

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

Volume 5

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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
3614	P-ALPHA-DIMETHYL STYRENE	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>
3615	P-ANISIC ACID	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.3%.</p>
3616	PADIMATE O	A	<p>Only for use as an active ingredient in sunscreens 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 8%.</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</p>

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

Volume 5

<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>
			to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3617	PADINA PAVONICA THALLUS PHYTOSTEROLS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
3618	PAEONIA LACTIFLORA	A, E, H	
3619	PAEONIA OBOVATA	A, H	
3620	PAEONIA SUFFRUTICOSA	A, E, H	
3621	PAEONIA VEITCHII	A, H	
3622	PALIURUS SPINA-CHRISTI	A, H	
3623	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3624	PALM FRUIT OIL	A, E, H	
3625	PALM GLYCERIDES	E	

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

Volume 5

<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>
3626	PALM KERNEL OIL	A, E, H	
3627	PALM TOCOTRIENOLS COMPLEX	A, H	
3628	PALMARIA PALMATA	A, H	
3629	PALMAROSA OIL	A, E, H	
3630	PALMIDROL	A	<p>Only to be used in a medicine where Pharmako Biotechnologies Pty Ltd (Client ID 62358), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 02 December 2021.</p> <p>Only permitted for use in medicines limited to oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not contain more than 600mg of palmidrol.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- 'The medicine may interact with other prescription analgesic medicines, please consult your healthcare practitioner before use' (or words to that effect).</li> <li>- (ADULT) 'Adults only' (or words to that effect)</li> <li>- 'Not to be used for more than 21 consecutive days' (or words to that effect).</li> </ul>
3631	PALMITIC ACID	E	
3632	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	

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

Volume 5

<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>
3633	PALMITOYL DIPEPTIDE-7	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
3634	PALMITOYL HYDROXYPROPYLTRIMONIUM AMYLOPECTIN/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%
3635	PALMITOYL OLIGOPEPTIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
3636	PALMITOYL PENTAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
3637	PALMITOYL TETRAPEPTIDE-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.001%.

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

Volume 5

<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>
3638	PANAX GINSENG	A, E, H	
3639	PANAX JAPONICUS	A, H	
3640	PANAX NOTOGINSENG	A, H	
3641	PANAX PSEUDOGINSENG	A, H	
3642	PANAX QUINQUEFOLIUS	A, H	
3643	PANICUM MILIACEUM	A, H	
3644	PANTETHINE	E	Only for use in topical medicines for dermal application.
3645	PANTHENOL	A, E	
3646	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3647	PANTOLACTONE	E	
3648	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3649	PANTOTHENIC ACID POLYPEPTIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3650	PAPAIN	A, E	
3651	PAPER	E	Only for use in topical medicines for dermal application.
3652	PAPRIKA OLEORESIN	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 5

<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 flavour the total flavour concentration in a medicine must be no more than 5%.
3653	PARA-CRESOL	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%.
3654	PARA-CRESYL ACETATE	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%.
3655	PARA-CRESYL ISOBUTYRATE	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%.
3656	PARA-CRESYL PHENYLACETATE	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

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

Volume 5

<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>
			1%.
3657	PARA-CYMENE	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%.
3658	PARA-ETHOXYBENZALDEHYDE	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%.
3659	PARA-ETHYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The maximum recommended daily dose must contain no more than 0.12 mg of para-ethylphenol. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3660	PARA-HYDROXY BENZALACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

Volume 5

<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>
3661	PARA-HYDROXYBENZOIC ACID	E	
3662	PARA-MENTHA-8-THIOL-3-ONE	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%.
3663	PARA-METHYL ACETOPHENONE	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%.
3664	PARA-METHYL ANISOLE	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%.
3665	PARA-METHYL DIMETHYLBENZYL CARBINOL	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



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

Volume 5

<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 1%.
3666	PARA-PROPYL ANISOLE	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%.
3667	PARA-TERT-BUTYLCYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3668	PARA-TERT-BUTYLPHENYL-ALPHA-METHYLHYDROCINNAMIC ALDEHYDE	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%.
3669	PARA-TOLUALDEHYDE	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%.
3670	PARA-TOLYL ACETALDEHYDE	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 5

<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 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%.
3671	PARAMERIA LAEVIGATA	A, H	
3672	PARIETARIA JUDAICA	A, H	
3673	PARIS POLYPHYLLA	A, H	
3674	PARIS QUADRIFOLIA	A, H	
3675	PARSLEY	E, H	
3676	PARSLEY HERB DRY	A, E, H	
3677	PARSLEY HERB OIL	A, E, H	
3678	PARSLEY HERB POWDER	A, E, H	
3679	PARSLEY SEED OIL	A, E, H	
3680	PARTHENOCISSUS TRICUSPIDATA	A, H	
3681	PARTIALLY HYDROGENATED SOYA 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 the medicine must be no more than 5%.
3682	PARTIALLY REFINED PORPHYRA YEZOENSIS CYTOPLASM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00002%.
3683	PASPALUM NOTATUM	A, H	

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

Volume 5

<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>
3684	PASSIFLORA CAERULEA	A, H	
3685	PASSIFLORA EDULIS	E	
3686	PASSIFLORA HERB DRY	A, H	
3687	PASSIFLORA INCARNATA	A, E, H	
3688	PATCHOULI OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total 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%.
3689	PATENT BLUE V	E	Permitted for use only as a colour for oral and topical use.
3690	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3691	PATRINIA SCABIOSIFOLIA	A, H	
3692	PATRINIA VILLOSA	A, H	
3693	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below

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

Volume 5

<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>apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is supplied after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is supplied before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state</li> </ul>

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

Volume 5

<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>quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</p> <p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
3694	PAULLINIA PINNATA	A, H	
3695	PAWPAW	E	
3696	PEA	E	
3697	PEA STARCH	E	
3698	PEACH	E	
3699	PEANUT	E	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (PEANUT) 'Contains Peanut' (or words to that effect).</p>
3700	PEAR	E	

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

Volume 5

<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>
3701	PECAN	E	
3702	PECTIN	A, E	
3703	PEG-10 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must be no more than 4.0%.
3704	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3705	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.
3706	PEG-12 DILAURATE	E	
3707	PEG-12 DIMETICONE/PPG-20 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3708	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3709	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3710	PEG-15 COCAMINE	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 5

<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>
3711	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.
3712	PEG-20 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3713	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3714	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3715	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3716	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3717	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following

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

Volume 5

<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>statements on the medicine label:</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> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <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>
3718	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3719	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3720	PEG-35 CASTOR OIL	E	
3721	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3722	PEG-4 LAURATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate.</p>



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

Volume 5

<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>The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p>
3723	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3724	PEG-40 CASTOR OIL	E	
3725	PEG-40 HYDROGENATED CASTOR OIL	E	
3726	PEG-40 SORBITAN DIISOSTEARATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Dioxane and Ethylene oxide are mandatory components of PEG-40 sorbitan diisostearate. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p>
3727	PEG-40 STEARATE	E	Only for use in topical medicines for dermal application.
3728	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3729	PEG-5 GLYCERYL STEARATE	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 5

<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>
3730	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3731	PEG-55 PROPYLENE GLYCOL OLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.6%.
3732	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.
3733	PEG-60 ALMOND GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration when used in medicines applied directly to the skin must be no more than 10%. The concentration when used in bath oil medicines must be no more than 30%.
3734	PEG-60 GLYCERYL ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3735	PEG-60 HYDROGENATED CASTOR OIL	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 5

<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>
3736	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.
3737	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3738	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3739	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3740	PEG-75 STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3741	PEG-8 CETYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
3742	PEG-8 DILAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.

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

Volume 5

<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>
3743	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3744	PEG-8 LAURATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%. The levels of possible impurities such as ethylene oxide (and related material) must be kept below the level of detection.
3745	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3746	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3747	PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
3748	PEG/PPG-14/7 DIMETHYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 7%.
3749	PEG/PPG-18/18 DIMETHICONE	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

Volume 5

<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%.
3750	PELARGONIUM GRAVEOLENS	A, E, H	
3751	PELLITORINE	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%.
3752	PELTIGERA CANINA	A, H	
3753	PENICILLIUM EXPANSUM	A, H	
3754	PENNYROYAL OIL	E	D-Pulegone/Pulegone is a mandatory component of Pennyroyal Oil. The concentration of D Pulegone/ Pulegone in the medicine must be no more than 4%. 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 the medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%. When the medicine is for a use other than topical, the maximum recommended daily dose must be no more than 50 mg of Pennyroyal Oil.

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

Volume 5

<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>
3755	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.018%
3756	PENTAERYTHRITYL TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 61%.
3757	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 80%.
3758	PENTAMETHYLHEPTENONE	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%.
3759	PENTANE	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

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

Volume 5

<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 1%.
3760	PENTASODIUM ETHYLENEDIAMINE TETRAMETHYLENE PHOSPHONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.1%.
3761	PENTYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 5%.
3762	PEPPER BLACK	E, H	
3763	PEPPER OIL TERPENELESS	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%.
3764	PEPPER WHITE	E, H	
3765	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint american ext.  When the medicine is for topical use for dermal application: a) the medicine must not be intended for use in the eye or on damaged skin; b) the medicine must not deliver more than 25% total menthol when administered according to the directions for

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

Volume 5

<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>use;</p> <p>c) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>d) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>e) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3766	PEPPERMINT LEAF DRY	A, E, H	<p>Menthol is a mandatory component of peppermint leaf dry.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total</p>



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

Volume 5

<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>menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) Avoid contact with eyes (or words to that effect).</li> </ul> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3767	PEPPERMINT LEAF POWDER	A, E, H	<p>Menthol is a mandatory component of peppermint leaf powder.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p>

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

Volume 5

<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>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3768	PEPPERMINT OIL	A, E, H	<p>Menthol is a mandatory component of peppermint oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or</p>

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

Volume 5

<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>on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3769	PEPPERMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient

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

Volume 5

<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>formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.</p> <p>Menthol is a mandatory component of peppermint oil terpeneless.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p>

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

Volume 5

<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>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3770	PEPPERMINT OIL TERPENES AND TERPENOIDS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>Menthol is a mandatory component of peppermint oil terpenes and terpenoids.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have</p>

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

Volume 5

<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>sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3771	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.
3772	PERHYDRO-3,6-DIMETHYLBENZO [B] FURAN-2-ONE	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>
3773	PERILLA FRUTESCENS	A, E, H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of <i>Perilla frutescens</i> is leaf.
3774	PERILLALDEHYDE	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 5

<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 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%.
3775	PERLITE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3776	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3777	PERSEA AMERICANA	A, E, H	
3778	PERSIC OIL	A, E, H	Amygdalin and Hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must be no more than 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
3779	PERSICARIA CHINENSIS	A, H	
3780	PERSICARIA TINCTORIA	A, H	
3781	PERSIMMON	E	
3782	PERU BALSAM	A, E, H	
3783	PERU BALSAM OIL	A, E, H	
3784	PETITGRAIN MANDARIN OIL	E	Permitted for use only in

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

Volume 5

<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>combination with other permitted ingredients as a flavour</p> <p>The final concentration of the oil in the flavour does not exceed 30%</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%</p>
3785	PETITGRAIN 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>
3786	PETITGRAIN OIL CITRONNIER	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 petitgrain oil citronnier must be no more than 0.1%.</p> <p>When included in dermal creams for infant use the concentration of petitgrain oil citronnier must be no more than 0.5%</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3787	PETITGRAIN OIL PARAGUAY	A, E, H	When used internally, oxedrine



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

Volume 5

<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>
			is a mandatory component of petitgrain oil paraguay. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3788	PETITGRAIN OIL TERPENELESS	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%.
3789	PETROSELINUM CRISPUM	A, E, H	
3790	PEUCEDANUM PRAERUPTORUM	A, E, H	
3791	PEUMUS BOLDUS	A, H	Volatile oil components (of Peumus boldus) is a mandatory component. The maximum recommended daily dose must be no more than 100 mg of volatile oil components (of Peumus boldus).
3792	PHALARIS ARUNDINACEA	A, H	
3793	PHALARIS CANARIENSIS	A, H	
3794	PHASEOLUS COCCINEUS	A, H	
3795	PHASEOLUS VULGARIS	A, H	
3796	PELLINUS ROBINIAE	A, E, H	
3797	PHELLODENDRON AMURENSE	A, E, H	
3798	PHELLODENDRON CHINENSE	A, H	
3799	PHENACETIN	E	Only for use in topical

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

Volume 5

<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>medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
3800	PHENETHYL 2-METHYLBUTYRATE	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>
3801	PHENETHYL ACETATE	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>
3802	PHENETHYL ALCOHOL	E	<p>Permitted for use only:</p> <p>a) in topical medicines for dermal application; and</p> <p>b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation 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 5

<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>
3803	PHENETHYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3804	PHENETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%
3805	PHENETHYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3806	PHENETHYL 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%.
3807	PHENETHYL ISOVALERATE	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 5

<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>
3808	PHENETHYL PHENYLACETATE	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>
3809	PHENETHYL SALICYLATE	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>
3810	PHENOL	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration of phenol in the medicine must be no more than 1%.</p>
3811	PHENOXYACETALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than</p>

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

Volume 5

<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>
			1%.
3812	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application. The concentration of phenoxyethanol in the preparation must not exceed 15%.
3813	PHENOXYETHYL 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%.
3814	PHENOXYETHYL PARABEN	E	Only for use in topical medicines for dermal application.
3815	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3816	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.
3817	PHENYLACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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

Volume 5

<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 1%.
3818	PHENYLACETALDEHYDE DIMETHYL ACETAL	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%.
3819	PHENYLACETALDEHYDE GLYCERYLACETAL	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%.
3820	PHENYLACETIC ACID	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%.
3821	PHENYLALANINE	A, E	When for oral ingestion the medicine requires the following warning statement on the medicine label: - (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect).

