

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

(section 4)

### Part 2 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3600	P-ALPHA-DIMETHYL STYRENE	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%.
3601	P-ANISIC ACID	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 0.3%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3602	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> <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</li> </ul>

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			to this effect); and  - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3603	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%.
3604	PAEONIA LACTIFLORA	A, E, H	
3605	PAEONIA OBOVATA	A, H	
3606	PAEONIA SUFFRUTICOSA	A, E, H	
3607	PAEONIA VEITCHII	A, H	
3608	PALIURUS SPINA-CHRISTI	A, H	
3609	PALLADIUM	H	Only for use as an active homoeopathic ingredient.
3610	PALM FRUIT OIL	A, E, H	

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
3611	PALM GLYCERIDES	E	
3612	PALM KERNEL OIL	A, E, H	
3613	PALM TOCOTRIENOLS COMPLEX	A, H	
3614	PALMARIA PALMATA	A, H	
3615	PALMAROSA OIL	A, E, H	
3616	PALMITIC ACID	E	
3617	PALMITOLEIC ACID-RICH FATTY ACID ETHYL ESTERS	A	
3618	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%.
3619	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%

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3620	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%.
3621	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%.
3622	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%.
3623	PANAX GINSENG	A, E, H	
3624	PANAX JAPONICUS	A, H	

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
3625	PANAX NOTOGINSENG	A, H	
3626	PANAX PSEUDOGINSENG	A, H	
3627	PANAX QUINQUEFOLIUS	A, H	
3628	PANICUM MILIACEUM	A, H	
3629	PANTETHINE	E	Only for use in topical medicines for dermal application.
3630	PANTHENOL	A, E	
3631	PANTHENYL ETHYL ETHER	E	Only for use in topical medicines for dermal application.
3632	PANTOLACTONE	E	
3633	PANTOTHENIC ACID	A, E	When used topically, the concentration in the medicine must be no more than 0.1%.
3634	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3635	PAPAIN	A, E	
3636	PAPER	E	Only for use in topical medicines for dermal application.
3637	PAPRIKA OLEORESIN	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%.
3638	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%.
3639	PARA-CRESYL ACETATE	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3640	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%.
3641	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 1%.
3642	PARA-CYMENE	E	Permitted for use only in combination with other



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3643	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%.
3644	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
3645	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%.
3646	PARA-HYDROXYBENZOIC ACID	E	
3647	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%.
3648	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3649	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%.
3650	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 fragrance concentration in a medicine must be no more 1%.
3651	PARA-PROPYL ANISOLE	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3652	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%.
3653	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%.
3654	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3655	PARA-TOLYL ACETALDEHYDE	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%.
3656	PARAMERIA LAEVIGATA	A, H	
3657	PARIETARIA JUDAICA	A, H	
3658	PARIS POLYPHYLLA	A, H	
3659	PARIS QUADRIFOLIA	A, H	
3660	PARSLEY	E, H	
3661	PARSLEY HERB DRY	A, E, H	
3662	PARSLEY HERB OIL	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3663	PARSLEY HERB POWDER	A, E, H	
3664	PARSLEY SEED OIL	A, E, H	
3665	PARTHENOCISSUS TRICUSPIDATA	A, H	
3666	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%.
3667	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%.
3668	PASPALUM NOTATUM	A, H	
3669	PASSIFLORA CAERULEA	A, H	
3670	PASSIFLORA EDULIS	E	
3671	PASSIFLORA HERB DRY	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3672	PASSIFLORA INCARNATA	A, E, H	
3673	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%.
3674	PATENT BLUE V	E	Permitted for use only as a colour for oral and topical use.
3675	PATENT BLUE V ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
3676	PATRINIA SCABIOSIFOLIA	A, H	
3677	PATRINIA VILLOSA	A, H	
3678	PAULLINIA CUPANA	A, E, H	Caffeine is a mandatory component of Paullinia cupana when used for oral ingestion.  When the route of administration is oral or sublingual and the medicine provides a maximum

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
3679	PAULLINIA PINNATA	A, H	
3680	PAWPAW	E	
3681	PEA	E	
3682	PEA STARCH	E	
3683	PEACH	E	
3684	PEANUT	E	The medicine requires the



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			following warning statement on the medicine label:  - (PEANUT) 'Contains Peanut' (or words to that effect).
3685	PEAR	E	
3686	PECAN	E	
3687	PECTIN	A, E	
3688	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%.
3689	PEG-10 SOYA STEROL	E	Only for use in topical medicines for dermal application.
3690	PEG-100 STEARATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3691	PEG-12 DILAURATE	E	
3692	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%.
3693	PEG-120 METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3694	PEG-120 STEARATE	E	Only for use in topical medicines for dermal application.
3695	PEG-15 COCAMINE	E	Only for use in topical medicines for dermal application.
3696	PEG-150 DISTEARATE	E	Only for use in topical medicines for dermal application.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3697	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%.
3698	PEG-20 METHYL GLUCOSE DISTEARATE	E	Only for use in topical medicines for dermal application.
3699	PEG-20 METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3700	PEG-20 SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
3701	PEG-20 STEARATE	E	Only for use in topical medicines for dermal application.
3702	PEG-25 PABA	A	Only for use as an active ingredient in sunscreens for

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3703	PEG-30 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3704	PEG-30 STEARATE	E	Only for use in topical medicines for dermal application.
3705	PEG-35 CASTOR OIL	E	
3706	PEG-4 DILAURATE	E	Only for use in topical medicines for dermal application.
3707	PEG-4 LAURATE	E	Only for use in topical medicines for dermal application.  Dioxane and Ethylene oxide are mandatory components of PEG-4 laurate.  The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.  The concentration of Ethylene

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3708	PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3709	PEG-40 CASTOR OIL	E	
3710	PEG-40 HYDROGENATED CASTOR OIL	E	
3711	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.</p> <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>
3712	PEG-40 STEARATE	E	Only for use in topical medicines for dermal

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3713	PEG-45/DODECYL GLYCOL COPOLYMER	E	Only for use in topical medicines for dermal application.
3714	PEG-5 GLYCERYL STEARATE	E	Only for use in topical medicines for dermal application.
3715	PEG-50 STEARATE	E	Only for use in topical medicines for dermal application.
3716	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%.
3717	PEG-6 LAURAMIDE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3718	PEG-60 ALMOND GLYCERIDES	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 when used in medicines applied directly to the skin must be no more than 10%.</p> <p>The concentration when used in bath oil medicines must be no more than 30%.</p>
3719	PEG-60 GLYCERYL ISOSTEARATE	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 2%.</p>
3720	PEG-60 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3721	PEG-7 COCAMIDE	E	Only for use in topical medicines for dermal application.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3722	PEG-7 GLYCERYL COCOATE	E	Only for use in topical medicines for dermal application.
3723	PEG-7 HYDROGENATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
3724	PEG-75 LANOLIN	E	Only for use in topical medicines for dermal application.
3725	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%.
3726	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			0.0005%.
3727	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%.
3728	PEG-8 DISTEARATE	E	Only for use in topical medicines for dermal application.
3729	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3730	PEG-8 PROPYLENE GLYCOL COCOATE	E	
3731	PEG-8 STEARATE	E	Only for use in topical medicines for dermal application.
3732	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%.
3733	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%.
3734	PEG/PPG-18/18 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%.
3735	PELARGONIUM GRAVEOLENS	A, E, H	
3736	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%.
3737	PELTIGERA CANINA	A, H	
3738	PENICILLIUM EXPANSUM	A, H	
3739	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>5%.</p> <p>If used in a fragrance the total fragrance concentration in the medicine must be no more than 1%.</p> <p>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.</p>
3740	PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE	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 0.018%</p>
3741	PENTAERYTHRITYL TETRAISOSTEARATE	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 61%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3742	PENTAERYTHRITYL TETRALAURATE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 80%.
3743	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%.
3744	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 medicine must be no more than 1%.
3745	PENTASODIUM ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	TETRAMETHYLENE PHOSPHONATE		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%.
3746	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%.
3747	PEPPER BLACK	E, H	
3748	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%.
3749	PEPPER WHITE	E, H	
3750	PEPPERMINT AMERICAN EXT.	E	Menthol is a mandatory component of peppermint

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>american ext.</p> <p>When the medicine is for topical use:</p> <p>a) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>b) the maximum concentration of menthol must not exceed 5%; and</p> <p>c) 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; and</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3751	PEPPERMINT LEAF DRY	A, E, H	When the ingredient is included in a medicine that is listed in the Register:



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c);</p> <p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c).</p> <p>a) Menthol is a mandatory component of peppermint leaf dry.</p> <p>b) When the medicine is for topical use:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the maximum concentration of menthol must not exceed 5%; and</p> <p>(iii) 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (IRRIT) If irritation develops, discontinue use; and</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3752	PEPPERMINT LEAF POWDER	A, E, H	<p>When the ingredient is included in a medicine that is listed in the Register:</p> <p>- on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c);</p> <p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c).</p> <p>a) Menthol is a mandatory component of peppermint leaf powder.</p> <p>b) When the medicine is for</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>topical use:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the maximum concentration of menthol must not exceed 5%; and</p> <p>(iii) 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; and</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3753	PEPPERMINT OIL	A, E, H	<p>When the ingredient is included in a medicine that is listed in the Register:</p> <p>- on or after 1 July 2018, the medicine must comply with all</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>requirements under (a)-(c);</p> <p>- before 1 July 2018, and supplied on or after 1 January 2020 the medicine must comply with all requirements under (a)-(c); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c).</p> <p>a) Menthol is a mandatory component of peppermint oil.</p> <p>b) When the medicine is for topical use:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the maximum concentration of menthol must not exceed 5%; and</p> <p>(iii) 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; and</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3754	PEPPERMINT OIL TERPENELESS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient 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:</p> <p>a) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>b) the maximum concentration</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>of menthol must not exceed 5%; and</p> <p>c) 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; and</li> <li>- (EYE) Avoid contact with eyes (or words to that effect).</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>
3755	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>terpenes and terpenoids.</p> <p>When the medicine is for topical use:</p> <p>a) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>b) the maximum concentration of menthol must not exceed 5%; and</p> <p>c) 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; and</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3756	PERFLUOROPOLYMETHYLISOPROPYL ETHER	E	Only for use in topical medicines for dermal application.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3757	PERHYDRO-3,6-DIMETHYL-BENZO [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>
3758	PERILLA FRUTESCENS	A, E, H	Rosmarinic acid and vicenin-2 are only permitted for use if the plant part of Perilla frutescens is leaf.
3759	PERILLALDEHYDE	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>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3760	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%.
3761	PERMETHRIN	E	The concentration of in the medicine must be no more than 2%.
3762	PERSEA AMERICANA	A, E, H	
3763	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%.
3764	PERSICARIA CHINENSIS	A, H	

