must comply with all requirements under (a) &amp; (b);</li> <li>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</li> <li>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</li> </ul> <p>a) The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight'. (or words to that effect);</li> <li>- (IRRIT) 'If irritation develops, discontinue use.'; and</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</li> </ul>
5168	WITHANIA SOMNIFERA	A, E, H	
5169	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'.
5170	WOOL ALCOHOLS	E	Only for use in topical medicines for dermal application.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5171	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.
5172	XANTHAN GUM	E	
5173	XANTHIUM SIBIRICUM	A, H	
5174	XANTHIUM STRUMARIUM	A, H	
5175	XANTHOMONA CAMPESTRIS	A, H	
5176	XEROPHYLLUM ASPHODELOIDES	A, H	
5177	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%.
5178	XYLITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect]'.
5179	XYLOSE	E	
5180	YAM	E	
5181	YARROW HERB DRY	A, H	
5182	YARROW HERB POWDER	A, H	
5183	YEAST AUTOLYSATE	E	
5184	YEAST DRIED	A, E, H	
5185	YELLOW 2G	E	Permitted for use only as a colour for topical use.
5186	YELLOW BEESWAX	E	
5187	YELLOW MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
5188	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.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5189	YLANG YLANG OIL	A, E, H	
5190	YUCCA BACCATA	A, H	
5191	YUCCA ELATA	A, H	
5192	YUCCA FILAMENTOSA	A, H	
5193	YUCCA GLORIOSA	A, H	
5194	YUCCA WHIPPLEI	A, H	
5195	ZANTHOXYLUM AMERICANUM	A, H	
5196	ZANTHOXYLUM BUNGEANUM	A, E, H	
5197	ZANTHOXYLUM CLAVA-HERCULIS	A, H	
5198	ZANTHOXYLUM NITIDUM	A, H	
5199	ZANTHOXYLUM PIPERITUM	A, H	
5200	ZANTHOXYLUM SIMULANS	A, H	
5201	ZEAXANTHIN	A, E, H	
5202	ZEAXANTHIN	A, E	
5203	ZEIN	E	
5204	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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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)'.
5205	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).'
5206	ZINC ASCORBATE	A, E, H	When used internally, zinc is a mandatory component of zinc ascorbate.  When for internal use, the maximum recommended daily dose must be no more than

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<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 '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 ASCORBATE MONOHYDRATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc ascorbate 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.'</p> <p>OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5208	ZINC CHLORIDE	A, E, H	<p>effect)'.                      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>
5209	ZINC CITRATE	A, E, H	<p>When used internally, zinc is a mandatory component of zinc citrate.</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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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).'
5210	ZINC CITRATE DIHYDRATE	A, E, H	When used internally, zinc is a mandatory component of zinc citrate dihydrate. When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc. When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label: - (ZINC) 'WARNING: May be dangerous if taken in large amounts or for a long period.' OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5211	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>
5212	ZINC DIASPARTATE	A	<p>When used internally, zinc is a mandatory component of zinc diaspartate.</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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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).'
5213	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).'
5214	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.

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<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 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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5216	ZINC LACTATE	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 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>
5217	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 lactate dihydrate in a medicine</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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>
5218	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 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</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5219	ZINC METHIONINE SULFATE	A	<p>effect).'</p> <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.'</p> <p>OR 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'</p>
5220	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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5221	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 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> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul>
5222	ZINC PARA-PHENOLSULFONATE	E	<p>The concentration of zinc para-phenolsulfonate in the medicine must not exceed 5%. When used internally, zinc is a mandatory component of zinc para-phenolsulfate.</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> <ul style="list-style-type: none"> <li>- (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).</li> </ul>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5223	ZINC STEARATE	E	<p>When used internally, zinc is a mandatory component of zinc stearate.</p> <p>The percentage of zinc from zinc stearate should be calculated based on the molecular weight of zinc stearate.</p>
5224	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.'</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>
5225	ZINC SULFATE	A, E	<p>For topical use, the concentration of zinc sulfate must be no more than 5%.</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<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.'</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>
5226	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 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</p>

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

Volume 6

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<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.'</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>
5227	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 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.'</p> <p>OR</p>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			- 'WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).'
5228	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 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>

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

Volume 6

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5229	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>
5230	ZINGERONE	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>
5231	ZINGIBER OFFICINALE	A, E, H	<p>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:</p> <p>- (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'.</p>

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

Volume 6

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<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
5232	ZIZIPHUS JUJUBA	A, H	
5233	ZIZIPHUS JUJUBA VAR. SPINOSA	A, H	
5234	ZIZYPHUS SATIVA	A, H	
5235	ZOSTERA MARINA	A, H	
5236	ZUCCHINI	E	

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

Volume 6

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## **Schedule 2—Repeals**

Note: See section 7.

### ***Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2019***

#### **1 The whole of the instrument**

Repeal the instrument.