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

Volume 5

<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 the medicine contains more than 500mg in the maximum recommended daily dose it requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant'.</li> </ul>
3822	PHENYLBENZIMIDAZOLE SULFONIC ACID	A	<p>Only for use as an active ingredient in sunscreens 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 4%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> <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> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <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>

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

Volume 5

<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>
3823	PHENYLETHYL BUTYRATE	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%.
3824	PHENYLETHYL CAPROATE	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%.
3825	PHENYLETHYL CAPRYLATE	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%.
3826	PHENYLETHYL CINNAMATE	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%.
3827	PHENYLETHYL FORMATE	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 5

<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 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%.
3828	PHENYLETHYL METHYLETHYL CARBINOL	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%.
3829	PHENYLETHYL PROPIONATE	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 than 1%.
3830	PHENYLETHYL TIGLATE	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%.
3831	PHENYLISOPROPYL DIMETICONE	E	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

Volume 5

<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>
			The concentration in the medicine must be no more than 5%.
3832	PHENYLPROPANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.16%.
3833	PHLEUM PRATENSE	A, H	
3834	PHLOXINE B	E	Permitted for use only as a colour for oral and topical use.
3835	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3836	PHOENIX DACTYLIFERA	A, E, H	
3837	PHOSPHATIDYL CHOLINE	E	
3838	PHOSPHOLIPIDS	E	Only for use in topical medicines for dermal application and not intended for use in the eye. The concentration in the medicine must be no more than 20%.
3839	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3840	PHOSPHORUS	H	Only for use as an active homeopathic ingredient.
3841	PHOTINIA SERRULATA	A, H	
3842	PHRAGMITES AUSTRALIS	A, H	

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

Volume 5

<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>
3843	PHYLLANTHUS AMARUS	A, H	
3844	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application. When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3845	PHYLLOSTACHYS NIGRA	A, E, H	
3846	PHYSALIS ALKEKENGI	A, H	
3847	PHYSALIS PUBESCENS	A, H	
3848	PHYTANTRIOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.5%.
3849	PHYTOL	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%.
3850	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg of the equivalent dry herb.
3851	PHYTOMENADIONE	A, E	
3852	PHYTOSPHINGOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

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

Volume 5

<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>
3853	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3854	PICEA ABIES	A, H	
3855	PICEA MARIANA	A, H	
3856	PICRASMA EXCELSA	A, E, H	
3857	PICRORRHIZA KURROA	A, E, H	
3858	PIGMENT BLUE 15	E	Permitted for use only as a colour for topical and dental use. The concentration in medicine must be no more than 0.003%.
3859	PIGMENT BLUE 15:1	E	Permitted for use only as a colour for topical use. 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 0.21%.
3860	PIGMENT GREEN 7	E	Permitted for use only as a colour for topical and dental use. When for dental use, the concentration in the medicine must be no more than 0.003%. When for topical use, the concentration in the medicine must be no more than 0.17%.

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

Volume 5

<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>
3861	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.
3862	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3863	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3864	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3865	PIGMENT RED 57 BARIUM LAKE	E	Permitted for excipient use as a colour in topical medicines for dermal application. Not to be included in medicines intended for use in the eye.
3866	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3867	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3868	PIGMENT YELLOW 12	E	Permitted for use only as a colour for topical use.
3869	PILOCARPUS JABORANDI	A, H	Pilocarpine is a mandatory component of Pilocarpus jaborandi. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3870	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus. The concentration of pilocarpine in the medicine

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

Volume 5

<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>
			must be no more than 0.025%.
3871	PILOCARPUS PINNATIFOLIUS	A, H	Pilocarpine is a mandatory component of Pilocarpus pinnatifolius. The concentration of pilocarpine in the medicine must be no more than 0.025%.
3872	PIMENTA FRUIT OIL	A, E, H	
3873	PIMENTA LEAF OIL	A, E, H	
3874	PIMENTA OFFICINALIS	A, E, H	
3875	PIMENTA RACEMOSA	A, E, H	When the plant preparation for Pimenta racemosa is an oil and the concentration of this oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be fitted on the container. When the plant preparation for Pimenta racemosa is an oil, the concentration of this oil in the medicine is more than 25%, and the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.

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

Volume 5

<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>
3876	PIMPINELLA ANISUM	A, E, H	When the plant preparation for Pimpinella anisum is an oil or distillate and the concentration of this oil or distillate in the medicine is more than 50%: a) the nominal capacity of the container must be no more than 50 millilitres; and b) a restricted flow insert must be fitted on the container; and c) the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3877	PIMPINELLA SAXIFRAGA	A, E, H	
3878	PINE NEEDLE OIL SCOTCH	A, E, H	
3879	PINE NEEDLE OIL TERPENELESS	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 than 1%.
3880	PINE OIL AROMATIC	A, E, H	
3881	PINE OIL PUMILIO	A, E, H	
3882	PINEAPPLE	E	
3883	PINEAPPLE OILS	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

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

Volume 5

<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 1%.
3884	PINELLIA TERNATA	A, H	
3885	PINUS CONTORTA	A, E, H	
3886	PINUS ELLIOTTII	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 than 1%.
3887	PINUS MASSONIANA	A, E, H	When the plant preparation is oil or distillate the total concentration of Pinus massoniana oil or distillate in the preparation must be no more than 25%.
3888	PINUS MONTICOLA	A, E, H	
3889	PINUS MUGO	A, E, H	
3890	PINUS PALUSTRIS	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%.
3891	PINUS PINASTER	A, E, H	When the plant preparation is oil or distillate the total concentration of Pinus pinaster oil or distillate in the preparation must be no more than 25%.



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

Volume 5

<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>
3892	PINUS PONDEROSA	A, E, H	
3893	PINUS RADIATA	A, E, H	
3894	PINUS STROBUS	A, E, H	
3895	PINUS SYLVESTRIS	A, E, H	
3896	PINUS TABULIFORMIS	A, E, H	
3897	PINUS YUNNANENSIS	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%.
3898	PIPENZOLATE BROMIDE	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%.
3899	PIPER CHABA	A, E, H	
3900	PIPER CUBEBA	A, E, H	
3901	PIPER KADSURA	A, E, H	
3902	PIPER LONGUM	A, E, H	
3903	PIPER METHYSTICUM	A, H	Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum. Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'. When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg. If the dosage form is tablet or

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

Volume 5

<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>capsule then the quantity of kavalactones (of Piper methysticum) must be no more than 125 mg per tablet or capsule.</p> <p>Oral medicines containing more than 25 mg of kavalactones (of Piper methysticum) per dose require the following warning statement on the medicine label:</p> <p>- (PIPER) 'Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women (or words to that effect). May harm the liver'.</p> <p>The plant part must be root or rhizome.</p> <p>When for oral use, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When for topical use on the rectum, vagina or throat, the medicine may only contain dried whole or peeled root or rhizome or aqueous dispersions or aqueous extracts of whole or peeled root or rhizome.</p> <p>When the container type is tea bag the maximum quantity per tea bag must be no more than 3 grams of dried whole or peeled root or rhizomes.</p>
3904	PIPER NIGRUM	A, E, H	
3905	PIPER SARMENTOSUM	A, E, H	
3906	PIPERIDINE	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

Volume 5

<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 flavour the total flavour concentration in a medicine must be no more than 5%.
3907	PIPERINE	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary formulation.  The total flavour proprietary formulation in a medicine must not be more than 5% and the concentration of piperine in the medicine must not be more than 0.15%.
3908	PIPERITONE	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%.
3909	PIPERONAL	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%.
3910	PIPERONYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used as 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 5

<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 as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3911	PIPERONYL BUTOXIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (PIPBUT) 'Contains piperonyl butoxide' (or words to that effect).</p>
3912	PIROCTONE OLAMINE	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 1% in wash-on/wash-off medicines and 0.5% in leave-on medicines.</p>
3913	PISCIDIA PISCIPULA	A, E, H	
3914	PISTACIA LENTISCUS	A, E, H	
3915	PISUM SATIVUM	A, E, H	
3916	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3917	PLANTAGO AFRA	A, E, H	<p>When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label:</p> <p>- (PSYLL) 'On medical advice' (or words to that effect).</p>

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

Volume 5

<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>
3918	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3919	PLANTAGO ASIATICA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3920	PLANTAGO LANCEOLATA	A, E, H	The medicine requires the following warning statement on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended' When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3921	PLANTAGO MAJOR	A, E, H	When a dose for children is stated and the plant part is flower, seed or pollen, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3922	PLANTAGO OVATA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the

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

Volume 5

<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 requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3923	PLANTAGO SEED DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
3924	PLATANUS OCCIDENTALIS	A, E, H	
3925	PLATANUS RACEMOSA	A, H	
3926	PLATANUS X ACERIFOLIA	A, H	
3927	PLATYCODON GRANDIFLORUS	A, E, H	
3928	PLECTRANTHUS BARBATUS	A, E, H	
3929	PLICATONE	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%.
3930	PLUM	E	
3931	PLUMBAGO EUROPAEA	A, H	
3932	PLUMERIA ALBA	A, E, H	
3933	PLUMERIA RUBRA	A, E, H	
3934	POA NEMORALIS	A, H	
3935	POA PRATENSIS	A, H	
3936	PODOPHYLLUM PELTATUM	A, H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum. The concentration of

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

Volume 5

<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>podophyllin in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.</p> <p>The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
3937	POGOSTEMON CABLIN	A, E, H	
3938	POLACRILIN	E	
3939	POLACRILIN POTASSIUM	E	
3940	POLAPREZINC	A	<p>Only for use in oral medicines. Zinc is a mandatory component of Polaprezinc.</p> <p>The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc.</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>
3941	POLIGLUSAM	A, E	<p>When for internal use, the following warning statements are required on the medicine label:</p> <p>- (CHITO) 'Poliglusam should</p>

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

Volume 5

<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>be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect); and</p> <ul style="list-style-type: none"> <li>- (SFOOD) 'Derived from seafood'.</li> </ul> <p>When for internal use and the dosage form is a powdered preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (DNTPOW) 'Do not take powder alone. Mix with food or fluid'.</li> </ul> <p>When used as an excipient, only for use in topical medicines for dermal application.</p> <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 requirements under (a) &amp; (b).</li> </ul> <ul style="list-style-type: none"> <li>a) The average molecular mass of poliglusam must be greater than 2 kilodaltons.</li> <li>b) When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose.</li> </ul>



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

Volume 5

<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>
3942	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	<p>When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from <i>Aspergillus niger</i> per maximum recommended daily dose and requires the following warning statement on the medicine label:</p> <p>- (CHITO) 'Poliglusam should be taken at least one hour after any other medication as it may reduce the effect of other medication' (or words to that effect).</p> <p>If the medicine is a powdered dosage form, the medicine also requires the following warning statement on the medicine label:</p> <p>- 'Do not take powder alone. Mix with food or fluid.'</p> <p>When used as an excipient, Poliglusam derived from <i>Aspergillus niger</i> is only permitted for use in topical medicines for dermal application.</p>
3943	POLLACK-LIVER OIL	A, E	<p>Colecalciferol and Vitamin A are mandatory components of Pollack-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine</p>

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

Volume 5

<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 warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA3) 'The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'</li> </ul> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3944	POLLEN	E	<p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).</li> </ul>
3945	POLOXAMER	E	<p>Only for use in topical medicines for dermal application.</p>
3946	POLOXAMINE	E	<p>Permitted for use only in combination with other</p>

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

Volume 5

<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 fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3947	POLOXAMINE 1301	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%.
3948	POLY C10-30 ALKYL ACRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3949	POLYACRYLAMIDE	E	Only for use in topical medicines for dermal application. Acrylamide is a mandatory component of Polyacrylamide. The concentration of Acrylamide in the medicine must be no more than 0.01%.
3950	POLYACRYLATE CROSSPOLYMER-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.