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
3765	PERSICARIA TINCTORIA	A, H	
3766	PERSIMMON	E	
3767	PERU BALSAM	A, E, H	
3768	PERU BALSAM OIL	A, E, H	
3769	PETITGRAIN MANDARIN OIL	E	<p>Permitted for use only in 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>
3770	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3771	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>
3772	PETITGRAIN OIL PARAGUAY	A, E, H	<p>When used internally, oxedrine is a mandatory component of petitgrain oil paraguay.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3773	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%.
3774	PETROSELINUM CRISPUM	A, E, H	
3775	PEUCEDANUM PRAERUPTORUM	A, E, H	
3776	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).
3777	PHALARIS ARUNDINACEA	A, H	
3778	PHALARIS CANARIENSIS	A, H	
3779	PHASEOLUS COCCINEUS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3780	PHASEOLUS VULGARIS	A, H	
3781	PELLINUS ROBINIAE	A, E, H	
3782	PHELLODENDRON AMURENSE	A, E, H	
3783	PHELLODENDRON CHINENSE	A, H	
3784	PHENACETIN	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.1%.
3785	PHENETHYL 2-METHYLBUTYRATE	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%.
3786	PHENETHYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3787	PHENETHYL ALCOHOL	E	Permitted for use only:  a) in topical medicines for dermal application; and  b) for internal use in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.  The total flavour proprietary excipient formulation concentration in a medicine must be no more than 5%.
3788	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3789	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%
3790	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%.
3791	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3792	PHENETHYL ISOVALERATE	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>
3793	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>
3794	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</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3795	PHENOL	E	Only for use in topical medicines for dermal application.  The concentration of phenol in the medicine must be no more than 1%.
3796	PHENOXYACETALDEHYDE	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%.
3797	PHENOXYETHANOL	E	Only for use in topical medicines for dermal application.  The concentration of phenoxyethanol in the preparation must not exceed

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			15%.
3798	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%.
3799	PHENOXYETHYLPARABEN	E	Only for use in topical medicines for dermal application.
3800	PHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
3801	PHENYL TRIMETHICONE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3802	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%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3803	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%.
3804	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3805	PHENYLACETIC 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>
3806	PHENYLALANINE	A, E	<p>When for oral ingestion the medicine requires the following warning statement on the medicine label:</p> <p>- (PKU) 'Phenylketonurics are warned that this medicine contains phenylalanine' (or words to that effect).</p> <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> <p>- (PREGNT2) 'Do not use if pregnant or likely to become</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			pregnant'.
3807	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3808	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%.
3809	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3810	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 than 1%.
3811	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%.
3812	PHENYLETHYL FORMATE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3813	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%.
3814	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%.
3815	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



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
3816	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.  The concentration in the medicine must be no more than 5%.
3817	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%.
3818	PHLEUM PRATENSE	A, H	
3819	PHLOXINE B	E	Permitted for use only as a colour for oral and topical use.
3820	PHLOXINE B ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3821	PHOENIX DACTYLIFERA	A, E, H	
3822	PHOSPHATIDYL CHOLINE	E	
3823	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%.
3824	PHOSPHORIC ACID	E, H	The concentration in liquid medicines must be no more than 15%.
3825	PHOSPHORUS	H	Only for use as an active homoeopathic ingredient.
3826	PHOTINIA SERRULATA	A, H	
3827	PHRAGMITES AUSTRALIS	A, H	
3828	PHYLLANTHUS AMARUS	A, H	
3829	PHYLLANTHUS EMBLICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.  When ascorbic acid is claimed as a component the plant part is restricted to fruit.
3830	PHYLLOSTACHYS NIGRA	A, E, H	
3831	PHYSALIS ALKEKENGII	A, H	
3832	PHYSALIS PUBESCENS	A, H	
3833	PHYTANTRIOL	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.5%.
3834	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%.
3835	PHYTOLACCA AMERICANA	A, H	The maximum recommended daily dose of the medicine must contain no more than 1mg

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			of the equivalent dry herb.
3836	PHYTOMENADIONE	A, E	
3837	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%.
3838	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%.
3839	PICEA ABIES	A, H	
3840	PICEA MARIANA	A, H	
3841	PICRAMIS EXCELSA	A, E, H	
3842	PICRORRHIZA KURROA	A, E, H	
3843	PIGMENT BLUE 15	E	Permitted for use only as a colour for topical and dental

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			use.  The concentration in medicine must be no more than 0.003%.
3844	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%.
3845	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%.
3846	PIGMENT RED 4	E	Permitted for use only as a colour for topical use.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3847	PIGMENT RED 53	E	Permitted for use only as a colour for topical use.
3848	PIGMENT RED 57	E	Permitted for use only as a colour for topical use.
3849	PIGMENT RED 57 ALUMINIUM LAKE	E	Permitted for use only as a colour for topical use.
3850	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.
3851	PIGMENT RED 63	E	Permitted for use only as a colour for topical use.
3852	PIGMENT WHITE 26	E	Permitted for use only as a colour for topical use.
3853	PIGMENT YELLOW 12	E	Permitted for use only as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			colour for topical use.
3854	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%.
3855	PILOCARPUS MICROPHYLLUS	A, H	Pilocarpine is a mandatory component of Pilocarpus microphyllus.  The concentration of pilocarpine in the medicine must be no more than 0.025%.
3856	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%.
3857	PIMENTA FRUIT OIL	A, E, H	
3858	PIMENTA LEAF OIL	A, E, H	
3859	PIMENTA OFFICINALIS	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3860	PIMENTA RACEMOSA	A, E, H	<p>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.</p> <p>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.</p> <p>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.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or word to that effect)</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3861	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).
3862	PIMPINELLA SAXIFRAGA	A, E, H	
3863	PINE NEEDLE OIL SCOTCH	A, E, H	
3864	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3865	PINE OIL AROMATIC	A, E, H	
3866	PINE OIL PUMILIO	A, E, H	
3867	PINEAPPLE	E	
3868	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 medicine must be no more than 1%.
3869	PINELLIA TERNATA	A, H	
3870	PINUS CONTORTA	A, E, H	
3871	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3872	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%.
3873	PINUS MONTICOLA	A, E, H	
3874	PINUS MUGO	A, E, H	
3875	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%.
3876	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%.
3877	PINUS PONDEROSA	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3878	PINUS RADIATA	A, E, H	
3879	PINUS STROBUS	A, E, H	
3880	PINUS SYLVESTRIS	A, E, H	
3881	PINUS TABULIFORMIS	A, E, H	
3882	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%.
3883	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%.
3884	PIPER CHABA	A, E, H	
3885	PIPER CUBEBA	A, E, H	
3886	PIPER KADSURA	A, E, H	
3887	PIPER LONGUM	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3888	PIPER METHYSTICUM	A, H	<p>Kavalactones (of Piper methysticum) is a mandatory component of Piper methysticum.</p> <p>Only for oral use when the dosage form is 'tablet' or 'capsule'; or when the container type is 'tea bag'.</p> <p>When used in oral medicines, the maximum daily dose of kavalactones (of Piper methysticum) must be no more than 250 mg.</p> <p>If the dosage form is tablet or 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>The 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>
3889	PIPER NIGRUM	A, E, H	
3890	PIPER SARMENTOSUM	A, E, H	
3891	PIPERIDINE	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</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
3892	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%.
3893	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%.
3894	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
3895	PIPERONYL ACETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used as a flavour the total flavour concentration in a 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>
3896	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>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3897	PIROCTONE OLAMINE	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% in wash-on/wash-off medicines and 0.5% in leave-on medicines.
3898	PISCIDIA PISCIPULA	A, E, H	
3899	PISTACIA LENTISCUS	A, E, H	
3900	PISUM SATIVUM	A, E, H	
3901	PLACENTA	H	Only for use as an active homoeopathic ingredient.
3902	PLANTAGO AFRA	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).
3903	PLANTAGO ARENARIA	A, H	When a dose for children is stated and the plant part is flower, seed or pollen, the

Table 1 **Part 2**

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			medicine requires the following warning statement on the medicine label:  - (PSYLL) 'On medical advice' (or words to that effect).
3904	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).
3905	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).