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

Volume 5

<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>
3951	POLYACRYLATE-1 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.4%.
3952	POLYACRYLIC ACID	E	
3953	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3954	POLYAMINOPROPYL BIGUANIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.3%.
3955	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3956	POLYBUTYLENE GLYCOL/PPG- 9/1 COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 2%.
3957	POLYCAPROLACTONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than

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

Volume 5

<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>
			0.1%.
3958	POLYDECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
3959	POLYDEXTROSE	E	
3960	POLYDIETHYLSILOXANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
3961	POLYDIMETHYL SILOXANE	E	Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
3962	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
3963	POLYESTER-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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

Volume 5

<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>
			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
3964	POLYESTER-7	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3965	POLYESTER-8	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration of Polyester-8 must be no more than 5%.
3966	POLYETHYLENE	E	
3967	POLYGALA CHINENSIS	A, H	
3968	POLYGALA SENEGA	A, E, H	Except when used in a medicine containing only homoeopathic preparations, a child resistant closure and restricted flow insert must be fitted onto the container.
3969	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3970	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3971	POLYGLYCERYL-10 PENTASTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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

Volume 5

<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>
			for use in the eye. The concentration in the medicine must be no more than 1.5%.
3972	POLYGLYCERYL-2 CAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must not be more than 0.5%.
3973	POLYGLYCERYL-2 DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3.0%.
3974	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3975	POLYGLYCERYL-2 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 3%.
3976	POLYGLYCERYL-2 TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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

Volume 5

<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>
			for use in the eye. When the concentration of polyglyceryl-2 triisostearate is greater than 3%, the medicine must not be intended for use on damaged skin. The concentration in the medicine must not be more than 5%.
3977	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3978	POLYGLYCERYL-3 BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
3979	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3980	POLYGLYCERYL-3 DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3981	POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than



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

Volume 5

<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>
			6%.
3982	POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 5.5%.
3983	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3984	POLYGLYCERYL-3 STEARATE/ISOSTEARATE/DIME R DILINOLEATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 5%.
3985	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROX YSTEARATE/SEBACATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 3%.
3986	POLYGLYCERYL-4 ISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 5%.
3987	POLYGLYCERYL-4 OLEATE	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 5

<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>
3988	POLYGLYCERYL-6 POLYRICINOLEATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3989	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3990	POLYGONATUM MULTIFLORUM	A, H	
3991	POLYGONATUM OFFICINALE	A, H	
3992	POLYGONATUM SIBIRICUM	A, E, H	
3993	POLYGONUM AVICULARE	A, E, H	When used as an excipient, the medicine is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.16%.
3994	POLYGONUM BISTORTA	A, H	
3995	POLYGONUM ODORATUM	A, H	
3996	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
3997	POLYISOBUTYLENE	E	Only for use when the dosage form is 'chewing gum'. Must comply with: a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States

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

Volume 5

<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>
			Pharmacopoeial Convention, as in force or existing from time to time; and b) the requirements for residual solvents and catalysts in the British Pharmacopoeia or the United States Pharmacopoeia National Formulary, as in force or existing from time to time.
3998	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
3999	POLYLIMONENE	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%.
4000	POLYMETHACRYLIC ACID	E	
4001	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
4002	POLYMETHYLSILSESQUIOXAN E	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4003	POLYPORUS UMBELLATUS	A, H	
4004	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
4005	POLYPROPYLENE GLYCOL	E	Permitted for use only in

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

Volume 5

<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>combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
4006	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
4007	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
4008	POLYQUATERNIUM-22	E	<p>Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4009	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
4010	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.
4011	POLYQUATERNIUM-37	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

Volume 5

<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 2.5%.
4012	POLYQUATERNIUM-4	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.4%.
4013	POLYQUATERNIUM-44	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
4014	POLYQUATERNIUM-51	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4015	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal application.
4016	POLYSILICONE-11	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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

Volume 5

<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 2.1%
4017	POLYSILICONE-14	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 of Polysilicone-14 must be no more than 1%.</p>
4018	POLYSILICONE-15	A	<p>Only for use as an active ingredient in sunscreens 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 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> <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> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective</li> </ul>

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

Volume 5

<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>
			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4019	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.13%.
4020	POLYSORBATE 20	E	
4021	POLYSORBATE 40	E	
4022	POLYSORBATE 60	E	
4023	POLYSORBATE 65	E	
4024	POLYSORBATE 80	E	
4025	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4026	POLYTEF	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4027	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications.

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

Volume 5

<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>
4028	POLYURETHANE-62	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
4029	POLYVINYL ACETATE	E	Only permitted for use in medicines that are for oral routes of administration.
4030	POLYVINYL ACETATE PHTHALATE	E	
4031	POLYVINYL ALCOHOL	E	
4032	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.
4033	POMEGRANATE	E	
4034	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4035	PONCIRUS TRIFOLIATA	A, H	When used internally, oxedrine is a mandatory component of Poncirus trifoliata. The quantity of Oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4036	PONGAMOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.



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

Volume 5

<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>
4037	POPPY SEED	E, H	
4038	POPPY SEED OIL	E, H	
4039	POPULUS ALBA	A, H	
4040	POPULUS BALSAMIIFERA	A, E, H	
4041	POPULUS CANDICANS	A, H	
4042	POPULUS DELTOIDES	A, H	
4043	POPULUS NIGRA	A, H	
4044	POPULUS TREMULA	A, H	
4045	POPULUS TREMULOIDES	A, H	
4046	PORCINE	H	Only for use as an active homoeopathic ingredient.
4047	PORPHYRIDIDIUM PURPUREUM EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4048	PORTULACA OLERACEA	A, E, H	
4049	POTABLE WATER	E	
4050	POTASSIUM ACETATE	E	
4051	POTASSIUM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4052	POTASSIUM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate.
4053	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.

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

Volume 5

<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>
4054	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4055	POTASSIUM ASPARTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium aspartate.
4056	POTASSIUM ASPARTATE DIHYDRATE	A, E, H	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate dihydrate. The percentage of potassium from potassium aspartate dihydrate should be calculated based on the molecular weight of potassium aspartate dihydrate.
4057	POTASSIUM ASPARTATE MONOHYDRATE	A, E	If used as an active ingredient and the preparation is intended as a mineral supplementation, potassium is a mandatory component of Potassium aspartate monohydrate. The percentage of potassium from potassium aspartate monohydrate should be calculated based on the molecular weight of potassium aspartate monohydrate.
4058	POTASSIUM BICARBONATE	E	
4059	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4060	POTASSIUM CARBONATE	E, H	When used in a solid preparation, the pH of a 10 g/L

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

Volume 5

<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>
			aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4061	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4062	POTASSIUM CHLORIDE	A, E, H	When for oral use: a) potassium is a mandatory component of potassium chloride; b) the medicine requires the following warning statement on the medicine label: - (POTAS) 'Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines - consult your doctor or pharmacist before use. Keep out of reach of children.'; and c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit. Medicines for use as oral rehydration therapy, are subject to the following conditions: a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts; b) the sodium, potassium and glucose content, and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World

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

Volume 5

<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>
			Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and c) the medicine requires the warning statements: - (UOAD) 'Use only as directed' - (DIAR3) 'If diarrhoea persists, seek medical advice.' When for dental use, the concentration in the medicine must be no more than 3.75%.
4063	POTASSIUM CITRATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium citrate.
4064	POTASSIUM COCOYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4065	POTASSIUM COCOYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.15%.
4066	POTASSIUM DICHROMATE	H	Only for use as an active

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

Volume 5

<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>
			homoeopathic ingredient.
4067	POTASSIUM GLUCONATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium gluconate.
4068	POTASSIUM GLYCEROPHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium glycerophosphate.
4069	POTASSIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4070	POTASSIUM HYDROXYCITRATE	A, H	
4071	POTASSIUM IODATE	A, H	Iodine is a mandatory component of potassium iodate. The percentage of iodine from potassium iodate should be calculated based on the molecular weight of potassium iodate. When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate.

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

Volume 5

<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>
			When for use in children aged 1-3 years, the medicine must contain a daily dose of no more than 337 micrograms of potassium iodate.
4072	POTASSIUM IODIDE	A, E, H	<p>Iodine is a mandatory component of potassium iodide.</p> <p>The percentage of iodine from potassium iodide should be calculated based on the molecular weight of potassium iodide.</p> <p>When for internal use, the maximum recommended daily dose of the medicine must contain less than 300 micrograms of iodine.</p> <p>When for external use, the concentration of iodine in the medicine (excluding salts derivatives or iodophors) must not exceed 2.5%.</p>
4073	POTASSIUM METABISULFITE	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>
4074	POTASSIUM METAPHOSPHATE	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 0.5%.</p>
4075	POTASSIUM NITRATE	A, H	Only for dental use.

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

Volume 5

<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>
			The concentration in the medicine must be no more than 5%.
4076	POTASSIUM OROTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium orotate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4077	POTASSIUM PYROPHOSPHATE	E	Only for oral application, dental or topical use. Not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
4078	POTASSIUM SORBATE	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
4079	POTASSIUM STANNATE	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 5

<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%.
4080	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4081	POTASSIUM SULFATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of potassium sulfate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
4082	POTATO STARCH	E	
4083	POTENTILLA ANSERINA	A, H	
4084	POTENTILLA CHINENSIS	A, H	
4085	POTENTILLA DISCOLOR	A, H	
4086	POTENTILLA ERECTA	A, E, H	
4087	POTENTILLA REPTANS	A, H	
4088	POTERIUM OFFICINALE	A, E, H	
4089	POTERIUM SANGUISORBA	A, H	
4090	POVIDONE	E	
4091	POWDERED CELLULOSE	E	
4092	PPG-1-PEG-9 LAURYL GLYCOL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the



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

Volume 5

<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%.
4093	PPG-12/SMDI COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4094	PPG-15 STEARYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4095	PPG-15 STEARYL ETHER BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.4%.
4096	PPG-17/IPDI/DMPA 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 or on damaged skin. The concentration of PPG-17/IPDI/DMPA Copolymer in the medicine must be no more than 10%.
4097	PPG-2 LANOLIN ALCOHOL ETHER	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

Volume 5

<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.
4098	PPG-2 MYRISTYL ETHER PROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4099	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4100	PPG-20 METHYL GLUCOSE ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
4101	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4102	PPG-3 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4103	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4104	PPG-5-CETETH-20	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

Volume 5

<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.
4105	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4106	PRALINE	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%.
4107	PREGELATINISED MAIZE STARCH	E	
4108	PREGELATINISED POTATO STARCH	E	
4109	PREGELATINISED RICE STARCH	E	
4110	PREGELATINISED STARCH	E	
4111	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.
4112	PRENYL ACETATE	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%.
4113	PRICKLY ASH BARK DRY	A, H	
4114	PRICKLY ASH BARK POWDER	A, H	

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

Volume 5

<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>
4115	PRIMULA VERIS	A, E, H	
4116	PRIMULA VULGARIS	A, E, H	
4117	PRINSEPIA UNIFLORA	A, H	
4118	PROBOSCIDEA PARVIFLORA	A, H	
4119	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4120	PROLINE	A, E	
4121	PROPAN-1-OL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 18%.
4122	PROPANE	E	Only for use as an excipient propellant ingredient.
4123	PROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 10%.
4124	PROPENYL GUAETHOL	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%.
4125	PROPIONALDEHYDE	E	Permitted for use only in

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

Volume 5

<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>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>
4126	PROPIONIC ACID	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>
4127	PROPIONYLLEVO-CARNITINE HYDROCHLORIDE	A, H	
4128	PROPOLIS	A, E	<p>Lead is a mandatory component of Propolis.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:                      -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:                      - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the</p>

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

Volume 5

<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>
			mouth or throat occurs, discontinue use.'
4129	PROPOLIS BALSAM	A, E	<p>Lead is a mandatory component of Propolis balsam. The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:                      -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:                      - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4130	PROPOLIS DRY EXTRACT	A, E	<p>Lead is a mandatory component of Propolis dry extract. The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:                      -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:                      - (PROP2) 'Warning: Propolis</p>

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

Volume 5

<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>
			may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4131	PROPOLIS LIQUID EXTRACT	A, E	<p>Lead is a mandatory component of Propolis liquid extract.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:                      -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:                      - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4132	PROPOLIS RESIN	A, E	<p>Lead is a mandatory component of propolis resin.</p> <p>The concentration of lead in the medicine must be no more than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:                      -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine</p>

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

Volume 5

<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>
			label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4133	PROPOLIS TINCTURE	A, E	Lead is a mandatory component of Propolis tincture. The concentration of lead in the medicine must be no more than 0.001%. When used topically, the medicine requires the following warning statement on the medicine label: -(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use' When used for other than for topical, the medicine requires the following warning statement on the medicine label: - (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'
4134	PROPYL ACETATE	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%.
4135	PROPYL CAPROATE	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 5

<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%.
4136	PROPYL GALLATE	E	
4137	PROPYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
4138	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4139	PROPYLENE GLYCOL	E	
4140	PROPYLENE GLYCOL ALGINATE	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%.
4141	PROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 20%.
4142	PROPYLENE GLYCOL	E	Only for use in topical

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

Volume 5

<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>
	DIDECANOATE		medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4143	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4144	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4145	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.
4146	PROPYLENE GLYCOL ISOCETETH-3 ACETATE	E	Only for use in topical medicines for dermal application only and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4147	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4148	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4149	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4150	PROPYLENE GLYCOL	E	Only for use in topical

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

Volume 5

<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>
	MYRISTYL ETHER ACETATE		medicines for dermal application.
4151	PROSOPIS JULIFLORA	A, H	
4152	PROTEASE	A	<p>Must be derived from <i>Aspergillus oryzae</i> or <i>Aspergillus niger</i>.</p> <p>When the dosage form is undivided, the units 'haemoglobin unit on the tyrosine basis per gram' and 'Thousand haemoglobin units on the tyrosine basis per gram' are permitted.</p> <p>When the dosage form is divided, the units 'haemoglobin units on the tyrosine basis' and 'thousand haemoglobin units on the tyrosine basis' are permitted.</p>
4153	PROTEIN HYDROLYSATE	E	
4154	PRUNE JUICE	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>
4155	PRUNE JUICE CONCENTRATE	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>
4156	PRUNELLA VULGARIS	A, H	
4157	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory

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

Volume 5

<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>components of <i>Prunus africana</i>.                      The concentration of Amygdalin in the medicine must be 0%.                      The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4158	PRUNUS ARMENIACA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus armeniaca</i> and must be declared in the application.                      The concentration of Amygdalin in the medicine must be 0%.                      The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4159	PRUNUS AVIUM	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus avium</i>.                      The concentration of Amygdalin in the medicine must be 0%.                      The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4160	PRUNUS CERASIFERA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of <i>Prunus cerasifera</i>.                      The concentration of Amygdalin in the medicine must be 0%.                      The concentration of Hydrocyanic acid in the</p>

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

Volume 5

<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 1 microgram/kg or 1 microgram/L or 0.0000001%.
4161	PRUNUS CERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4162	PRUNUS DOMESTICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
4163	PRUNUS DULCIS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed.</p> <p>When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p> <p>The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1</p>

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

Volume 5

<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>
			microgram/L or 0.0000001%.
4164	PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4165	PRUNUS JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4166	PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4167	PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. The concentration of Amygdalin in the medicine

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

Volume 5

<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>
			must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4168	PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4169	PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4170	PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4171	PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory

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

Volume 5

<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>
			components of <i>Prunus spinosa</i> . The concentration of Amygdalin in the medicine must be 0%. The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4172	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4173	PSEUDOCYDONIA SINENSIS	A, H	
4174	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4175	PSEUDOTSUGA MENZIESII	A, H	
4176	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.
4177	PSIDIUM GUAJAVA	A, E, H	
4178	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4179	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4180	PSYLLIUM HUSK DRY	A, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4181	PSYLLIUM HUSK POWDER	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).



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

Volume 5

<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>
4182	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label: - (PSYLL) 'On medical advice' (or words to that effect).
4183	PTELEA TRIFOLIATA	A, H	
4184	PTEROCARPUS MARSUPIUM	A, H	
4185	PTEROCARPUS SANTALINUS	A, E, H	
4186	PUERARIA LOBATA	A, E, H	
4187	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4188	PULLULAN	E	
4189	PUMICE	E	
4190	PUMPKIN	E	
4191	PUMPKIN SEED	E, H	
4192	PUMPKIN SEED OIL	E, H	
4193	PUNICA GRANATUM	A, E, H	
4194	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4195	PURIFIED HONEY	A, E	When the route of administration is oral, the medicine requires the following warning statement on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).  When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the

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

Volume 5

<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>maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4196	PURIFIED SILICEOUS EARTH	E, H	
4197	PURIFIED TALC	E	
4198	PURIFIED WATER	E	
4199	PVM/MA COPOLYMER	E	
4200	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4201	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4202	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4203	PYRETHRINS	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>The medicine requires the following warning statement</p>

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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			on the medicine label: - (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect).
4204	PYRIDOXAL 5-PHOSPHATE	A, E	<p>Pyridoxine is a mandatory component of Pyridoxal 5-phosphate.</p> <p>The percentage of pyridoxine from pyridoxal 5-phosphate should be calculated based on the molecular weight of pyridoxal 5-phosphate.</p> <p>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label: - (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'</p>
4205	PYRIDOXAL 5-PHOSPHATE MONOHYDRATE	A	<p>Pyridoxine is a mandatory component of Pyridoxal 5-phosphate monohydrate.</p> <p>The percentage of pyridoxine from pyridoxal 5-phosphate monohydrate should be calculated based on the molecular weight of pyridoxal 5-phosphate monohydrate.</p> <p>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more</p>

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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label:</p> <p>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'</p>
4206	PYRIDOXINE HYDROCHLORIDE	A, E, H	<p>When not used as an active homoeopathic ingredient, pyridoxine is a mandatory component of Pyridoxine hydrochloride.</p> <p>The percentage of pyridoxine from pyridoxine hydrochloride should be calculated based on the molecular weight of pyridoxine hydrochloride.</p> <p>The maximum recommended daily dose must provide no more than 200 mg of pyridoxine.</p> <p>If the medicine contains more than 50 mg and no more than 200 mg of pyridoxine per maximum recommended daily dose the medicine requires the following warning statement on the medicine label:</p> <p>- (VITB6SX) 'WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].'</p>
4207	PYROGLUTAMIC ACID	E	
4208	PYROLA DECORATA	A, H	

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

Volume 5

<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>
4209	PYROLIGNEOUS ACID	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%.
4210	PYRROSIA LINGUA	A, H	
4211	PYRROSIA PETIOLOSA	A, H	
4212	PYRROSIA SHEARERI	A, H	
4213	PYRUS COMMUNIS	A, E, H	Arbutin is a mandatory component of Pyrus communis. 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 %.
4214	PYRUS PYRIFOLIA	A, H	Arbutin is a mandatory component of Pyrus pyrifolia. 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 %.
4215	PYRUVIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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

Volume 5

<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 concentration in a medicine must be no more than 5%.
4216	QUASSIA	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%.
4217	QUASSIA AMARA	A, E, H	
4218	QUASSIA WOOD JAMAICAN DRY	A, H	
4219	QUASSIA WOOD JAMAICAN POWDER	A, H	
4220	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.
4221	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4222	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4223	QUATERNIUM-52	E	Only for use in wash-on/wash-off 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 1%. Not be used in medicines in which N-nitroso compounds may be formed.

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

Volume 5

<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>
4224	QUATERNIUM-80	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.5%.
4225	QUERCETIN	A	
4226	QUERCETIN DIHYDRATE	A	
4227	QUERCUS ACUTISSIMA	A, H	
4228	QUERCUS ALBA	A, E, H	
4229	QUERCUS PALUSTRIS	A, H	
4230	QUERCUS ROBUR	A, H	
4231	QUERCUS RUBRA	A, H	
4232	QUERCUS VIRGINIANA	A, H	
4233	QUILLAIA DRY	A, H	
4234	QUILLAIA POWDER	A, E, H	
4235	QUILLAJA SAPONARIA	A, H	
4236	QUINCE	E	
4237	QUININE ARSENITE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of Quinine arsenite. The maximum recommended daily dose must be no more than 50 mg of quinine.
4238	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient. Quinine is a mandatory component of quinine sulfate dihydrate. The maximum recommended daily dose must be no more than 50 mg of quinine.

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

Volume 5

<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>
4239	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4240	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4241	QUISQUALIS INDICA	A, H	
4242	R-ALPHA LIPOIC ACID	A	
4243	RACEMENTHOL	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 than 1%.
4244	RACEMIC CAMPHOR	E, H	Only for use as an active homoeopathic or excipient ingredient. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach



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

Volume 5

<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>of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4245	RADISH	E	
4246	RAISIN JUICE CONCENTRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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

Volume 5

<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 concentration in a medicine must be no more than 5%.
4247	RANUNCULUS BULBOSUS	A, H	
4248	RANUNCULUS FICARIA	A, H	
4249	RANUNCULUS TERNATUS	A, H	
4250	RAPE SEED OIL	A, E, H	Allyl isothiocyanate is a mandatory component of rape seed oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4251	RAPHANUS SATIVUS	A, H	
4252	RASPBERRY	E	
4253	RASPBERRY BRANDY	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%.
4254	RASPBERRY DISTILLATE	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%.
4255	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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

Volume 5

<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 concentration in a medicine must be no more than 5%.
4256	RASPBERRY JUICE CONCENTRATE	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%.
4257	RAUWOLFIA SERPENTINA	A, H	The concentration of equivalent dry Rauwolfia serpentina in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4258	RAUWOLFIA SERPENTINA DRY	A, H	The concentration of Rauwolfia Serpentina Dry in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4259	RAUWOLFIA SERPENTINA POWDER	A, H	The concentration of Rauwolfia Serpentina Powder in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4260	RED 27	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.
4261	RED 27 ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The concentration in the medicine must be no more than 0.5%.

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

Volume 5

<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>
4262	RED ANT	H	Only for use as an active homoeopathic ingredient.
4263	RED CLOVER FLOWER DRY	A, H	
4264	RED CLOVER FLOWER POWDER	A, H	
4265	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4266	RED DEER	A	
4267	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.
4268	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4269	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4270	REHMANNIA GLUTINOSA	A, E, H	
4271	REL-1-((1R,2S)-1,2,3,4,5,6,7,8-OCTAHYDRO-1,2,8,8-TETRAMETHYL-2-NAPHTHALENYL)-1-ETHANONE	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%.
4272	RESORCINOL	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%.
4273	RESORCINOL DIMETHYLETHER	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 5

<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%.
4274	RESVERATROL	A	Only permitted for use in medicines that are for oral routes of administration. The maximum recommended daily dose of the medicine must not contain more than 150 milligrams of resveratrol. The following warning statements are required on the medicine label: - (RESVER) 'Resveratrol may affect the way some medicines work, including Warfarin. Consult your health professional before taking with other medicines (or words to that effect)'; - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)'; and - (CHILD2) 'Not suitable for children'.
4275	RETINOL	A, E	Vitamin A is a mandatory component of retinol. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided

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

Volume 5

<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>preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
4276	RETINOL ACETATE	A, E	<p>Vitamin A is a mandatory component of retinol acetate.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine</p>

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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
4277	RETINOL PALMITATE	A, E	<p>Vitamin A is a mandatory component of retinol palmitate.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering</p>

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

Volume 5

<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>becoming pregnant - do not take Vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - Vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of Vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
4278	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4279	RHAMNOSE	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>
4280	RHAMNUS CATHARTICA	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine</p>



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

Volume 5

<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 warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not</li> </ul>

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

Volume 5

<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>
			recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4281	RHAMNUS FRANGULA	A, H	<p>Glucofrangulins calculated as glucofrangulin A is a mandatory component of Rhamnus frangula.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>

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

Volume 5

<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>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4282	RHATANY ROOT DRY	A, H	
4283	RHATANY ROOT POWDER	A, H	
4284	RHEUM OFFICINALE	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum officinale.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may</p>

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

Volume 5

<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>cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>

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

Volume 5

<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>
4285	RHEUM PALMATUM	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of <i>Rheum palmatum</i>.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may</li> </ul>

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

Volume 5

<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>have laxative effect’.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) ‘Use in children under 12 years is not recommended’;</li> <li>- (LAX1) ‘Drink plenty of water’ (or words to that effect);</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX2) ‘Prolonged use may cause serious bowel problems’.</li> </ul>
4286	RHEUM RHAPONTICUM	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rheum rhaponticum.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) ‘Use in children under 12 years is not recommended’;</li> <li>- (LAX2) ‘Prolonged use may cause serious bowel problems’;</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product’ (or words to that</li> </ul>

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

Volume 5

<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>effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4287	RHEUM TANGUTICUM	A, H	<p>The plant part must not be leaf.</p> <p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum tanguticum.</p> <p>When used in oral medicines, if the maximum recommended</p>

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

Volume 5

<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>daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)']; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements</p>



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

Volume 5

<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: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4288	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4289	RHODINOL	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%.
4290	RHODINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4291	RHODIOLA ROSEA	A	Only for use in oral medicines. Only available for use when the plant preparation is dry root powder, dry root powder as an aqueous extract or dry root powder as a hydroethanolic extract with no more than 70% ethanol v/v.

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

Volume 5

<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>
4292	RHODODENDRON AUREUM	A, H	
4293	RHODODENDRON FERRUGINEUM	A, H	<p>Arbutin is a mandatory component of Rhododendron ferrugineum.</p> <p>The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair.</p> <p>When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.</p>
4294	RHODODENDRON MOLLE	A, H	<p>The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.</p>
4295	RHUBARB	E, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhubarb.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that</li> </ul>

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

Volume 5

<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>effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4296	RHUBARB ROOT DRY	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than</p>

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

Volume 5

<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>10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)']; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p>

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

Volume 5

<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>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4297	RHUBARB ROOT POWDER	A, H	<p>When the route of administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of rhubarb root powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the</p>

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

Volume 5

<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 requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4298	RHUS AROMATICA	A, E, H	
4299	RHUS CHINENSIS	A, H	
4300	RHUS GLABRA	A, E, H	
4301	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4302	RIBES GROSSULARIA	A, E, H	
4303	RIBES NIGRUM	A, E, H	
4304	RIBOFLAVIN	A, E	
4305	RIBOFLAVIN SODIUM PHOSPHATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

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

Volume 5

<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>
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4306	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal application.
4307	RIBOFLAVINE	A, E	
4308	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4309	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4310	RIBOSE	A	Only for use in oral medicines. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).

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

Volume 5

<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>
4311	RICE	E	
4312	RICE BRAN	E	
4313	RICE BRAN OIL	E	
4314	RICE BRAN WAX	A, E, H	
4315	RICE STARCH	E	
4316	RICE VINEGAR	E	
4317	RICE WINE	E	Ethanol is a mandatory component of Rice wine. When the concentration of ethanol in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol' or 'contains alcohol'
4318	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.
4319	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4320	ROBINIA PSEUDOACACIA	A, E, H	When the herbal substance is derived from plant parts other than the leaf or flower, the maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4321	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4322	ROSA ARVENSIS	A, E, H	
4323	ROSA CANINA	A, E, H	



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

Volume 5

<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>
4324	ROSA CYMOSA	A, E, H	
4325	ROSA EGLANTERIA	A, E, H	
4326	ROSA GALLICA	A, E, H	
4327	ROSA LAEVIGATA	A, E, H	
4328	ROSA MULTIFLORA	A, E, H	
4329	ROSA ROXBURGHII FRUIT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.002%.
4330	ROSA RUGOSA	A, E, H	
4331	ROSA VILLOSA	A, E, H	
4332	ROSA X CENTIFOLIA	A, E, H	
4333	ROSA X DAMASCENA	A, E, H	
4334	ROSANA	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%.
4335	ROSE 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%.
4336	ROSE FRUIT FRESH	A, E, H	

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

Volume 5

<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>
4337	ROSE HIP	E	
4338	ROSE OIL	A, E, H	
4339	ROSE OXIDE	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%.
4340	ROSEMARY OIL	A, E, H	Safrole is a mandatory component of Rosemary oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
4341	ROSMARINUS OFFICINALIS	A, E, H	Camphor and cineole are mandatory components of Rosmarinus officinalis. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is

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

Volume 5

<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>more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4342	ROYAL JELLY	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD2) 'Not suitable for</li> </ul>

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

Volume 5

<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>
			children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4343	ROYAL JELLY FRESH	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.
4344	ROYAL JELLY LYOPHILISED	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised. The medicine requires the following warning statements on the medicine label: - (CHILD2) 'Not suitable for children' - (ROYJ) 'Not to be taken by asthma and allergy sufferers' in 3 mm type, prominent on front and 'This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers'.