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3906	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).
3907	PLANTAGO OVATA	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).
3908	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).
3909	PLATANUS OCCIDENTALIS	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3910	PLATANUS RACEMOSA	A, H	
3911	PLATANUS X ACERIFOLIA	A, H	
3912	PLATYCODON GRANDIFLORUS	A, E, H	
3913	PLECTRANTHUS BARBATUS	A, E, H	
3914	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%.
3915	PLUM	E	
3916	PLUMBAGO EUROPAEA	A, H	
3917	PLUMERIA ALBA	A, E, H	
3918	PLUMERIA RUBRA	A, E, H	
3919	POA NEMORALIS	A, H	
3920	POA PRATENSIS	A, H	
3921	PODOPHYLLUM PELTATUM	A, H	Podophyllin and podophyllotoxin are mandatory components of Podophyllum peltatum.  The concentration of podophyllin in the medicine must be no more than 1 mg/kg

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			or 1 mg/L or 0.0001%.  The concentration of podophyllotoxin in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3922	POGOSTEMON CABLIN	A, E, H	
3923	POLACRILIN	E	
3924	POLACRILIN POTASSIUM	E	
3925	POLAPREZINC	A	Only for use in oral medicines.  Zinc is a mandatory component of Polaprezinc.  The maximum recommended daily dose must be no more than 34 milligrams of zinc sourced from polaprezinc.  When for internal use, the maximum recommended daily dose must be no more than 50mg of zinc.  When for internal use and the maximum recommended daily dose is more than 25mg but no more than 50mg of zinc, the medicine requires the following warning statement on the medicine label:  - (ZINC) 'WARNING: May be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3926	POLIGLUSAM	A, E	<p>When for internal use, the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (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); and</li> <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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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> <p>a) The average molecular mass of poliglusam must be greater than 2 kilodaltons.</p> <p>b) When for internal use, the medicine must not contain more than 1750 milligrams of poliglusam per maximum recommended daily dose.</p>
3927	POLIGLUSAM DERIVED FROM ASPERGILLUS NIGER	A, E	When for oral use, the medicine must provide no more than 2000 milligrams of Poliglusam derived from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>Aspergillus niger 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 Aspergillus niger is only permitted for use in topical medicines for dermal application.</p>
3928	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</p>



<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			<p>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</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'  When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3929	POLLEN	E	The medicine requires the following warning statement on the medicine label:  - (POLLEN) 'This medicine can cause severe allergic reactions' (or words to that effect).
3930	POLOXAMER	E	Only for use in topical medicines for dermal application.
3931	POLOXAMINE	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3932	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%.
3933	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%.
3934	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3935	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%.
3936	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%.
3937	POLYACRYLIC ACID	E	
3938	POLYAMINO SUGAR CONDENSATE	E	Only for use in topical medicines for dermal application.
3939	POLYAMINOPROPYL BIGUANIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 0.3%.
3940	POLYBUTENE	E	Only for use in topical medicines for dermal application.
3941	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%.
3942	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 0.1%.
3943	POLYDECENE	E	Only for use in topical medicines for dermal

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 6%.
3944	POLYDEXTROSE	E	
3945	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%.
3946	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%
3947	POLYESTER-10	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 1.5%.
3948	POLYESTER-25	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%.
3949	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%.
3950	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.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration of Polyester-8 must be no more than 5%.
3951	POLYETHYLENE	E	
3952	POLYGALA CHINENSIS	A, H	
3953	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.
3954	POLYGALA SIBIRICA	A, E, H	Only for use when the plant part is root or root bark.
3955	POLYGALA TENUIFOLIA	A	Only for use when the plant part is root or root bark.
3956	POLYGLYCERYL-10 PENTASTEARATE	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%.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3957	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%.
3958	POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 5%.
3959	POLYGLYCERYL-2 TRIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3960	POLYGLYCERYL-2-PEG-4 STEARATE	E	Only for use in topical medicines for dermal application.
3961	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%.
3962	POLYGLYCERYL-3 DIISOSTEARATE	E	Only for use in topical medicines for dermal application.
3963	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%.
3964	POLYGLYCERYL-3 METHYLGLUCOSE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	DISTEARATE		included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 6%.
3965	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%.
3966	POLYGLYCERYL-3 POLYRICINOLEATE	E	
3967	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%.
3968	POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROX	E	Only for use in topical medicines for dermal application and not to be

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	YSTEARATE/SEBACATE		included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 3%.
3969	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%.
3970	POLYGLYCERYL-4 OLEATE	E	Only for use in topical medicines for dermal application.
3971	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3972	POLYGLYCERYL-6 RICINOLEATE	E	Only for use in topical medicines for dermal application.
3973	POLYGONATUM MULTIFLORUM	A, H	
3974	POLYGONATUM OFFICINALE	A, H	
3975	POLYGONATUM SIBIRICUM	A, E, H	
3976	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%.
3977	POLYGONUM BISTORTA	A, H	
3978	POLYGONUM ODORATUM	A, H	
3979	POLYHYDROXYSTEARIC ACID	E	Only for use in topical medicines for dermal application.
3980	POLYISOBUTYLENE	E	Only for use when the dosage form is 'chewing gum'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Must comply with: a) the Polyisobutylene monograph in the Food Chemicals Codex published by the United States Pharmacopeial 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 Pharmacopeia National Formulary, as in force or existing from time to time.
3981	POLYISOPRENE	E	Only for use in topical medicines for dermal application.
3982	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%.
3983	POLYMETHACRYLIC ACID	E	
3984	POLYMETHYL METHACRYLATE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3985	POLYMETHYLSILSESQUIOXANE	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	POLYPORUS UMBELLATUS	A, H	
3987	POLYPROPYLENE	E	Only for use in topical medicines for dermal application.
3988	POLYPROPYLENE GLYCOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.  When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.  When used in a fragrance, the total fragrance proprietary excipient formulation in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
3989	POLYQUATERNIUM-10	E	Only for use in topical medicines for dermal application.
3990	POLYQUATERNIUM-11	E	Only for use in topical medicines for dermal application.
3991	POLYQUATERNIUM-22	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 or on damaged skin.  The concentration in the medicine must be no more than 2%.
3992	POLYQUATERNIUM-24	E	Only for use in topical medicines for dermal application.
3993	POLYQUATERNIUM-28	E	Only for use in topical medicines for dermal application.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3994	POLYQUATERNIUM-37	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%.
3995	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%.
3996	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%.
3997	POLYQUATERNIUM-7	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3998	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 medicine must be no more than 2.1%
3999	POLYSILICONE-14	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 Polysilicone-14 must be no more than 1%.
4000	POLYSILICONE-15	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4001	POLYSILICONE-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 0.13%.
4002	POLYSORBATE 20	E	
4003	POLYSORBATE 40	E	
4004	POLYSORBATE 60	E	
4005	POLYSORBATE 65	E	
4006	POLYSORBATE 80	E	
4007	POLYSORBATE 85	E	Only for use in topical medicines for dermal application.
4008	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%.
4009	POLYURETHANE-34	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 2% in spray applications and 6% in non-spray applications.
4010	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%.
4011	POLYVINYL ACETATE	E	Only for use when the dosage form is chewing gum.
4012	POLYVINYL ACETATE PHTHALATE	E	
4013	POLYVINYL ALCOHOL	E	
4014	POLYVINYL CHLORIDE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4015	POMEGRANATE	E	
4016	PONCEAU SX	E	Permitted for use only as a colour for topical use.
4017	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.
4018	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%.
4019	POPPY SEED	E, H	
4020	POPPY SEED OIL	E, H	
4021	POPULUS ALBA	A, H	
4022	POPULUS BALSAMIFERA	A, E, H	
4023	POPULUS CANDICANS	A, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4024	POPULUS DELTOIDES	A, H	
4025	POPULUS NIGRA	A, H	
4026	POPULUS TREMULA	A, H	
4027	POPULUS TREMULOIDES	A, H	
4028	PORCINE	H	Only for use as an active homoeopathic ingredient.
4029	PORPHYRIDIVM 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%.
4030	PORTULACA OLERACEA	A, E, H	
4031	POTABLE WATER	E	
4032	POTASSIVM ACETATE	E	
4033	POTASSIVM ARSENITE	H	Only for use as an active homoeopathic ingredient.
4034	POTASSIVM ASCORBATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ascorbate.
4035	POTASSIUM ASCORBATE DIHYDRATE	A, E, H	When for oral or sublingual use, potassium is a mandatory component of potassium ascorbate dihydrate.
4036	POTASSIUM ASCORBYL TOCOPHERYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4037	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.
4038	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



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			should be calculated based on the molecular weight of potassium aspartate dihydrate.
4039	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.
4040	POTASSIUM BICARBONATE	E	
4041	POTASSIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4042	POTASSIUM CARBONATE	E, H	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4043	POTASSIUM CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
4044	POTASSIUM CHLORIDE	A, E, H	<p>When for oral use:</p> <p>a) potassium is a mandatory component of potassium chloride;</p> <p>b) the medicine requires the following warning statement on the medicine label:</p> <p>- (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</p> <p>c) other than when used for oral rehydration therapy, the concentration must be no more than 550 mg per dosage unit.</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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>Salts;</p> <p>b) the sodium, potassium and glucose content, and total osmolality 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 Children's Fund (UNICEF) in the document 'Expert consultation on oral rehydration salts formulation' 18 July 2001; and</p> <p>c) the medicine requires the warning statements:</p> <p>- (UOAD) 'Use only as directed'</p> <p>- (DIAR3) 'If diarrhoea persists, seek medical advice.'</p> <p>When for dental use, the concentration in the medicine must be no more than 3.75%.</p>
4045	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4046	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%.
4047	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%.
4048	POTASSIUM DICHROMATE	H	Only for use as an active homoeopathic ingredient.
4049	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4050	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.
4051	POTASSIUM HYDROXIDE	E	<p>The concentration in the medicine must be no more than 5%.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4052	POTASSIUM HYDROXYCITRATE	A, H	
4053	POTASSIUM IODATE	A, H	<p>Iodine is a mandatory component of potassium iodate.</p> <p>The percentage of iodine from potassium iodate should be calculated based on the</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>molecular weight of potassium iodate.</p> <p>When for use in adults, the medicine must contain a daily dose of no more than 505 micrograms of potassium iodate.</p> <p>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.</p>
4054	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4055	POTASSIUM METABISULFITE	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%.
4056	POTASSIUM METAPHOSPHATE	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%.
4057	POTASSIUM NITRATE	A, H	Only for dental use.  The concentration in the medicine must be no more than 5%.
4058	POTASSIUM OROTATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>a mandatory component of potassium orotate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4059	POTASSIUM PYROPHOSPHATE	E	<p>Only for oral application, dental or topical use.</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 3%.</p>
4060	POTASSIUM SORBATE	E	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (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</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to this effect) if medicine contains one sorbate source.
4061	POTASSIUM STANNATE	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%.
4062	POTASSIUM STEARATE	E	Only for use in topical medicines for dermal application.
4063	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.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4064	POTATO STARCH	E	
4065	POTENTILLA ANSERINA	A, H	
4066	POTENTILLA CHINENSIS	A, H	
4067	POTENTILLA DISCOLOR	A, H	
4068	POTENTILLA ERECTA	A, E, H	
4069	POTENTILLA REPTANS	A, H	
4070	POTERIUM OFFICINALE	A, E, H	
4071	POTERIUM SANGUISORBA	A, H	
4072	POVIDONE	E	
4073	POWDERED CELLULOSE	E	
4074	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 medicine must be no more than 5%.
4075	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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 2%.
4076	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%.
4077	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%.
4078	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-