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

Volume 5

<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>
4345	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4346	RUBIA CORDIFOLIA	A, H	
4347	RUBIA TINCTORUM	A, H	
4348	RUBUS CHINGII	A, H	
4349	RUBUS CORCHORIFOLIUS	A, H	
4350	RUBUS COREANUS	A, E, H	
4351	RUBUS FRUTICOSUS	A, E, H	
4352	RUBUS IDAEUS	A, E, H	
4353	RUBUS OCCIDENTALIS	A, E, H	
4354	RUBUS PARVIFOLIUS	A, H	
4355	RUBUS ROSIFOLIUS	A, H	
4356	RUDBECKIA HIRTA	A, H	
4357	RUE OIL	A, H	
4358	RUM	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%.
4359	RUMEX ACETOSA	A, H	
4360	RUMEX ACETOSELLA	A, H	
4361	RUMEX CONGLOMERATUS	A, H	
4362	RUMEX CRISPUS	A, E, H	
4363	RUMEX PULCHER	A, H	
4364	RUMEX SCUTATUS	A, H	
4365	RUSCUS ACULEATUS	A, H	
4366	RUTA GRAVEOLENS	A, E, H	
4367	RUTOSIDE	A, E	

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

Volume 5

<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>
4368	RYE	E	Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.
4369	RYE BRAN	E	Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.
4370	S-ISOPROPYL 3-METHYLTHIOCROTONATE	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%.
4371	SABINENE HYDRATE	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%.
4372	SACCHARIDE ISOMERATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.66%.
4373	SACCHARIN	E	When the medicine is for oral use, the following warning statement is required on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect).

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

Volume 5

<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>
4374	SACCHARIN SODIUM	E	The medicine requires the following warning statement on the medicine label: - (SACCH) 'Contains saccharin' (or words to that effect). When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4375	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.
4376	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4377	SACCHAROMYCES CEREVISIAE POLYSACCHARIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4378	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4379	SACCHARUM OFFICINARUM	A, E, H	
4380	SAFFLOWER OIL	A, E, H	
4381	SAFFRON	E	Permitted for use only as a

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

Volume 5

<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>
			colour for either topical use or with an oral route of administration.
4382	SAGE LEAF DRY	A, E, H	Thujone is a mandatory component of Sage leaf dry. The concentration of thujone in the medicine must be no more than 4%.
4383	SAGE LEAF POWDER	A, H	Thujone is a mandatory component of Sage leaf powder. The concentration of thujone in the medicine must be no more than 4%.
4384	SAGE OIL DALMATIAN	A	Thujone is a mandatory component of Sage oil dalmatian. The concentration of thujone in the medicine must be no more than 4%. When the concentration of Sage oil dalmatian in the medicine is more than 10% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert and child resistant closure must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
4385	SAGE OIL SPANISH	A, E, H	
4386	SALICORNIA EUROPAEA EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in medicines intended for use in the eye or



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

Volume 5

<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 damaged skin. The concentration in the medicine must be no more than 0.002%.
4387	SALICYLALDEHYDE	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%.
4388	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 40%.
4389	SALIX ALBA	A, E, H	
4390	SALIX DAPHNOIDES	A, H	
4391	SALIX DISCOLOR	A, H	
4392	SALIX FRAGILIS	A, H	
4393	SALIX NIGRA	A, H	
4394	SALIX PURPUREA	A, H	
4395	SALSOLA KALI	A, H	
4396	SALVIA CHINENSIS	A, H	
4397	SALVIA FRUTICOSA	A, H	
4398	SALVIA HISPANICA	A, E, H	
4399	SALVIA LAVANDULAEFOLIA	A, H	
4400	SALVIA MILTIORRHIZA	A, H	
4401	SALVIA OFFICINALIS	A, E, H	Thujone is a mandatory component of Salvia

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

Volume 5

<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>
			officinalis. The concentration of thujone in the medicine must be no more than 4%.
4402	SALVIA SCLAREA	A, E, H	
4403	SAMBUCUS CANADENSIS	A, H	
4404	SAMBUCUS EBULUS	A, H	
4405	SAMBUCUS NIGRA	A, E, H	
4406	SANDALWOOD OIL EAST INDIAN	A, E, H	
4407	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient. The potency must be more than 4X.
4408	SANICULA EUROPAEA	A, H	
4409	SANTALUM ALBUM	A, E, H	
4410	SANTALUM SPICATUM	A, E, H	The route of administration must be topical or inhalation. The plant preparation must be oil. The plant part must be root or stem wood including heartwood.
4411	SAPINDUS MUKOROSI	A, H	
4412	SAPONARIA OFFICINALIS	A, H	
4413	SAPOSHNIKOVIA DIVARICATA	A, H	
4414	SARCOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.

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

Volume 5

<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>
4415	SARGASSUM FUSIFORME	A, H	<p>Iodine is a mandatory component of Sargassum fusiforme.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
4416	SARGASSUM SILIQUASTRUM	A, H	<p>Iodine is a mandatory component of Sargassum siliquastrum.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
4417	SASSAFRAS ALBIDUM	A, H	<p>Safrole is a mandatory component of Sassafras albidum.</p> <p>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in the medicine must be no more than 1%.</p>
4418	SATUREIA HORTENSIS	A, H	
4419	SATUREIA MONTANA	A, H	
4420	SAUROPUS SPATULIFOLIUS	A, H	

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

Volume 5

<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>
4421	SAURURUS CHINENSIS	A, H	
4422	SAUSSUREA COSTUS	A, H	
4423	SAVORY OIL SUMMER	A, H	
4424	SAXIFRAGA GRANULATA	A, E, H	
4425	SAXIFRAGA STOLONIFERA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.0816%.
4426	SCAPHIUM SCAPHIGERUM	A, H	
4427	SCHEFFLERA HEPTAPHYLLA	A, H	
4428	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4429	SCHINUS MOLLE	A, H	
4430	SCHINUS MOLLE OIL	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%.
4431	SCHISANDRA CHINENSIS	A, E, H	
4432	SCHIZONEPETA TENUIFOLIA	A, E, H	
4433	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no more than the equivalent of 1mg of the dry herbal material.
4434	SCLAREOL	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 5

<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%.
4435	SCLAREOLIDE	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%.
4436	SCLERANTHUS ANNUUS	A, H	
4437	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4438	SCOPOLIA CARNIOLICA	A, H	The concentration of equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
4439	SCROPHULARIA NINGPOENSIS	A, H	
4440	SCROPHULARIA NODOSA	A, H	
4441	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4442	SCUTELLARIA BAICALENSIS	A, E, H	
4443	SCUTELLARIA BARBATA	A, H	
4444	SCUTELLARIA LATERIFLORA	A, E, H	
4445	SEA WHIP EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4446	SEC BUTYL 3-METHYLBUT-2-	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 5

<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>
	ENETHIOATE		permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4447	SEC-BUTYL THIOISOVALERATE	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%.
4448	SECALE CEREALE	A, H	Gluten is a mandatory component of Secale cereale when the plant part is seed and the route of administration is other than topical and mucosal.
4449	SEDUM ACRE	A, H	
4450	SELAGINELLA TAMARISCINA	A, H	
4451	SELENICEREUS GRANDIFLORUS	A, E, H	
4452	SELENIUM	H	Only for use as an active homoeopathic ingredient. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be

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

Volume 5

<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>
			exceeded.'
4453	SELENOCYSTEINE	A	<p>Selenium is a mandatory component of Selenocysteine for oral and sublingual use.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses.</p> <p>A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'</p>
4454	SELENOMETHIONINE	A	<p>Selenium is a mandatory component of Selenomethionine for oral and sublingual use.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4455	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4456	SEMECARPUS ANACARDIUM	A, H	When the plant part is other than seed, the maximum

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

Volume 5

<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>
			recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4457	SEMOLINA	E	
4458	SEMPERVIVUM TECTORUM	A, H	
4459	SENEGA ROOT DRY	A, H	
4460	SENEGA ROOT POWDER	A, H	
4461	SENNA ALEXANDRINA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna alexandrina.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or</p>



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

Volume 5

<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>marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4462	SENNA FRUIT ALEXANDRIAN DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems';</li> </ul>

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

Volume 5

<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>and</p> <ul style="list-style-type: none"> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect);</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>

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

Volume 5

<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>
4463	SENNA FRUIT ALEXANDRIAN POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit alexandrian powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul>

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

Volume 5

<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 used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect);</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4464	SENNA FRUIT TINNEVELLY DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul>

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

Volume 5

<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 promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4465	SENNA FRUIT TINNEVELLY POWDER	A, H	<p>When for oral or sublingual, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna fruit tinnevelly powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning</p>

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

Volume 5

<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>statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> </ul>

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

Volume 5

<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>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4466	SENNA LEAF DRY	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna leaf dry.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product</p>

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

Volume 5

<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>contains [name of the herb(s) or the chemical component(s)];</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect); and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
4467	SENNA LEAF POWDER	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna Leaf Powder.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are</p>



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

Volume 5

<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>pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4468	SENNA OCCIDENTALIS	A, H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna occidentalis when the route of administration is oral

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

Volume 5

<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>administration.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' [or words to that effect].</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)']; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or</p>

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

Volume 5

<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>marketed as laxative, the medicine the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended;</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4469	SENNA TORA	A, H	<p>When for oral or sublingual use, Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna tora.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of</li> </ul>

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

Volume 5

<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>water' (or words to that effect).                      When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4470	SEPIA	H	Only for use as an active homoeopathic ingredient.
4471	SEQUOIA SEMPERVIRENS	A, H	
4472	SEQUOIADENDRON GIGANTEUM	A, H	
4473	SERENOA REPENS	A, H	
4474	SERINE	A, E	
4475	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4476	SESAME OIL	A, E, H	

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

Volume 5

<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>
4477	SESAME SEED	E	
4478	SESAMUM INDICUM	A, E, H	
4479	SETARIA ITALICA	A, H	
4480	SHARK CALCIUM CHONDROITIN SULFATE	A	
4481	SHARK CARTILAGE	A, E	The medicine requires the following warning statement on the medicine label: - (SHARK) 'Children, pregnant or breastfeeding women, and those who have recently had a heart attack, surgery or a major accident should not consume this product without medical advice' (or words to that effect)
4482	SHARK CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4483	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4484	SHARK SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
4485	SHARK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of

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

Volume 5

<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>Shark-liver oil.</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</li> </ul>

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

Volume 5

<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>
4486	SHEA BUTTER	E	
4487	SHEA BUTTER UNSAAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4488	SHELLAC	E	
4489	SHEPHERD'S PURSE HERB DRY	A, H	
4490	SHEPHERD'S PURSE HERB POWDER	A, H	
4491	SHERRY WINE	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%.
4492	SIGESBECKIA ORIENTALIS	A, E, H	
4493	SILICA	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%.
4494	SILICA DIMETHYL SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 4%.
4495	SILICA SILYLATE	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 5

<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>
4496	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4497	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4498	SILICONE QUATERNIUM-8	E	Only for use in wash-off 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 2.5%.  The medicine requires the following warning statement on the medicine label:  - (EYE) 'Avoid contact with eyes' (or words to that effect).
4499	SILVER	H	Only for use as an active homeopathic ingredient.  The concentration in the medicine must be no more than 1%.
4500	SILVER BEET	E, H	
4501	SILVER BOROSILICATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine should be no more than 0.6%.  Silver is a mandatory component of Silver borosilicate when the route of administration is topical.  The concentration of silver in the medicine must be no more



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

Volume 5

<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 1%.
4502	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4503	SILYBUM MARIANUM	A, E, H	
4504	SIMABA CEDRON	A, H	
4505	SIMETHICONE	E	
4506	SIMMONDSIA CHINENSIS	A, E, H	
4507	SINAPIS ALBA	A, H	Allyl isothiocyanate is a mandatory component of Sinapis alba when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4508	SINAPIS ARVENSIS	A, H	
4509	SINOMENIUM ACUTUM	A, H	
4510	SIPHONESTEGIA CHINENSIS	A, H	
4511	SIRAITIA GROSVENORII	A, E, H	
4512	SISYMBRIUM OFFICINALE	A, H	
4513	SKATOLE	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%.
4514	SKIPJACK-LIVER OIL	A, E	Vitamin A and Colecalciferol are mandatory components of Shark-liver oil. When for internal use, the

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

Volume 5

<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>maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p>
4515	SLIPPERY ELM BARK DRY	A, H	
4516	SLIPPERY ELM BARK POWDER	A, E, H	

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

Volume 5

<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>
4517	SMILAX ARISTOLOCHIIIFOLIA	A, H	
4518	SMILAX CHINA	A, H	
4519	SMILAX GLABRA	A, H	
4520	SMILAX OFFICINALIS	A, E, H	
4521	SMILAX ORNATA	A, E, H	
4522	SMOKE 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%.
4523	SODIUM ACETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4524	SODIUM ACETYLATED HYALURONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
4525	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines. When used as an active, only for use in oral medicines. When for oral or sublingual use