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			17/IPDI/DMPA Copolymer in the medicine must be no more than 10%.
4079	PPG-2 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4080	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%.
4081	PPG-20 LANOLIN ALCOHOL ETHER	E	Only for use in topical medicines for dermal application.
4082	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4083	PPG-20 METHYL GLUCOSE ETHER DISTEARATE	E	Only for use in topical medicines for dermal application.
4084	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%.
4085	PPG-3 MYRISTYL ETHER	E	Only for use in topical medicines for dermal application.
4086	PPG-5-CETETH-20	E	Only for use in topical medicines for dermal application.
4087	PPG-5-LAUROMACROGOL 250	E	Only for use in topical medicines for dermal application.
4088	PRALINE	E	Permitted for use only in combination with other

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
4089	PREGELATINISED MAIZE STARCH	E	
4090	PREGELATINISED POTATO STARCH	E	
4091	PREGELATINISED RICE STARCH	E	
4092	PREGELATINISED WHEAT STARCH	E	When the route of administration is other than topical or mucosal, gluten is a mandatory component of pregelatinised wheat starch.  When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:  - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4093	PRENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</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%.
4094	PRICKLY ASH BARK DRY	A, H	
4095	PRICKLY ASH BARK POWDER	A, H	
4096	PRIMULA VERIS	A, E, H	
4097	PRIMULA VULGARIS	A, E, H	
4098	PRINSEPIA UNIFLORA	A, H	
4099	PROBOSCIDEA PARVIFLORA	A, H	
4100	PROGESTERONE	H	Only for use as an active homoeopathic ingredient.
4101	PROLINE	A, E	
4102	PROPAN-1-OL	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 18%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4103	PROPANE	E	Only for use as an excipient propellant ingredient.
4104	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%.
4105	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%.
4106	PROPIONALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour 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%.
4107	PROPIONIC 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%.
4108	PROPIONYLLEVO-CARNITINE HYDROCHLORIDE	A, H	
4109	PROPOLIS	A, E	Lead is a mandatory component of Propolis.  The concentration of lead in the medicine must be no more than 0.001%.  When used topically, the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>medicine requires the following warning statement on the medicine label:</p> <p>-(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:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4110	PROPOLIS BALSAM	A, E	<p>Lead is a mandatory component of Propolis balsam.</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:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4111	PROPOLIS DRY EXTRACT	A, E	<p>Lead is a mandatory component of Propolis dry 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:</p> <p>-(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:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs,</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			discontinue use.'
4112	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:</p> <p>-(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:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4113	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>than 0.001%.</p> <p>When used topically, the medicine requires the following warning statement on the medicine label:</p> <p>-(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:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4114	PROPOLIS TINCTURE	A, E	<p>Lead is a mandatory component of Propolis tincture.</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:</p> <p>-(PROP1) 'WARNING: Propolis may cause skin</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>irritation. Test before use'</p> <p>When used for other than for topical, the medicine requires the following warning statement on the medicine label:</p> <p>- (PROP2) 'Warning: Propolis may cause allergic reactions. If irritation or swelling of the mouth or throat occurs, discontinue use.'</p>
4115	PROPYL 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>
4116	PROPYL CAPROATE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4117	PROPYL GALLATE	E	
4118	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.
4119	PROPYLENE CARBONATE	E	Only for use in topical medicines for dermal application.
4120	PROPYLENE GLYCOL	E	
4121	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4122	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%.
4123	PROPYLENE GLYCOL DIDECANOATE	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%.
4124	PROPYLENE GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application.
4125	PROPYLENE GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
4126	PROPYLENE GLYCOL DIPELARGONATE	E	Only for use in topical medicines for dermal application.



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4127	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%.
4128	PROPYLENE GLYCOL ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4129	PROPYLENE GLYCOL MONOLAURATE	E	Only for use in topical medicines for dermal application.
4130	PROPYLENE GLYCOL MONOSTEARATE	E	Only for use in topical medicines for dermal application.
4131	PROPYLENE GLYCOL MYRISTYL ETHER ACETATE	E	Only for use in topical medicines for dermal application.
4132	PROSOPIS JULIFLORA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4133	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>
4134	PROTEIN HYDROLYSATE	E	
4135	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>
4136	PRUNE JUICE CONCENTRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4137	PRUNELLA VULGARIS	A, H	
4138	PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana.  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%.
4139	PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1 microgram/kg or 1 microgram/L or 0.0000001%.
4140	PRUNUS AVIUM	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus avium.</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>
4141	PRUNUS CERASIFERA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera.</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>
4142	PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4143	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>
4144	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			seed.  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%.
4145	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%.
4146	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4147	PRUNUS LAUROCERASUS	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus.</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>
4148	PRUNUS MUME	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus mume.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4149	PRUNUS PERSICA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus persica.</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>
4150	PRUNUS SALICINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina.</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>
4151	PRUNUS SEROTINA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina.</p> <p>The concentration of Amygdalin in the medicine must be 0%.</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration of Hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
4152	PRUNUS SPINOSA	A, E, H	<p>Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa.</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>
4153	PRUSSIAN BLUE	E	Permitted for use only as a colour for topical use.
4154	PSEUDOCYDONIA SINENSIS	A, H	
4155	PSEUDOSTELLARIA HETEROPHYLLA	A, E, H	
4156	PSEUDOTSUGA MENZIESII	A, H	
4157	PSEUDOWINTERA COLORATA	A, H	Only for use when the plant part is leaf.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4158	PSIDIUM GUAJAVA	A, E, H	
4159	PSORALEN (OF CULLEN CORYLIFOLIUM)	E	
4160	PSORINUM	H	Only for use as an active homoeopathic ingredient.
4161	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).
4162	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).
4163	PSYLLIUM SEED DRY	A, E, H	When a dose for children is stated, the medicine requires the following warning statement on the medicine label:

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (PSYLL) 'On medical advice' (or words to that effect).
4164	PTELEA TRIFOLIATA	A, H	
4165	PTEROCARPUS MARSUPIUM	A, H	
4166	PTEROCARPUS SANTALINUS	A, E, H	
4167	PUERARIA LOBATA	A, E, H	
4168	PUERARIA MONTANA VAR. LOBATA	A, E, H	
4169	PULLULAN	E	
4170	PUMICE	E	
4171	PUMPKIN	E	
4172	PUMPKIN SEED	E, H	
4173	PUMPKIN SEED OIL	E, H	
4174	PUNICA GRANATUM	A, E, H	
4175	PURE BEE VENOM	H	Only for use as an active homoeopathic ingredient.
4176	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>infants under the age of twelve months' (or words to that effect).</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>
4177	PURIFIED SILICEOUS EARTH	E, H	
4178	PURIFIED TALC	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4179	PURIFIED WATER	E	
4180	PVM/MA COPOLYMER	E	
4181	PVM/MA DECADIENE CROSSPOLYMER	E	Only for use in topical medicines for dermal application.
4182	PVP/EICOSENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4183	PVP/HEXADECENE COPOLYMER	E	Only for use in topical medicines for dermal application.
4184	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 on the medicine label:</p> <p>- (PYRTH3) 'Contains pyrethrins [insert quantity]' (or words to that effect).</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4185	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:</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>
4186	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 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>
4187	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4188	PYROGLUTAMIC ACID	E	
4189	PYROLA DECORATA	A, H	
4190	PYROLIGNEOUS 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>



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4191	PYRROSIA LINGUA	A, H	
4192	PYRROSIA PETIOLOSA	A, H	
4193	PYRROSIA SHEARERI	A, H	
4194	PYRUS COMMUNIS	A, E, H	<p>Arbutin is a mandatory component of Pyrus communis.</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>
4195	PYRUS PYRIFOLIA	A, H	<p>Arbutin is a mandatory component of Pyrus pyrifolia.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4196	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 flavour concentration in a medicine must be no more than 5%.
4197	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%.
4198	QUASSIA AMARA	A, E, H	
4199	QUASSIA WOOD JAMAICAN DRY	A, H	
4200	QUASSIA WOOD JAMAICAN POWDER	A, H	
4201	QUATERNIUM-15	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4202	QUATERNIUM-18 BENTONITE	E	Only for use in topical medicines for dermal application.
4203	QUATERNIUM-18 HECTORITE	E	Only for use in topical medicines for dermal application.
4204	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.
4205	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4206	QUERCETIN	A	
4207	QUERCETIN DIHYDRATE	A	
4208	QUERCUS ACUTISSIMA	A, H	
4209	QUERCUS ALBA	A, E, H	
4210	QUERCUS PALUSTRIS	A, H	
4211	QUERCUS ROBUR	A, H	
4212	QUERCUS RUBRA	A, H	
4213	QUERCUS VIRGINIANA	A, H	
4214	QUILLAIA DRY	A, H	
4215	QUILLAIA POWDER	A, E, H	
4216	QUILLAIA SAPONARIA	A, H	
4217	QUINCE	E	
4218	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.
4219	QUININE SULFATE DIHYDRATE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>Quinine is a mandatory component of quinine sulfate dihydrate.</p> <p>The maximum recommended daily dose must be no more than 50 mg of quinine.</p>
4220	QUINOLINE YELLOW	E	Permitted for use only as a colour for oral and topical use.
4221	QUINOLINE YELLOW ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4222	QUISQUALIS INDICA	A, H	
4223	R-ALPHA LIPOIC ACID	A	
4224	RACEMENTHOL	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 than 1%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4225	RACEMIC CAMPHOR	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>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:</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 less than 15</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4226	RADISH	E	
4227	RAISIN 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%.
4228	RANUNCULUS BULBOSUS	A, H	
4229	RANUNCULUS FICARIA	A, H	
4230	RANUNCULUS TERNATUS	A, H	
4231	RAPE OIL/TUNG OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 1%.
4232	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



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
4233	RAPHANUS SATIVUS	A, H	
4234	RASPBERRY	E	
4235	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%.
4236	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%.
4237	RASPBERRY ESSENCE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4238	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%.
4239	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%.
4240	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%.
4241	RAUWOLFIA SERPENTINA POWDER	A, H	The concentration of Rauwolfia Serpentina Powder in the medicine must be no more than 10mg/Kg or 10mg/L

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			or 0.001%.
4242	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%.
4243	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%.
4244	RED ANT	H	Only for use as an active homoeopathic ingredient.
4245	RED CLOVER FLOWER DRY	A, H	
4246	RED CLOVER FLOWER POWDER	A, H	
4247	RED CORAL	H	Only for use as an active homoeopathic ingredient.
4248	RED DEER	A	
4249	RED MERCURIC IODIDE	H	Only for use as an active homoeopathic ingredient.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4250	RED MERCURIC OXIDE	H	Only for use as an active homoeopathic ingredient.
4251	RED MERCURIC SULFIDE	H	Only for use as an active homoeopathic ingredient.
4252	REHMANNIA GLUTINOSA	A, E, H	
4253	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%.
4254	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%.
4255	RESORCINOL DIMETHYLETHER	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4256	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 preparation, the medicine requires the following warning statements on the medicine label:  - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take Vitamin A supplements without consulting your doctor

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4257	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4258	RETINOL PALMITATE	A, E	Vitamin A is a mandatory component of retinol palmitate.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When 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>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (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.'
4259	REYNOUTRIA JAPONICA	A, E, H	When used as an excipient, only for use in topical medicines for dermal application.
4260	RHAMNOSE	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%.
4261	RHAMNUS CATHARTICA	A, H	When the route of administration is oral, Hydroxyanthracene derivatives is a mandatory component of Rhamnus cathartica.  When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4262	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4263	RHATANY ROOT DRY	A, H	
4264	RHATANY ROOT POWDER	A, H	
4265	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>mandatory component of 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> <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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When 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>
4266	RHEUM PALMATUM	A, E, H	<p>The plant part must not be leaf.</p> <p>When the route of</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>administration is oral, Hydroxyanthracene derivatives calculated as rhein is a mandatory component of Rheum palmatum.</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>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4267	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'; 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4268	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 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>- (CHIL3) '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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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);</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			and - (LAX2) 'Prolonged use may cause serious bowel problems'.
4269	RHODAMINE B	E	Permitted for use only as a colour for topical use.
4270	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%.
4271	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4272	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.
4273	RHODODENDRON AUREUM	A, H	
4274	RHODODENDRON FERRUGINEUM	A, H	Arbutin is a mandatory component of Rhododendron ferrugineum.  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 %.
4275	RHODODENDRON MOLLE	A, H	The maximum recommended daily dose of the medicine must be no more than 1mg of the dry herbal material.
4276	RHUBARB	E, H	When the route of administration is oral,

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>- (CHLD3) '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>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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> <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>- (CHIL3) '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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4277	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 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHIL3) '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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4278	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> <ul style="list-style-type: none"> <li>- (CHIL3) '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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>- (CHIL3) '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</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			cause serious bowel problems'.
4279	RHUS AROMATICA	A, E, H	
4280	RHUS CHINENSIS	A, H	
4281	RHUS GLABRA	A, E, H	
4282	RHUS VENENATA	H	Only for use as an active homoeopathic ingredient.
4283	RIBES GROSSULARIA	A, E, H	
4284	RIBES NIGRUM	A, E, H	
4285	RIBOFLAVIN	A, E	
4286	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 label:  - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
4287	RIBOFLAVIN TETRAACETATE	E	Only for use in topical medicines for dermal

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			application.
4288	RIBOFLAVINE	A, E	
4289	RIBOFLAVINE SODIUM PHOSPHATE	A, E	
4290	RIBONUCLEIC ACID	E	Only for use in topical medicines for dermal application.
4291	RIBOSE	A	<p>Only for use in oral medicines.</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</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			statement on the medicine label:  - (LACT) 'Contains lactose' (or words to that effect).
4292	RICE	E	
4293	RICE BRAN	E	
4294	RICE BRAN OIL	E	
4295	RICE BRAN WAX	A, E, H	
4296	RICE STARCH	E	
4297	RICE VINEGAR	E	
4298	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'
4299	RICINOLEIC ACID	E	Only for use in topical medicines for dermal application.



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4300	RICINUS COMMUNIS	A, H	Only for use when the plant part must be seed and the plant preparation is oil fixed.
4301	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.
4302	ROHDEA JAPONICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4303	ROSA ARVENSIS	A, E, H	
4304	ROSA CANINA	A, E, H	
4305	ROSA CYMOSA	A, E, H	
4306	ROSA EGLANTERIA	A, E, H	
4307	ROSA GALLICA	A, E, H	
4308	ROSA LAEVIGATA	A, E, H	
4309	ROSA MULTIFLORA	A, E, H	
4310	ROSA ROXBURGHII FRUIT EXTRACT	E	Only for use in topical medicines for dermal application and not to be

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.002%.
4311	ROSA RUGOSA	A, E, H	
4312	ROSA VILLOSA	A, E, H	
4313	ROSA X CENTIFOLIA	A, E, H	
4314	ROSA X DAMASCENA	A, E, H	
4315	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%.
4316	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
4317	ROSE FRUIT FRESH	A, E, H	
4318	ROSE HIP	E	
4319	ROSE OIL	A, E, H	
4320	ROSE OXIDE	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>
4321	ROSEMARY OIL	A, E, H	<p>Safrole is a mandatory component of Rosemary oil.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4322	ROSMARINUS OFFICINALIS	A, E, H	<p>Camphor and cineole are mandatory components of Rosmarinus officinalis.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>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.</p> <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 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> <p>- (CHILD) 'Keep out of reach</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <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> <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>
4323	ROYAL JELLY	A, E	10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD2) 'Not suitable for children'</li> <li>- (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'.</li> </ul>
4324	ROYAL JELLY FRESH	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly fresh.</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 children'</li> <li>- (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</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			asthma and allergy sufferers'.
4325	ROYAL JELLY LYOPHILISED	A, E	<p>10-Hydroxy-2-decenoic acid is a mandatory component of Royal jelly lyophilised.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <p>- (CHIL2) 'Not suitable for children'</p> <p>- (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'.</p>
4326	RUBBER NATURAL	E	Only for use in topical medicines for dermal application.
4327	RUBIA CORDIFOLIA	A, H	
4328	RUBIA TINCTORUM	A, H	
4329	RUBUS CHINGII	A, H	

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
4330	RUBUS CORCHORIFOLIUS	A, H	
4331	RUBUS COREANUS	A, E, H	
4332	RUBUS FRUTICOSUS	A, E, H	
4333	RUBUS IDAEUS	A, E, H	
4334	RUBUS OCCIDENTALIS	A, E, H	
4335	RUBUS PARVIFOLIUS	A, H	
4336	RUBUS ROSIFOLIUS	A, H	
4337	RUDBECKIA HIRTA	A, H	
4338	RUE OIL	A, H	
4339	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%.
4340	RUMEX ACETOSA	A, H	
4341	RUMEX ACETOSELLA	A, H	
4342	RUMEX CONGLOMERATUS	A, H	
4343	RUMEX CRISPUS	A, E, H	
4344	RUMEX PULCHER	A, H	



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4345	RUMEX SCUTATUS	A, H	
4346	RUSCUS ACULEATUS	A, H	
4347	RUTA GRAVEOLENS	A, E, H	
4348	RUTOSIDE	A, E	
4349	RYE	E	<p>Gluten is a mandatory component of Rye when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).</p>
4350	RYE BRAN	E	<p>Gluten is a mandatory component of Rye bran when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' (or words</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to that effect).
4351	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%.
4352	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%.
4353	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4354	SACCHARIN	E	The medicine requires the following warning statement on the medicine label:  - (SACCH) 'Contains saccharin' (or words to that effect).
4355	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).'
4356	SACCHAROMYCES CEREVISIAE	A, E	When for topical use, the concentration in the medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4357	SACCHAROMYCES CEREVISIAE (BOULARDII)	A	
4358	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%.
4359	SACCHAROMYCES/ZINC FERMENT	E	Only for use in topical medicines for dermal application.
4360	SACCHARUM OFFICINARUM	A, E, H	
4361	SAFFLOWER OIL	A, E, H	
4362	SAFFRON	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4363	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			than 4%.
4364	SAGE LEAF POWDER	A, H	<p>Thujone is a mandatory component of Sage leaf powder.</p> <p>The concentration of thujone in the medicine must be no more than 4%.</p>
4365	SAGE OIL DALMATIAN	A	<p>Thujone is a mandatory component of Sage oil dalmatian.</p> <p>The concentration of thujone in the medicine must be no more than 4%.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect)</p> <p>- (NTAKEN) 'Not to be taken'</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4366	SAGE OIL SPANISH	A, E, H	
4367	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 on damaged skin.  The concentration in the medicine must be no more than 0.002%.
4368	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%.
4369	SALICYLIC ACID	E, H	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 40%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4370	SALIX ALBA	A, E, H	
4371	SALIX DAPHNOIDES	A, H	
4372	SALIX DISCOLOR	A, H	
4373	SALIX FRAGILIS	A, H	
4374	SALIX NIGRA	A, H	
4375	SALIX PURPUREA	A, H	
4376	SALSOLA KALI	A, H	
4377	SALVIA CHINENSIS	A, H	
4378	SALVIA FRUTICOSA	A, H	
4379	SALVIA HISPANICA	A, E, H	
4380	SALVIA LAVANDULAEFOLIA	A, H	
4381	SALVIA MILTIORRHIZA	A, H	
4382	SALVIA OFFICINALIS	A, E, H	Thujone is a mandatory component of Salvia officinalis.  The concentration of thujone in the medicine must be no more than 4%.
4383	SALVIA SCLAREA	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4384	SAMBUCUS CANADENSIS	A, H	
4385	SAMBUCUS EBULUS	A, H	
4386	SAMBUCUS NIGRA	A, E, H	
4387	SANDALWOOD OIL EAST INDIAN	A, E, H	
4388	SANGUINARIA CANADENSIS	H	Only for use as an active homoeopathic ingredient.  The potency must be more than 4X.
4389	SANICULA EUROPAEA	A, H	
4390	SANTALUM ALBUM	A, E, H	
4391	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.
4392	SAPINDUS MUKOROSI	A, H	
4393	SAPONARIA OFFICINALIS	A, H	
4394	SAPOSHNIKOVIA DIVARICATA	A, H	