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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4526	SODIUM ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.8%.
4527	SODIUM ACRYLATES CROSSPOLYMER-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.7 % (w/w).
4528	SODIUM ACRYLOYLDIMETHYLTAURATE/VP CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2% (w/w).
4529	SODIUM ALGINATE	E	
4530	SODIUM ASCORBATE	A, E, H	When for oral or sublingual use and the total amount of sodium

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

Volume 5

<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>
			from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4531	SODIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When used in a sunscreen, the concentration in the medicine must be no more than 0.1%. When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%.
4532	SODIUM ASCORBYL/CHOLESTERYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4533	SODIUM BENZOATE	E	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one

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

Volume 5

<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>
			benzoate source. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4534	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4535	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4536	SODIUM BICARBONATE	A, E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
			When used as an active

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

Volume 5

<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>ingredient, the medicine may only be for oral rehydration salts in powdered and effervescent tablet dosage forms.</p> <p>Medicines for use as oral rehydration therapy are subject to the following conditions:</p> <p>a) the medicine complies with the requirements specified in the British Pharmacopoeia, as in force or existing from time to time, for Oral Rehydration Salts;</p> <p>b) the sodium content and total osmolarity of the solution after it has been prepared according to the instructions on the packet are consistent with the criteria specified by the World Health Organisation (WHO) and the United Nations Childrens Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation 18 July 2001.'</p> <p>c) the medicine requires the following warning statements on the medicine label:</p> <p>- (UOAD) 'Use only as directed.'</p> <p>- (DIAR) 'If diarrhoea persists for more than 6 hours in infants under 6 months - 12 hours in children under 3 years - 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years - seek medical advice (or words to that effect).'</p> <p>- (DIAR3) 'If diarrhoea persists, seek medical advice.'</p>
4537	SODIUM BISULFITE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the

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

Volume 5

<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>maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4538	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4539	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4540	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal application.
4541	SODIUM CARBONATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state</p>



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

Volume 5

<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>
			quantity and units] of sodium' (or words to that effect).
4542	SODIUM CARBONATE MONOHYDRATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4543	SODIUM CARBOXYMETHYL BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
4544	SODIUM CARRAGEENAN	E	
4545	SODIUM CASEINATE	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%.
4546	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4547	SODIUM CHLORIDE	A, E, H	

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

Volume 5

<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>
4548	SODIUM CHONDROITIN SULFATE	A, E	<p>When used as an excipient ingredient:</p> <p>a) only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye;</p> <p>b) the concentration in the medicine must not be more than 0.001%.</p> <p>When used as an active ingredient:</p> <p>a) the route of administration must only be oral;</p> <p>b) the maximum daily dose must not provide more than 1,200 mg of sodium chondroitin sulfate;</p> <p>c) the following statements must be included on the medicine label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect);</li> <li>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</li> </ul>
4549	SODIUM CITRATE	A, E	<p>Only for oral use when used as an active ingredient.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</li> </ul>
4550	SODIUM CITRATE DIHYDRATE	A, E	Only for oral use when used as

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

Volume 5

<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>an active ingredient.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4551	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	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 0.05%.</p>
4552	SODIUM COCOAMPHOACETATE	E	<p>Only for use in topical medicines for dermal application.</p>
4553	SODIUM COCOYL SARCOSINATE	E	<p>Only for use in topical medicines for dermal application.</p>
4554	SODIUM CYCLAMATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>

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

Volume 5

<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>
4555	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal application.
4556	SODIUM DNA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4557	SODIUM DODECYLBENZENESULFONAT E	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 30%.
4558	SODIUM ERYTHORBATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4559	SODIUM ETHYL HYDROXYBENZOATE	E	
4560	SODIUM FLUORIDE	A, E, H	Fluoride is a mandatory component of Sodium fluoride. Only for use when the route of administration is dental and the dosage form is pastes, powders or gels for dental hygiene. When used as an active

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

Volume 5

<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>ingredient, it is subject to the following conditions:</p> <p>a) Only for use in combination with at least one other listable therapeutically active ingredient.</p> <p>b) The concentration of fluoride ion must be no more than 1,500 mg/kg.</p> <p>When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (DNTSW) 'Do not swallow.'</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'</li> </ul> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</li> </ul>
4561	SODIUM FUMARATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).'</li> </ul>

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

Volume 5

<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>
4562	SODIUM GLYCEROPHOSPHATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4563	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4564	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4565	SODIUM HYDROXIDE	E	The concentration in the medicine must be no more than 5%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect). When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH

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

Volume 5

<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>
			of the preparation must not exceed 11.5.
4566	SODIUM HYDROXYCITRATE	A	
4567	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4568	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4569	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of Sodium hypochlorite. The concentration of chlorine in the medicine must be no more than 4%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4570	SODIUM ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4571	SODIUM LACTATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the

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

Volume 5

<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>maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4572	SODIUM LAURETH SULFATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p>
4573	SODIUM LAUROAMPHOACETATE	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 5%.</p>
4574	SODIUM LAUROYL METHYL ISETHIONATE	E	<p>Only for use in wash-off topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 11%.</p>
4575	SODIUM LAUROYL	E	Only for use in topical



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

Volume 5

<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>
	SARCOSINATE		medicines for dermal application.
4576	SODIUM LAURYL PHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4577	SODIUM LAURYL SULFATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4578	SODIUM LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4579	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4580	SODIUM MANNOSE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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

Volume 5

<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 0.5%.
4581	SODIUM METABISULFITE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4582	SODIUM METAPHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin.</p> <p>The concentration in the medicine must not be more than 0.1%.</p>
4583	SODIUM METHYL COCOYL TAURATE	E	<p>Only for dental use.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4584	SODIUM METHYL	E	When for oral or sublingual use

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

Volume 5

<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>
	HYDROXYBENZOATE		<p>and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.</p>
4585	SODIUM MOLYBDATE DIHYDRATE	A	<p>Only for use in oral medicines. Molybdenum is a mandatory component of Sodium molybdate dihydrate.</p> <p>The percentage of molybdenum from sodium molybdate dihydrate should be calculated based on the molecular weight of sodium molybdate dihydrate.</p> <p>The maximum daily dose of molybdenum from Sodium molybdate dihydrate must be no more than 125 micrograms.</p>
4586	SODIUM MONOFLUOROPHOSPHATE	A	<p>Fluoride is a mandatory component of sodium monofluorophosphate.</p> <p>Only for use when the route of</p>

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

Volume 5

<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>administration is dental and the dosage form is pastes, powders or gels for dental hygiene.</p> <p>When used as an active ingredient, it is subject to the following conditions:</p> <p>a) Only for use in combination with at least one other listable therapeutically active ingredient.</p> <p>b) The concentration of fluoride ion must be no more than 1,500 mg/kg.</p> <p>When the concentration of fluoride ion is more than 1000 mg/kg, the medicine requires the following statements on the medicine label:</p> <p>- (DNTSW) 'Do not swallow.'</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less.'</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
4587	SODIUM MYRISTOYL GLUTAMATE	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 0.0164%.</p>

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

Volume 5

<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>
4588	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4589	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4590	SODIUM PANTOTHENATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).
4591	SODIUM PCA	E	Only for use in topical medicines for dermal application.
4592	SODIUM PERBORATE	A, H	Boron is a mandatory component of sodium perborate. When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron. When used preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron from all ingredients in the product must not exceed 3500 mg/kg or 3500 mg/L or 0.35%. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning

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

Volume 5

<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>
			statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4593	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 15%.
4594	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4595	SODIUM POLYACRYLATE STARCH	E	Only to be used in a medicine where Procter & Gamble Australia Pty Ltd (Client ID 11364), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020. 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 not be more than 1%.
4596	SODIUM POLYMETAPHOSPHATE	E	

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

Volume 5

<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>
4597	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4598	SODIUM PROPYL HYDROXYBENZOATE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.</p>
4599	SODIUM RNA	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 0.2%.</p>
4600	SODIUM SELENATE	A, H	<p>Selenium is a mandatory component of sodium selenate.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum</p>

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

Volume 5

<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>recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4601	SODIUM SELENATE DECAHYDRATE	A	<p>Selenium is a mandatory component of sodium selenate decahydrate.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4602	SODIUM SELENITE	A, H	<p>Selenium is a mandatory component of Sodium selenite.</p> <p>Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose.</p> <p>When for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (SELE) 'This medicine</p>



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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4603	SODIUM SELENITE PENTAHYDRATE	A	Selenium is a mandatory component of Sodium selenite pentahydrate. Oral medicines must contain no more than 150 micrograms of selenium per maximum recommended daily dose. When for oral use, the medicine requires the following warning statement on the medicine label: - (SELE) 'This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.'
4604	SODIUM SILICATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of

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

Volume 5

<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>
			this medicine contains [state quantity and units] of sodium' (or words to that effect).
4605	SODIUM STARCH GLYCOLLATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4606	SODIUM STARCH GLYCOLLATE TYPE A	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4607	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4608	SODIUM STEAROXY PG-HYDROXYETHYLCELLULOSE SULFONATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.

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

Volume 5

<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>
4609	SODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 2.5%.
4610	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4611	SODIUM STEARYL PHTHALAMATE	E	Only for use in medicines for dermal application and not to be used in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 1.5%.
4612	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4613	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label:  - (LAX4) 'Substance may have a laxative effect'.  When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:  - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).

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

Volume 5

<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>
4614	SODIUM SULFATE DECAHYDRATE	A, E, H	<p>When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX4) 'Substance may have a laxative effect'.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p>
4615	SODIUM SULFITE	E	<p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>

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

Volume 5

<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>
4616	SODIUM SULFITE HEPTAHYDRATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing sulfites salts require the following warning statement on the medicine label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4617	SODIUM TRIPOLYPHOSPHATE	E	<p>Only for use when the route of administration is topical for dermal application, mucous membrane (buccal mucosa) or dental.</p> <p>Not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
4618	SOLANUM DULCAMARA	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum dulcamara.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4619	SOLANUM FEROX	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum ferox.</p> <p>When for internal use, the</p>

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

Volume 5

<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>
			maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4620	SOLANUM LYCOCARPUM FRUIT EXTRACT	E	Only for use in topical medicines for dermal use and not to be included in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.02%.
4621	SOLANUM MELONGENA	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena.  When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4622	SOLANUM NIGRUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum.  When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4623	SOLANUM TUBEROSUM	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum.  When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal

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

Volume 5

<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>
			alkaloids calculated as solanine.
4624	SOLIDAGO GIGANTEA	A, H	
4625	SOLIDAGO GIGANTEA MIS	A, E, H	
4626	SOLIDAGO VIRGAUREA	A, E, H	
4627	SOLUBLE MAIZE STARCH	E	
4628	SOLUBLE POTATO STARCH	E	
4629	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4630	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4631	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4632	SOLVENT YELLOW 172	E	Permitted for use only as a colour for topical use. The concentration in the medicine must be no more than 0.3%.
4633	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.
4634	SOPHORA FLAVESCENS	A, E, H	
4635	SOPHORA TONKINENSIS	A, H	
4636	SORBIC ACID	E	The medicine requires the following warning statement on the medicine label: - (SORB8) 'Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

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

Volume 5

<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>
4637	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4638	SORBITAN MONO-OLEATE	E	
4639	SORBITAN MONOLAURATE	E	
4640	SORBITAN MONOSTEARATE	E	
4641	SORBITAN OLEATE	E	
4642	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
4643	SORBITAN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4644	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4645	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4646	SORBITAN STEARATE	E	
4647	SORBITAN TRISTEARATE	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 5

<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>
4648	SORBITOL	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.
4649	SORBITOL SOLUTION (70 PER CENT) (CRYSTALLISING)	A, E	<p>Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (crystallising).</p> <p>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.</p> <p>When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'</p>
4650	SORBITOL SOLUTION (70 PER CENT) (NON-CRYSTALLISING)	A, E	<p>Sorbitol is a mandatory component of Sorbitol solution (70 per cent) (non-crystallising).</p> <p>When used as an active ingredient, can only be</p>

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

Volume 5

<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>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.</p> <p>When the quantity of sugar alcohols per maximum recommended daily dose is more than 2 grams, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea (or words to that effect).'</p>
4651	SORBUS AUCUPARIA	A, H	
4652	SORBUS DOMESTICA	A, H	
4653	SORGHUM	E	
4654	SORGHUM VULGARE	A, H	
4655	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN LIQUID	A	<p>Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin liquid.</p> <p>The concentration of soy phosphatidylserine in the medicine must be no more than 15%.</p>
4656	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	<p>Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder.</p> <p>The concentration of soy phosphatidylserine in the medicine must be no more than</p>

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

Volume 5

<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>
			15%.
4657	SOY POLYSACCHARIDE	E	
4658	SOY PROTEIN	E	
4659	SOY STEROL	E	
4660	SOYA BEAN	E	
4661	SOYA BRAN	E	
4662	SOYA OIL	A, E, H	
4663	SOYBEAN FLOUR	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%.
4664	SOYBEAN GLYCERIDES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4665	SPARGANIUM STOLONIFERUM	A, H	
4666	SPARTIUM JUNCEUM	A, H	
4667	SPATHOLOBUS SUBERECTUS	A, H	
4668	SPEARMINT OIL	A, E, H	Menthol is a mandatory component of spearmint oil. When the medicine is for topical use for dermal application: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered

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

Volume 5

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) Avoid contact with eyes (or words to that effect).</li> <li>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: <ul style="list-style-type: none"> <li>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</li> <li>- (IRRIT) If irritation develops, discontinue use.</li> </ul> </li> <li>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> <li>- (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</li> </ul> </li> </ul> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
4669	SPEARMINT OIL TERPENELESS	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</p>

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

Volume 5

<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 1%.</p> <p>Menthol is a mandatory component of spearmint oil terpeneless.</p> <p>When the medicine is for topical use for dermal application:</p> <p>i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram</p>

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

Volume 5

<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>
			of menthol.
4670	SPHINGOLIPIDS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4671	SPIGELIA ANTHELMIA	A, H	
4672	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4673	SPIKE LAVENDER OIL	A, E, H	Camphor is a mandatory component of spike lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is

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

Volume 5

<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>more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.</p>
4674	SPINACH	E	
4675	SPINACIA OLERACEA	A, E, H	
4676	SPIRODELA POLYRRHIZA	A, H	
4677	SPIRULINA	E	
4678	SPRAY-DRIED GLUCOSE SYRUP	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p>

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

Volume 5

<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%.
4679	SPRAY-DRIED LIQUID GLUCOSE	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%.
4680	SPRUCE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4681	SQUALANE	E	Only for use in topical medicines for dermal application.
4682	SQUALENE	A, E	
4683	SQUID OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'. Must be obtained from species of the order Teuthida of the class Cephalopoda, be used in combination with other ingredients in the medicine and be presented in a therapeutic dosage form for therapeutic use.
4684	SQUILL DRY	A, H	
4685	SQUILL INDIAN DRY	A, H	



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

Volume 5

<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>
4686	SQUILL INDIAN POWDER	A, H	
4687	SQUILL POWDER	A, H	
4688	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4689	ST JOHN'S WORT HERB DRY	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4690	ST JOHN'S WORT HERB POWDER	A, H	When used for oral ingestion, the medicine requires the following warning statement on the medicine label: - (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'
4691	STACHYS OFFICINALIS	A, E, H	
4692	STACHYS PALUSTRIS	A, H	
4693	STACHYURUS HIMALAICUS	A, H	
4694	STANNIC OXIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.005%.

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

Volume 5

<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>
4695	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4696	STAR ANISE OIL	A, E	When the concentration in the medicine is more than 50% and the nominal capacity of the container is equal to or less than 50mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
4697	STARCH	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%.
4698	STARCH SODIUM OCTENYL SUCCINATE	E	
4699	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4700	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4701	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4702	STEARAMIDOETHYL DIETHYLAMINE	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

Volume 5

<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.
4703	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4704	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 2%. When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4705	STEARETH-10	E	Only for use in topical medicines for dermal application.
4706	STEARETH-100	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
4707	STEARETH-2	E	Only for use in topical medicines for dermal application.
4708	STEARETH-20	E	Only for use in topical medicines for dermal application.
4709	STEARETH-21	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

Volume 5

<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.
4710	STEARETH-5	E	Only for use in topical medicines for dermal application.
4711	STEARIC ACID	E	
4712	STEAROPTENES	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%.
4713	STEAROXY DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
4714	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4715	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines. The concentration in the medicine must be no more than 0.6%.
4716	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4717	STEARYL ALCOHOL	E	
4718	STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be

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

Volume 5

<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>
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.5%. The medicine requires the following warning statements on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect) - (EYE) 'Avoid contact with eyes' (or words to that effect).
4719	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4720	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4721	STEARYL MYRISTATE	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%.
4722	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4723	STELLARIA CHAMAEJASME	A, H	
4724	STELLARIA DICHOTOMA	A, H	
4725	STELLARIA MEDIA	A, E, H	
4726	STEMONA JAPONICA	A, H	
4727	STEMONA SESSILIFOLIA	A, H	
4728	STENOTAPHRUM SECUNDATUM	A, H	

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

Volume 5

<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>
4729	STEPHANIA TETRANDA	A, H	
4730	STERCULIA	A, H	
4731	STERCULIA TRAGACANTHA	A, H	
4732	STERCULIA URENS	A, H	
4733	STEVIA REBAUDIANA	A, E, H	
4734	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4735	STILLINGIA SYLVATICA	A, H	
4736	STORAX PREPARED	A, E, H	
4737	STRAWBERRY	E	
4738	STRAWBERRY ESSENCE	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%.
4739	STREPTOCOCCUS SALIVARIUS	A	Only permitted for use in medicines: - that are for oral routes of administration; and - when the strain of Streptococcus salivarius is confirmed to be K12 or M18. The name of the Streptococcus salivarius strain must be declared on the label. The following warning statement is required on the medicine label: - (CHILD5) 'Use in children under 3 years is not recommended'.
4740	STREPTOCOCCUS THERMOPHILUS	A	
4741	STROBILANTHES CUSIA	A, H	

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

Volume 5

<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>
4742	STRONG AMMONIA SOLUTION	E	Ammonia is a mandatory component of dilute ammonia solution. The concentration of ammonia in the medicine must be no more than 0.5%. When for internal use, the concentration in the medicine must be no more than 0.25%.
4743	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4744	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4745	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4746	STRYCHNOS IGNATII	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Strychnos ignatii. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4747	STRYCHNOS NUX-VOMICA	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Strychnos nux-vomica. The concentration of Strychnine (of Strychnos spp.) must be no more than 1 milligram/Kg or 1 milligram/L or 0.1%.
4748	STYPHNOLOBIUM JAPONICUM	A, E, H	
4749	STYRALLYL PROPIONATE	E	Only for use in medicines in combination with other

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

Volume 5

<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 fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
4750	STYRAX BENZOIN	A, E, H	
4751	STYRAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total 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%.
4752	STYRAX PARALLELONEURUM	A, H	
4753	STYRAX TONKINENSIS	A, H	
4754	STYRENE	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%.
4755	STYRENE/ACRYLATES COPOLYMER	E	Only for use in topical medicines for dermal application.
4756	STYROLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than



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

Volume 5

<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>
			1%.
4757	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4758	SUCCINIC ACID	E	
4759	SUCRALOSE	E	
4760	SUCROSE	E	<p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4761	SUCROSE ACETATE ISOBUTYRATE	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>
4762	SUCROSE ACETATE PALMITATE STEARATE	E	Only for use in topical medicines for dermal application and not intended

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

Volume 5

<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>
			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
4763	SUCROSE COCOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
4764	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4765	SUCROSE LAURATE	E	When for oral or sublingual use, Sucrose is a mandatory component of Sucrose laurate. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or

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

Volume 5

<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>
			words to that effect).
4766	SUCROSE OCTAACETATE	E	<p>When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4767	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4768	SUCROSE POLYCOTTONSEEDATE	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 1%.</p> <p>The medicine requires the following warning statements</p>

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

Volume 5

<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: - (EYE) 'Avoid contact with the eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
4769	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When for topical use, the concentration in the medicine must be no more than 0.25%. For oral use as a manufacturing aid only. When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.
4770	SUCROSE TRISTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
4771	SUDAN III	E	Permitted for use only as a colour for topical use.
4772	SUGAR CANE WAX ALCOHOLS	A, H	The maximum recommended daily dose must not provide more than 12mg. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).

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

Volume 5

<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>
4773	SUGARCANE	E, H	<p>When for oral or sublingual use, sucrose is a mandatory component of Sugarcane.</p> <p>When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:</p> <p>- (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
4774	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4775	SULFATED LOW MOLECULAR WEIGHT FUCANS	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 0.025%.</p>
4776	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the

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

Volume 5

<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 label:</p> <p>- (SULF) 'Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.</p>
4777	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4778	SULFURIC ACID	E, H	<p>Only for use as an active homoeopathic ingredient or excipient ingredient.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
4779	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
4780	SULISOBENZONE	A	<p>Only for use as an active ingredient in sunscreens 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 10%.</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</p>

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

Volume 5

<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>exposure in the sun' (or words to this effect); and</p> <ul style="list-style-type: none"> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <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>
4781	SULISOBENZONE SODIUM	A	<p>Only for use as an active ingredient in sunscreens 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 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> <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> <p>When used in primary sunscreen products and listed in the Register before 1</p>

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

Volume 5

<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>
			January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
4782	SUNFLOWER OIL	A, E, H	
4783	SUNFLOWER SEED	E, H	
4784	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4785	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4786	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4787	SWEDE	E	
4788	SWEET ORANGE OIL TERPENES AND TERPENOIDS	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%.
4789	SWEET POTATO	E	



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

Volume 5

<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>
4790	SWERTIA CHIRATA	A, H	
4791	SWIETENIA MAHOGANI	A, H	
4792	SYAGRUS ROMANZOFFIANA	A, E, H	
4793	SYMPHYTUM OFFICINALE	H	When used orally as an active homoeopathic ingredient, the concentration must be a dilution of 12X or more. When used in topical medicines for dermal application, the concentration in the preparation must be no more than 10mg/kg or 10mg/L or 0.001%.
4794	SYMPLOCARPUS FOETIDUS	A, H	
4795	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4796	SYNTHETIC TERPENE RESIN	E	Only for use in topical, oral or oral application medicines. When the route of administration is oral, the dosage form must be chewing gum.
4797	SYNTHETIC WAX	E	
4798	SYRINGA RETICULATA	A, H	
4799	SYRINGA VULGARIS	A, H	
4800	SYZYGIUM AROMATICUM	A, E, H	When the plant preparation is oil or distillate and the concentration of this oil or distillate in the product is greater than 25%, the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that

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

Volume 5

<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>
			effect); and - (NTAKEN) 'Not to be taken'. When the plant preparation is oil or distillate, the concentration of this oil or distillate in the medicine is greater than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate, the concentration of oil or distillate in the product is greater than 25% and the nominal capacity of the container is less than 15 millilitres, a restricted flow insert must be fitted on the container. When the plant preparation is oil or distillate and the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of the oil or distillate and the concentration of oil or distillate in the product must not be greater than 25%.
4801	SYZYGIUM CUMINI	A, H	
4802	SYZYGIUM JAMBOS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.0693%.
4803	TABEBUIA SERRATIFOLIA	A, E, H	
4804	TAGETES ERECTA	A, H	

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

Volume 5

<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>
4805	TAGETES MINUTA	A, E, H	
4806	TAGETES OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total 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%.
4807	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4808	TALLOW	E	Only for use in topical medicines for dermal application.
4809	TALLOW GLYCERIDES	E	
4810	TAMARINDUS INDICA	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%.
4811	TAMARIX APHYLLA	A, H	
4812	TAMARIX CHINENSIS	A, H	
4813	TAMARIX GALLICA	A, H	
4814	TAMUS COMMUNIS	A, H	If the plant part is fruit or root, the maximum recommended daily dose must be no more than 1 mg of the equivalent dry fruit or dry root of Tamus communis.

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

Volume 5

<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>
4815	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4816	TANACETUM PARTHENIUM	A, E, H	
4817	TANACETUM VULGARE	A, H	Oil (of Tanacetum vulgare) is a mandatory component of Tanacetum vulgare. The concentration of oil (of Tanacetum vulgare) in the medicine must be no more than 0.8%.
4818	TANGERINE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total 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%.
4819	TANGERINE OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of tangerine oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
4820	TANNIC ACID	E	
4821	TAPIOCA STARCH	E	
4822	TARAXACUM MONGOLICUM	A, E, H	
4823	TARAXACUM OFFICINALE	A, E, H	
4824	TARO	E	
4825	TARRAGON OIL	A, E, H	

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

Volume 5

<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>
4826	TARTARIC ACID	E	
4827	TARTRAZINE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4828	TARTRAZINE ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use. The medicine requires the following warning statement on the medicine label: - (TART) 'Contains tartrazine' (or words to that effect).
4829	TASMANNIA LANCEOLATA	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%.
4830	TAURINE	A, E	
4831	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4832	TERMINALIA ARJUNA	A	Only for use in oral medicines. Only for use when the plant part is bark. The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents. The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not

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

Volume 5

<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>
			recommended for use by pregnant and lactating women' (or words to that effect) - (CHILD2) 'Not suitable for children'.
4833	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous extract of the fruit pericarp.
4834	TERMINALIA CATAPPA	A, H	
4835	TERMINALIA CHEBULA	A, H	
4836	TERMINALIA FERDINANDIANA	A, E, H	Only for use when the plant part is fruit flesh, fruit flesh dry or the preparation is as an aqueous extract of the fruit flesh. When used as an excipient, the ingredient is only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. When used as an excipient, the concentration in the medicine must be no more than 0.3%.
4837	TERMINALIA SERICEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. Only for use when the plant part is root bark. Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is approved. 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

Volume 5

<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>
4838	TERPINEN-4-OL	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%.
4839	TERPINEOL	E	
4840	TERPINEOL ACETATE	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%.
4841	TERPINOLENE	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%.
4842	TERPINYL ACETATE	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

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

Volume 5

<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>
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4843	TERPINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
4844	TERPINYL METHYL ETHER	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%.
4845	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4846	TERT-BUTYL HYDROQUINONE	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%.
4847	TERT-BUTYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.



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

Volume 5

<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>
4848	TERT-BUTYLPYRAZINE	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%.
4849	TETRACLINIS ARTICULATA	A, E, H	
4850	TETRADECYL AMINOBTYROYLVALYLAMIN OBUTYRIC UREA TRIFLUOROACETATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.002%.
4851	TETRADIIUM RUTICARPUM	A, H	When for internal use, oxedrine is a mandatory component of Tetradiium ruticarpum.  The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4852	TETRAHEXYLDECYL ASCORBATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 1%.
4853	TETRAHYDRO LINALYLACETATE	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

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

Volume 5

<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 1%.
4854	TETRAHYDRO PARA-METHYLQUINOLINE	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%.
4855	TETRAHYDRO-6-(3-PENTENYL)-2H-PYRAN-2-ONE	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%.
4856	TETRAHYDRODIFERULOYLME THANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
4857	TETRAHYDROFURFURYL ACETATE	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%.
4858	TETRAHYDROGERANYL ACETATE	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 5

<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 fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4859	TETRAHYDROLINALOOL	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%.
4860	TETRAHYDROMUGUOL	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%.
4861	TETRAHYDROMYRCENOL	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%.
4862	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4863	TETRAMETHYL ACETYLOCTAHYDRONAPHTHA LENES	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 5

<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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4864	TETRAPANAX PAPYRIFER	A, H	
4865	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.
4866	TETRASODIUM PYROPHOSPHATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium’ (or words to that effect).
4867	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium chamaedrys.
4868	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium marum.
4869	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Teucrium scorodonia.