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4395	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%.
4396	SARGASSUM FUSIFORME	A, H	Iodine is a mandatory component of Sargassum fusiforme.  Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.  Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4397	SARGASSUM SILIQUASTRUM	A, H	Iodine is a mandatory component of Sargassum siliquastrum.  Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			2.5% or less.  Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
4398	SASSAFRAS ALBIDUM	A, H	Safrole is a mandatory component of Sassafras albidum.  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%.
4399	SATUREIA HORTENSIS	A, H	
4400	SATUREIA MONTANA	A, H	
4401	SAUROPUS SPATULIFOLIUS	A, H	
4402	SAURURUS CHINENSIS	A, H	
4403	SAUSSUREA COSTUS	A, H	
4404	SAVORY OIL SUMMER	A, H	
4405	SAXIFRAGA GRANULATA	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4406	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%.
4407	SCAPHIUM SCAPHIGERUM	A, H	
4408	SCHEFFLERA HEPTAPHYLLA	A, H	
4409	SCHINOPSIS QUEBRACHO-COLORADO	A, H	
4410	SCHINUS MOLLE	A, H	
4411	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%.
4412	SCHISANDRA CHINENSIS	A, E, H	
4413	SCHIZONEPETA TENUIFOLIA	A, E, H	
4414	SCHOENOCAULON OFFICINALE	A, H	The maximum recommended daily dose must contain no more than the equivalent of

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1mg of the dry herbal material.
4415	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 medicine must be no more than 5%.
4416	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%.
4417	SCLERANTHUS ANNUUS	A, H	
4418	SCLEROTIUM GUM	E	Only for use in topical medicines for dermal application.
4419	SCOPOLIA CARNIOLICA	A, H	The concentration of equivalent dry Scopolia carniolica in the medicine must be no more than 10mg/Kg or

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			10mg/L or 0.001%.
4420	SCROPHULARIA NINGPOENSIS	A, H	
4421	SCROPHULARIA NODOSA	A, H	
4422	SCURRULA PARASITICA VAR. GRACILIFLORA	A, H	
4423	SCUTELLARIA BAICALENSIS	A, E, H	
4424	SCUTELLARIA BARBATA	A, H	
4425	SCUTELLARIA LATERIFLORA	A, E, H	
4426	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%.
4427	SEC BUTYL 3-METHYLBUT-2-ENETHIOATE	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4428	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%.
4429	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.  When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:  - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
4430	SEDUM ACRE	A, H	
4431	SELAGINELLA TAMARISCINA	A, H	
4432	SELENICEREUS GRANDIFLORUS	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4433	SELENIUM	H	<p>Only for use as an active homoeopathic ingredient.</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 micrograms for adults of selenium from dietary supplements should not be exceeded.'</p>
4434	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			contains selenium which is toxic in high doses.  A daily dose of 150 mcg for adults of selenium from dietary supplements should not be exceeded.'
4435	SELENOMETHIONINE	A	Selenium is a mandatory component of Selenomethionine for oral and sublingual use.  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 micograms for adults of selenium from dietary supplements should not be exceeded.'
4436	SELF-EMULSIFYING GLYCERYL MONOSTEARATE	E	
4437	SEMECARPUS ANACARDIUM	A, H	When the plant part is other



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			than seed, the maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
4438	SEMOLINA	E	
4439	SEMPERVIVUM TECTORUM	A, H	
4440	SENEGA ROOT DRY	A, H	
4441	SENEGA ROOT POWDER	A, H	
4442	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> <p>- (CHLD3) '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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHIL3) '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>
4443	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>- (CHIL3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4444	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';</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4445	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> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (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 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</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4446	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 statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<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>
4447	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> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 contains [name of the herb(s) or the chemical component(s)]';</p> <p>- (LAX4) 'This product may</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
4448	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>component(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>
4449	SENNA OCCIDENTALIS	A, H	<p>Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Senna occidentalis when the route of administration is oral administration.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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</li> </ul>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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 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>
4450	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHLD3) '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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (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>
4451	SEPIA	H	Only for use as an active homoeopathic ingredient.
4452	SEQUOIA SEMPERVIRENS	A, H	
4453	SEQUOIADENDRON	A, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	GIGANTEUM		
4454	SERENOA REPENS	A, H	
4455	SERINE	A, E	
4456	SERUM ANGUILLAE	H	Only for use as an active homoeopathic ingredient.
4457	SESAME OIL	A, E, H	
4458	SESAME SEED	E	
4459	SESAMUM INDICUM	A, E, H	
4460	SETARIA ITALICA	A, H	
4461	SHARK CALCIUM CHONDROITIN SULFATE	A	
4462	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)
4463	SHARK CHONDROITIN SULFATE	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4464	SHARK POTASSIUM CHONDROITIN SULFATE	A	
4465	SHARK SODIUM CHONDROITIN SULFATE	A	
4466	SHARK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of 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> <p>- (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4467	SHEA BUTTER	E	
4468	SHEA BUTTER UNSAPONIFIABLES	E	Only for use in topical medicines for dermal application.
4469	SHELLAC	E	
4470	SHEPHERD'S PURSE HERB DRY	A, H	
4471	SHEPHERD'S PURSE HERB POWDER	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4472	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%.
4473	SIGESBECKIA ORIENTALIS	A, E, H	
4474	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%.
4475	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%.
4476	SILICA SILYLATE	E	Only for use in topical medicines for dermal

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
4477	SILICIFIED MICROCRYSTALLINE CELLULOSE	E	Only for use when the route of administration is other than inhalation.
4478	SILICON DIOXIDE	A, E, H	Only for use when the route of administration is other than inhalation.
4479	SILICONE QUATERNIUM-8	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.</p> <p>The concentration in the medicine must be no more than 2.5%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (EYE) 'Avoid contact with eyes' (or words to that effect).</p>
4480	SILVER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The concentration in the medicine must be no more than</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
4481	SILVER BEET	E, H	
4482	SILVER BOROSILICATE	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 should be no more than 0.6%.</p> <p>Silver is a mandatory component of Silver borosilicate when the route of administration is topical.</p> <p>The concentration of silver in the medicine must be no more than 1%.</p>
4483	SILVER NITRATE	H	Only for use as an active homoeopathic ingredient.
4484	SILYBUM MARIANUM	A, E, H	
4485	SIMABA CEDRON	A, H	
4486	SIMETHICONE	E	
4487	SIMMONDSIA CHINENSIS	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4488	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%.
4489	SINAPIS ARVENSIS	A, H	
4490	SINOMENIUM ACUTUM	A, H	
4491	SIPHONESTEGIA CHINENSIS	A, H	
4492	SIRAITIA GROSVENORII	A, E, H	
4493	SISYMBRIUM OFFICINALE	A, H	
4494	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4495	SKIPJACK-LIVER OIL	A, E	<p>Vitamin A and Colecalciferol are mandatory components of 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> <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</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4496	SLIPPERY ELM BARK DRY	A, H	
4497	SLIPPERY ELM BARK POWDER	A, E, H	
4498	SMILAX ARISTOLOCHIIFOLIA	A, H	
4499	SMILAX CHINA	A, H	
4500	SMILAX GLABRA	A, H	
4501	SMILAX OFFICINALIS	A, E, H	
4502	SMILAX ORNATA	A, E, H	
4503	SMOKE EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
4504	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).'
4505	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%.
4506	SODIUM ACID CITRATE	A, E, H	When used as an active ingredient, only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When used as an active, only for use in oral medicines.</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>
4507	SODIUM ACRYLATES COPOLYMER	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 0.8%.</p>
4508	SODIUM ACRYLATES CROSSPOLYMER-2	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>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.7 % (w/w).
4509	SODIUM ACRYLOYDIMETHYLTAURATE/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).
4510	SODIUM ALGINATE	E	
4511	SODIUM ASCORBATE	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).'
4512	SODIUM ASCORBYL	E	Only for use in topical