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

Volume 5

<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>
4870	THAPSIA GARGANICA	A, H	
4871	THAUMATIN	E	
4872	THEASPIRANE	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%.
4873	THEMEDA TRIANDRA	A, H	
4874	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021;

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

Volume 5

<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>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>e) When the maximum recommended daily dose of the medicine provides greater than</p>

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

Volume 5

<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>
			80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
4875	THEOBROMA OIL	A, E, H	
4876	THIAMINE	A, E	
4877	THIAMINE HYDROCHLORIDE	A, E	
4878	THIAMINE NITRATE	A, E	
4879	THIOCINEOLE	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%.
4880	THIOTAURINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4881	THLASPI ARVENSE	A, E, H	
4882	THREONINE	A, E	
4883	THUJA OCCIDENTALIS	A, H	
4884	THUJA PLICATA	A, E, H	

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

Volume 5

<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>
4885	THYME HERB DRY	A, E, H	
4886	THYME OIL	A, E, H	When the concentration of Thyme oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the warning statement:  - (CHILD) 'Keep out of reach of children' (or words to that effect).
4887	THYMOL	A, E	When used as an active ingredient, the medicine must be medicated space spray or medicated throat lozenges.  When used as an excipient, only for use in medicated throat lozenges or topical medicines for dermal applications.
4888	THYMUS CAPITATUS	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:  - (CHILD) 'Keep out of reach of children' (or words to that effect).
4889	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4890	THYMUS MASTICHINA	A, E, H	When the plant preparation is an oil, and the concentration in



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

Volume 5

<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>
			the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4891	THYMUS SERPYLLUM	A, E, H	When the plant preparation is an oil, and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, a restricted flow insert must be fitted on the container and the medicine requires the following warning statement on the medicine label:- (CHILD) 'Keep out of reach of children' (or words to that effect).
4892	THYMUS VULGARIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Thymus vulgaris oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)
4893	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, the nominal capacity of the container must

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

Volume 5

<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>be no more than 25 millilitres.</p> <p>When the concentration of <i>Thymus vulgaris</i> mis oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect)</p>
4894	THYMUS ZYGIS	A, H	<p>When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres.</p> <p>When the concentration of <i>Thymus zygis</i> oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and the medicine must include the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
4895	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4896	TILACTASE	A	<p>Must be derived from <i>Aspergillus oryzae</i> and comply with the relevant USP monograph.</p> <p>When the dosage form is undivided, the units 'acid lactase units per gram' and 'Thousand acid lactase units per gram' are permitted.</p> <p>When the dosage form is divided, the units 'acid lactase</p>

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

Volume 5

<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>
			units' and 'thousand acid lactase units' are permitted.
4897	TILIA CORDATA	A, E, H	
4898	TILIA PLATYPHYLLOS	A, E, H	
4899	TILIA TOMENTOSA	A, H	
4900	TILIA X VULGARIS	A, E, H	
4901	TILIANOL	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%.
4902	TIN	H	Only for use as an active homoeopathic ingredient.
4903	TINOSPORA CORDIFOLIA	A, H	
4904	TINOSPORA SINENSIS	A, H	
4905	TITANIUM DIOXIDE	A, E	For use as an active ingredient only in sunscreens for dermal application. The concentration in sunscreens must be no more than 25%. For use as an excipient only as a colour in oral medicines and as a colour in topical medicines for dermal application. Not to be included in medicines intended for use in the eye. 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: - (AVOID) 'Avoid prolonged

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

Volume 5

<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>exposure in the sun' (or words to this effect); and</p> <ul style="list-style-type: none"> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <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>
4906	TOCOCYSTEAMIDE	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 0.01%.</p>
4907	TOCOFERSOLAN	E	<p>Only for oral and topical use.</p> <p>When for oral use, the concentration in the medicine must be no more than 10% w/w.</p> <p>When used in topical medicines for dermal application, it is not to be included in medicines intended for use in the eye.</p> <p>When for topical use, 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 5

<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>
4908	TOCOPHEROL	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%.
4909	TOCOPHERYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin or in the eye. The concentration in the medicine must be no more than 0.05%
4910	TOCOPHERYL LINOLEATE	E	Only for use in topical medicines for dermal application.
4911	TOCOPHERYL NICOTINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 0.3%.
4912	TOLU BALSAM	A, E, H	
4913	TOLUENE	E	The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose. The concentration in the medicine must be no more than

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

Volume 5

<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>
			0.089%.
4914	TOLYL ALDEHYDE	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%.
4915	TOLYLALDEHYDE GLYCERYLACETAL	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%.
4916	TOMATO	E	
4917	TONKA	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%.
4918	TONKA BEAN EXTRACT	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%.

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

Volume 5

<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>
4919	TONONE	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%.
4920	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4921	TOXICODENDRON PUBESCENS	H	Only for use as an active homoeopathic ingredient.  The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron pubescens.
4922	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4923	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4924	TRACHELOSPERMUM JASMINOIDES	A, E, H	
4925	TRACHYSPERMUM AMMI	A, E	Only for use in oral medicines when the plant part is fruit or seed.  The medicine requires the following warning statements on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)

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

Volume 5

<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>
			- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect). 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%.
4926	TRAGACANTH	A, E	
4927	TRAMETES VERSICOLOR	A, H	
4928	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4929	TRANS,TRANS-2,4-DECADIEN-1- AL	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%.
4930	TRANS,TRANS-2,4- HEXADIENAL	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 the medicine must be no more than 1%. The maximum daily dose must provide no more than 13.5 mg of Trans,Trans-2,4-Hexadienal.
4931	TRANS-1-(2,4,4-TRIMETHYL-2-	E	Permitted for use only in



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

Volume 5

<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>
	CYCLOHEXEN-1-YL)-2-BUTEN-1-ONE		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%.
4932	TRANS-2-DECENAL	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%.
4933	TRANS-2-DODECENAL	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%.
4934	TRANS-2-HEPTEN-1-AL	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%.
4935	TRANS-2-HEXENAL	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

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

Volume 5

<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>
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4936	TRANS-2-HEXENOIC ACID	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%.
4937	TRANS-2-HEXENOL	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%.
4938	TRANS-2-HEXENYL ACETATE	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%.
4939	TRANS-2-HEXENYL PHENYLACETATE	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%.

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

Volume 5

<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>
4940	TRANS-2-HYDROXYCINNAMIC 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%.
4941	TRANS-2-UNDECENAL	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%.
4942	TRANS-3-HEXENOIC ACID	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%.
4943	TRANS-4-DECENAL	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%.
4944	TRANS-8-(1-METHYLETHYL)-1-OXASPIRO(4.5)DECAN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

Volume 5

<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>
4945	TRANS-ETHYL 2-OCTENOATE	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%.
4946	TRANS-METHYL-2-HEXENOATE	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%.
4947	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle.  When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label:  - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars.  If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:  - (LACT) 'Contains lactose' (or words to that effect).

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

Volume 5

<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>
4948	TREEMOSS ABSOLUTE	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 treemoss absolute must be no more than 0.02%.</p> <p>When for dermal use or use on the hair the concentration of treemoss absolute must be no more than 0.1%</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
4949	TREFRIW WELLS MINERAL WATER	A	<p>When for internal use, iron is a mandatory component of Trefriw Wells mineral water.</p> <p>Solid dosage forms containing more than 5 milligrams of elemental iron in each dosage unit are required to have a child resistant closure.</p> <p>Liquid Preparations containing more than 250 milligrams of elemental iron in the total contents of the container are required to have a child resistant closure.</p> <p>Only able to be used when presented in single use sachets for therapeutic use as an iron supplement.</p>
4950	TREHALOSE DIHYDRATE	E	<p>When for oral use and the quantity of trehalose dihydrate per maximum recommended daily dose exceeds 20 grams, the quantity of trehalose dihydrate must be declared on the label.</p>

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

Volume 5

<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>
4951	TREMELLA FUCIFORMIS	A, H	
4952	TRIACETIN	E	
4953	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4954	TRIADICA SEBIFERA	A, H	
4955	TRIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of tribasic potassium phosphate. When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
4956	TRIBASIC SODIUM PHOSPHATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state

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

Volume 5

<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>
			quantity and units] of sodium' (or words to that effect).
4957	TRIBEHENIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4958	TRIBEHENIN PEG-20 ESTERS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 6%.
4959	TRIBULUS TERRESTRIS	A, E, H	
4960	TRIBUTYL ACETYLCITRATE	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%.
4961	TRICALCIUM PHOSPHATE	E	
4962	TRICAPRYLIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4963	TRICAPRYLYL CITRATE	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

Volume 5

<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 7%.
4964	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4965	TRICHLOROMETHYLPHENYLARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4966	TRICHODERMA VIRIDE	A, E, H	
4967	TRICHOSANTHES KIRILOWII	A, E, H	
4968	TRICLOSAN	E	The concentration in the medicine must be no more than 1%.
4969	TRICYCLODECENYL PROPIONATE	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%.
4970	TRIDECANAL	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



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

Volume 5

<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>
			1%.
4971	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4972	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.5%.
4973	TRIDECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4974	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate. Only for use in topical medicines for dermal application.
4975	TRIDECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 23%.
4976	TRIDECYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be

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

Volume 5

<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>
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4977	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4978	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4979	TRIETHOXYCAPRYLYLSILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
4980	TRIETHYL CITRATE	E	
4981	TRIETHYLENE GLYCOL	E	
4982	TRIFOLIUM PRATENSE	A, E, H	
4983	TRIFOLIUM REPENS	A, H	
4984	TRIGONELLA FOENUM- GRAECUM	A, E, H	
4985	TRIHYDROXPALMITAMIDOH YDROXYPROPYL MYRISTYL ETHER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.02%.
4986	TRIHYDROXYSTEARIN	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

Volume 5

<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.
4987	TRIISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4988	TRIIODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4989	TRIISONONANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
4990	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4991	TRILAURIN	E	Only for use in topical medicines for dermal application.
4992	TRILISA ODORATISSIMA	A, H	
4993	TRILLIUM ERECTUM	A, H	
4994	TRIMETHOXYCAPRYLYL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%.

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

Volume 5

<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>
4995	TRIMETHYL HYDROXPENTYL ISOBUTYRATE	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%.
4996	TRIMETHYL UNDECYLENIC ALDEHYDE	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%.
4997	TRIMETHYL-BICYCLO- HEPTANE- SPIROCYCLOHEXENONE	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%.
4998	TRIMETHYLBENZENEPROPANO L	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%.
4999	TRIMETHYLHEXANOL	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

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

Volume 5

<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>
			1%.
5000	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
5001	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5002	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
5003	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
5004	TRIOCTANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
5005	TRIOCTYLDODECYL CITRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 12%.
5006	TRIOLEIN	E	Only for use in topical medicines for dermal application and not to be

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

Volume 5

<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>
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
5007	TRIOSTEUM PERFOLIATUM	A, H	
5008	TRIOXAUNDECANEDIOIC ACID	E	
5009	TRIPAL	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%.
5010	TRYPEPTIDE-1	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.002%.
5011	TRIS-BIPHENYL TRIAZINE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. When used topically, the dosage form must not be spray. 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:

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

Volume 5

<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>- (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 requires the following statements on the medicine label if supplied after 1 July 2019:</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>
5012	TRISILOXANE	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 40%.</p>
5013	TRISODIUM EDETATE	E	<p>Only for use in topical medicines for dermal application.</p>
5014	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	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 0.2%.</p>

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

Volume 5

<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>
5015	TRISODIUM NTA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
5016	TRISTEARIN	E	
5017	TRITICUM AESTIVUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5018	TRITICUM DURUM	A, E, H	Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.
5019	TRIUNDECANOIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 11.2%.
5020	TROLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
5021	TROLAMINE LAURIL SULFATE	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 5

<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>
5022	TROLAMINE SALICYLATE	A	<p>Only for use as an active ingredient in sunscreens 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 12%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> <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> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> <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>
5023	TROLLIUS CHINENSIS	A, H	
5024	TROMETAMOL	E	
5025	TROMETAMOL HYDROCHLORIDE	E	
5026	TROPAEOLUM MAJUS	A, E, H	
5027	TROPICAL RATTLESNAKE	H	Only for use as an active

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

Volume 5

<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>
			homeopathic ingredient.
5028	TROPOLONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
5029	TSUGA CANADENSIS	A, H	
5030	TULIPA EDULIS	A, H	Colchicine is a mandatory component of Tulipa edulis. The concentration of colchicine in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
5031	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5032	TURNERA DIFFUSA	A, E, H	Arbutin is a mandatory component of Turnera diffusa. 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 %.
5033	TURNIP	E	
5034	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5035	TYPHA ANGUSTIFOLIA	A, H	

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

Volume 5

---

<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>
5036	TYPHA LATIFOLIA	A, H	
5037	TYPHONIUM GIGANTEUM	A, H	
5038	TYROSINE	A, E	

---