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	PHOSPHATE		<p>medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>When used in a sunscreen, the concentration in the medicine must be no more than 0.1%.</p> <p>When used in products other than sunscreens, the concentration in the medicine must be no more than 0.5%.</p>
4513	SODIUM ASCORBYL/CHOLESTERYL 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 5%.</p>
4514	SODIUM BENZOATE	E	<p>Medicines containing benzoates require the following warning statement on the medicine label:</p> <p>- (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</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			used]' (or words to this effect) if product contains one 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).'
4515	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).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4516	SODIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
4517	SODIUM BICARBONATE	A, 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>When used as an active 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 osmolality of the solution after</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4518	SODIUM BISULFITE	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4519	SODIUM BROMIDE	H	Only for use as an active homoeopathic ingredient.
4520	SODIUM C14-16 OLEFIN SULFONATE	E	Only for use in topical medicines for dermal application.
4521	SODIUM CARBOMER	E	Only for use as an excipient in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
4522	SODIUM CARBONATE	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).
4523	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).'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4524	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%.
4525	SODIUM CARRAGEENAN	E	
4526	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%.
4527	SODIUM CETOSTEARYL SULFATE	E	Only for use in topical medicines for dermal application.
4528	SODIUM CHLORIDE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4529	SODIUM CHONDROITIN SULFATE	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 0.001%.</p>
4530	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4531	SODIUM CITRATE DIHYDRATE	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> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p>
4532	SODIUM COCO PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 0.05%.
4533	SODIUM COCOAMPHOACETATE	E	Only for use in topical medicines for dermal application.
4534	SODIUM COCOYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4535	SODIUM CYCLAMATE	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).
4536	SODIUM DEHYDROACETATE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
4537	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%.
4538	SODIUM DODECYLBENZENESULFONATE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 30%.
4539	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'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			(or words to that effect).
4540	SODIUM ETHYL HYDROXYBENZOATE	E	
4541	SODIUM FLUORIDE	A, E, H	<p>Fluoride is a mandatory component of Sodium fluoride.</p> <p>Only for use when the route of 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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			less.'  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).'
4542	SODIUM FUMARATE	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 GLYCEROPHOSPHATE	A, E, H	When for oral or sublingual use and the total amount of sodium from all ingredients in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4544	SODIUM HYALURONATE	E	Only for use in topical medicines for dermal application.
4545	SODIUM HYDROGENATED TALLOW GLUTAMATE	E	Only for use in topical medicines for dermal application.
4546	SODIUM HYDROXIDE	E	<p>The concentration in the medicine must be no more than 5%.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
4547	SODIUM HYDROXYCITRATE	A	
4548	SODIUM HYDROXYETHYL ACRYLATE/ACRYLOYLDIMETHYL TAURATE COPOLYMER	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 1.5%.</p>
4549	SODIUM HYDROXYMETHYLGLYCINATE	E	Only for use in topical medicines for dermal application.
4550	SODIUM HYPOCHLORITE	E	Chlorine is a mandatory component of Sodium

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>hypochlorite.</p> <p>The concentration of chlorine in the medicine must be no more than 4%.</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 ISOSTEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4552	SODIUM LACTATE	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4553	SODIUM LAURETH 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).
4554	SODIUM LAUROAMPHOACETATE	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%.
4555	SODIUM LAUROYL METHYL ISETHIONATE	E	Only for use in wash-off topical medicines for dermal application and not to be



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 11%.
4556	SODIUM LAUROYL SARCOSINATE	E	Only for use in topical medicines for dermal application.
4557	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).
4558	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 LAURYL SULFOACETATE	E	Only for use in topical medicines for dermal application.
4560	SODIUM MAGNESIUM SILICATE	E	Only for use in topical medicines for dermal application.
4561	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 medicine must be no more than 0.5%.
4562	SODIUM METABISULFITE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4563	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4564	SODIUM METHYL COCOYL TAURATE	E	Only for dental use.  The concentration in the medicine must be no more than 2%.
4565	SODIUM METHYL HYDROXYBENZOATE	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).  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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4566	SODIUM MOLYBDATE DIHYDRATE	A	<p>Only for use in oral medicines.</p> <p>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>
4567	SODIUM MONOFLUOROPHOSPHATE	A	<p>Fluoride is a mandatory component of sodium monofluorophosphate.</p> <p>Only for use when the route of 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4568	SODIUM MYRISTOYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 0.0164%.
4569	SODIUM NITRATE	H	Only for use as an active homoeopathic ingredient.
4570	SODIUM NONOXYNOL-4 SULFATE	E	Only for use in topical medicines for dermal application.
4571	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).
4572	SODIUM PCA	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4573	SODIUM PERBORATE	A, H	<p>Boron is a mandatory component of sodium perborate.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 6 mg of boron.</p> <p>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%.</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>
4574	SODIUM PERCARBONATE	E	Only for use in topical medicines for dermal



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.  The concentration in the medicine must be no more than 15%.
4575	SODIUM POLYACRYLATE	E	Only for use in topical medicines for dermal application.
4576	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4577	SODIUM POLYMETAPHOSPHATE	E	
4578	SODIUM PROPIONATE	E	Only for use in topical medicines for dermal application.
4579	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)</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			if product contains one hydroxybenzoate source.
4580	SODIUM RNA	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%.
4581	SODIUM SELENATE	A, H	Selenium is a mandatory component of sodium selenate.  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.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4582	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>
4583	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			on the medicine label:  - (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.'
4584	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.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4585	SODIUM SILICATE	E	<p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</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>
4586	SODIUM STARCH GLYCOLLATE	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>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			quantity and units] of sodium' (or words to that effect).
4587	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).
4588	SODIUM STEARATE	E	Only for use in topical medicines for dermal application.
4589	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4590	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%.
4591	SODIUM STEAROYL LACTYLATE	E	Only for use in topical medicines for dermal application.
4592	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%.
4593	SODIUM SUCCINATE	E	Only for use in topical medicines for dermal application.
4594	SODIUM SULFATE	A, E, H	When it is not intended to be a laxative, the medicine requires the following warning statement on the medicine



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4595	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			label:  - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium' (or words to that effect).
4596	SODIUM SULFITE	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).  Medicines containing sulfites salts require the following warning statement on the medicine label:  - (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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4597	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>
4598	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>
4599	SOLANUM DULCAMARA	A, H	When for internal use, steroidal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			alkaloids calculated as solanine is a mandatory component of <i>Solanum dulcamara</i> .  When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4600	SOLANUM FEROX	A, H	When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of <i>Solanum ferox</i> .  When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.
4601	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4602	SOLANUM MELONGENA	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum melongena.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4603	SOLANUM NIGRUM	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum nigrum.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as solanine.</p>
4604	SOLANUM TUBEROSUM	A, H	<p>When for internal use, steroidal alkaloids calculated as solanine is a mandatory component of Solanum tuberosum.</p> <p>When for internal use, the maximum recommended daily dose must not provide more than 10mg of steroidal alkaloids calculated as</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			solanine.
4605	SOLIDAGO GIGANTEA	A, H	
4606	SOLIDAGO GIGANTEA MIS	A, E, H	
4607	SOLIDAGO VIRGAUREA	A, E, H	
4608	SOLUBLE MAIZE STARCH	E	
4609	SOLUBLE POTATO STARCH	E	
4610	SOLVENT GREEN 3	E	Permitted for use only as a colour for topical use.
4611	SOLVENT RED 1	E	Permitted for use only as a colour for topical use.
4612	SOLVENT VIOLET 13	E	Permitted for use only as a colour for topical use.
4613	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%.
4614	SOLVENT YELLOW 33	E	Permitted for use only as a colour for topical use.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4615	SOPHORA FLAVESCENS	A, E, H	
4616	SOPHORA TONKINENSIS	A, H	
4617	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.
4618	SORBITAN ISOSTEARATE	E	Only for use in topical medicines for dermal application.
4619	SORBITAN MONO-OLEATE	E	
4620	SORBITAN MONOLAURATE	E	
4621	SORBITAN MONOSTEARATE	E	
4622	SORBITAN OLEATE	E	
4623	SORBITAN OLIVATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 10%.
4624	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%.
4625	SORBITAN SESQUIISOSTEARATE	E	Only for use in topical medicines for dermal application.
4626	SORBITAN SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
4627	SORBITAN STEARATE	E	
4628	SORBITAN TRISTEARATE	E	Only for use in topical medicines for dermal application.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4629	SORBITOL	A, E	<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>
4630	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4631	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 supplied as an uncompounded medicine substance packed for retail sale, and must comply</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4632	SORBUS AUCUPARIA	A, H	
4633	SORBUS DOMESTICA	A, H	
4634	SORGHUM	E	
4635	SORGHUM VULGARE	A, H	
4636	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</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			phosphatidylserine in the medicine must be no more than 15%.
4637	SOY PHOSPHATIDYLSERINE-ENRICHED SOY LECITHIN POWDER	A	Soy phosphatidylserine is a mandatory component of soy phosphatidylserine-enriched soy lecithin powder.  The concentration of soy phosphatidylserine in the medicine must be no more than 15%.
4638	SOY POLYSACCHARIDE	E	
4639	SOY PROTEIN	E	
4640	SOY STEROL	E	
4641	SOYA BEAN	E	
4642	SOYA BRAN	E	
4643	SOYA OIL	A, E, H	
4644	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4645	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%.
4646	SPARGANIUM STOLONIFERUM	A, H	
4647	SPARTIUM JUNCEUM	A, H	
4648	SPATHOLOBUS SUBERECTUS	A, H	
4649	SPEARMINT OIL	A, E, H	When the ingredient is included in a medicine that is listed in the Register:  - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c);  - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or  - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>a) Menthol is a mandatory component of spearmint oil.</p> <p>b) When the medicine is for topical use:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the maximum concentration of menthol must not exceed 5%; and</p> <p>(iii) 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; and</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
4650	SPEARMINT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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> <p>Menthol is a mandatory component of spearmint oil terpeneless.</p> <p>When the medicine is for topical use:</p> <p>a) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>b) the maximum concentration of menthol must not exceed 5%; and</p> <p>c) the medicine requires the following warning statements 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; and</p> <p>- (EYE) Avoid contact with</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			eyes (or words to that effect).  When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
4651	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%.
4652	SPIGELIA ANTHELMIA	A, H	
4653	SPIGELIA MARILANDICA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
4654	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%.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>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:</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 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> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (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>
4655	SPINACH	E	
4656	SPINACIA OLERACEA	A, E, H	
4657	SPIRODELA POLYRRHIZA	A, H	
4658	SPIRULINA	E	
4659	SPRAY-DRIED GLUCOSE SYRUP	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4660	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%.
4661	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%.
4662	SQUALANE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4663	SQUALENE	A, E	
4664	SQUID OIL	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (SFOOD) 'Derived from seafood'.</p> <p>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.</p>
4665	SQUILL DRY	A, H	
4666	SQUILL INDIAN DRY	A, H	
4667	SQUILL INDIAN POWDER	A, H	
4668	SQUILL POWDER	A, H	
4669	ST JOHN'S WORT DRY EXTRACT QUANTIFIED	A	<p>When used for oral ingestion, the medicine requires the following warning statement on the medicine label:</p> <p>- (STJOHN) 'St John's Wort affects the way many prescription medicines work - including oral contraceptives.</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Consult your doctor.'
4670	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.'
4671	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.'
4672	STACHYS OFFICINALIS	A, E, H	
4673	STACHYS PALUSTRIS	A, H	
4674	STACHYURUS HIMALAICUS	A, H	
4675	STANNIC OXIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 0.005%.
4676	STANNOUS CHLORIDE	H	Only for use as an active homoeopathic ingredient.
4677	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).
4678	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4679	STARCH SODIUM OCTENYL SUCCINATE	E	
4680	STEARALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
4681	STEARALKONIUM HECTORITE	E	Only for use in topical medicines for dermal application.
4682	STEARAMIDE	E	Only for use in topical medicines for dermal application.
4683	STEARAMIDOETHYL DIETHYLAMINE	E	Only for use in topical medicines for dermal application.
4684	STEARAMIDOPROPYL DIMETHYLAMINE	E	Only for use in topical medicines for dermal application.
4685	STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application. The concentration in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>medicine must be no more than 2%.</p> <p>When the medicine is intended to be used on the eye, the medicine requires the following warning statement on the medicine label:</p> <p>- (EYE2) 'May be irritant to the eyes' (or words to that effect).</p>
4686	STEARETH-10	E	Only for use in topical medicines for dermal application.
4687	STEARETH-100	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 1.5%.</p>
4688	STEARETH-2	E	Only for use in topical medicines for dermal application.
4689	STEARETH-20	E	Only for use in topical medicines for dermal



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
4690	STEARETH-21	E	Only for use in topical medicines for dermal application.
4691	STEARETH-5	E	Only for use in topical medicines for dermal application.
4692	STEARIC ACID	E	
4693	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%.
4694	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4695	STEAROXYTRIMETHYLSILANE	E	Only for use in topical medicines for dermal application.
4696	STEAROYL MACROGOLGLYCERIDES	E	Only for use in oral medicines.  The concentration in the medicine must be no more than 0.6%.
4697	STEARYL ACETATE	E	Only for use in topical medicines for dermal application.
4698	STEARYL ALCOHOL	E	
4699	STEARYL 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 4.5%.  The medicine requires the following warning statements on the medicine label:  - (EYE2) 'May be irritant to the

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			eyes' (or words to that effect)  - (EYE) 'Avoid contact with eyes' (or words to that effect).
4700	STEARYL GLYCYRRHETINATE	E	Only for use in topical medicines for dermal application.
4701	STEARYL HEPTANOATE	E	Only for use in topical medicines for dermal application.
4702	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%.
4703	STEARYL STEARATE	E	Only for use in topical medicines for dermal application.
4704	STELLARIA CHAMAEJASME	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4705	STELLARIA DICHOTOMA	A, H	
4706	STELLARIA MEDIA	A, E, H	
4707	STEMONA JAPONICA	A, H	
4708	STEMONA SESSILIFOLIA	A, H	
4709	STENOTAPHRUM SECUNDATUM	A, H	
4710	STEPHANIA TETRANDA	A, H	
4711	STERCULIA	A, H	
4712	STERCULIA TRAGACANTHA	A, H	
4713	STERCULIA URENS	A, H	
4714	STEVIA REBAUDIANA	A, E, H	
4715	STEVIOL GLYCOSIDES	E	Only for use in oral medicines.
4716	STILLINGIA SYLVATICA	A, H	
4717	STORAX PREPARED	A, E, H	
4718	STRAWBERRY	E	
4719	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4720	STREPTOCOCCUS SALIVARIUS	A	<p>Permitted for use in only oral medicines and only when the strain of Streptococcus salivarius is confirmed to be K12.</p> <p>The name of strain must be declared on the label.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (CHILD5) 'Use in children under 3 years is not recommended'.</p>
4721	STREPTOCOCCUS THERMOPHILUS	A	
4722	STROBILANTHES CUSIA	A, H	
4723	STRONG AMMONIA SOLUTION	E	<p>Ammonia is a mandatory component of dilute ammonia solution.</p> <p>The concentration of ammonia in the medicine must be no more than 0.5%.</p> <p>When for internal use, the concentration in the medicine must be no more than 0.25%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4724	STRONTIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
4725	STROPHANTHUS GRATUS	H	Only for use as an active homoeopathic ingredient.
4726	STROPHANTHUS HISPIDUS	H	Only for use as an active homoeopathic ingredient.
4727	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%.
4728	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4729	STYPHNOLOBIUM JAPONICUM	A, E, H	
4730	STYRAX BENZOIN	A, E, H	
4731	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%.
4732	STYRAX PARALLELEONEURUM	A, H	
4733	STYRAX TONKINENSIS	A, H	
4734	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%.
4735	STYRENE/ACRYLATES	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	COPOLYMER		application.
4736	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 1%.
4737	SUBLIMED SULFUR	H	Only for use as an active homoeopathic ingredient.
4738	SUCCINIC ACID	E	
4739	SUCRALOSE	E	
4740	SUCROSE	E	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



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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			<p>'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>
4741	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>
4742	SUCROSE ACETATE PALMITATE STEARATE	E	<p>Only for use in topical medicines for dermal application and not 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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4743	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%.
4744	SUCROSE DISTEARATE	E	Only for use in topical medicines for dermal application.
4745	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
4746	SUCROSE OCTAACETATE	E	When for oral or sublingual use, sucrose is a mandatory component of sucrose octaacetate.  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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label:  - (LACT) 'Contains lactose' (or words to that effect).
4747	SUCROSE PALMITATE	E	Only for use in topical medicines for dermal application.
4748	SUCROSE POLYCOTTONSEEDATE	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%.  The medicine requires the following warning statements 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).
4749	SUCROSE STEARATE	E	For use in topical medicines for dermal application and not to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>be 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 0.25%.</p> <p>For oral use as a manufacturing aid only.</p> <p>When for oral use, the concentration in the medicine must be no more than 0.2 mg per dosage unit.</p>
4750	SUCROSE TRISTEARATE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 2%.</p>
4751	SUDAN III	E	Permitted for use only as a colour for topical use.
4752	SUGAR CANE WAX ALCOHOLS	A, H	The maximum recommended daily dose must not provide more than 12mg.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>The medicine requires the following warning statements on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</p>
4753	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</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			label:  - (LACT) 'Contains lactose' (or words to that effect).
4754	SULFATED CASTOR OIL	E	Only for use in topical medicines for dermal application.
4755	SULFATED LOW MOLECULAR WEIGHT FUCANS	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 0.025%.
4756	SULFUR DIOXIDE	E	Medicines containing sulfites salts require the following warning statement on the medicine label:  - (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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4757	SULFUR IODIDE	H	Only for use as an active homoeopathic ingredient.
4758	SULFURIC ACID	E, H	Only for use as an active homoeopathic ingredient or excipient ingredient.  The concentration in the medicine must be no more than 0.5%.
4759	SULFURISED 1-METHYL-4-(1-METHYLETHENYL)-CYCLOHEXENE	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%.
4760	SULISOBENZONE	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



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine 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>
4761	SULISOBENZONE SODIUM	A	Only for use as an active ingredient in sunscreens for dermal application and not to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>be 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 clothing - hats and eyewear</li> </ul>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			when exposed to the sun' (or words to this effect).
4762	SUNFLOWER OIL	A, E, H	
4763	SUNFLOWER SEED	E, H	
4764	SUNSET YELLOW FCF	E	Permitted for use only as a colour for either topical use or with an oral route of administration.
4765	SUNSET YELLOW FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
4766	SUPEROXIDE DISMUTASE	E	Only for use in topical medicines for dermal application.
4767	SWEDE	E	
4768	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4769	SWEET POTATO	E	
4770	SWERTIA CHIRATA	A, H	
4771	SWIETENIA MAHOGANI	A, H	
4772	SYAGRUS ROMANZOFFIANA	A, E, H	
4773	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%.
4774	SYMPLOCARPUS FOETIDUS	A, H	
4775	SYNTHETIC BEESWAX	E	Only for use in topical medicines for dermal applications.
4776	SYNTHETIC TERPENE RESIN	E	Only for use in topical, oral or

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			oral application medicines.  When the route of administration is oral, the dosage form must be chewing gum.
4777	SYNTHETIC WAX	E	
4778	SYRINGA RETICULATA	A, H	
4779	SYRINGA VULGARIS	A, H	
4780	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 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>resistant closure and restricted flow insert must be fitted on the container.</p> <p>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.</p> <p>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%.</p>
4781	SYZYGIUM CUMINI	A, H	
4782	SYZYGIUM JAMBOS	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 not be more than 0.0693%.</p>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4783	TABEBUIA SERRATIFOLIA	A, E, H	
4784	TAGETES ERECTA	A, H	
4785	TAGETES MINUTA	A, E, H	
4786	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%.
4787	TAIPAN SNAKE	H	Only for use as an active homoeopathic ingredient.
4788	TALLOW	E	Only for use in topical medicines for dermal application.
4789	TALLOW GLYCERIDES	E	
4790	TAMARINDUS INDICA	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour 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%.
4791	TAMARIX APHYLLA	A, H	
4792	TAMARIX CHINENSIS	A, H	
4793	TAMARIX GALLICA	A, H	
4794	TAMUS COMMUNIS	A, H	If the plant part is fruit or root, the maximum recommended daily dose must be no more than 1mg of the equivalent dry fruit or dry root of Tamus communis.
4795	TANACETUM CINERARIIFOLIUM	A, H	The concentration in the medicine must be no more than 10%.
4796	TANACETUM PARTHENIUM	A, E, H	
4797	TANACETUM VULGARE	A, H	Oil (of Tanacetum vulgare) is a mandatory component of Tanacetum vulgare.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration of oil (of <i>Tanacetum vulgare</i> ) in the medicine must be no more than 0.8%.
4798	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%.
4799	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.
4800	TANNIC ACID	E	
4801	TAPIOCA STARCH	E	
4802	TARAXACUM MONGOLICUM	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4803	TARAXACUM OFFICINALE	A, E, H	
4804	TARO	E	
4805	TARRAGON OIL	A, E, H	
4806	TARTARIC ACID	E	
4807	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).
4808	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).
4809	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
4810	TAURINE	A, E	
4811	TEA-STEARATE	E	Only for use in topical medicines for dermal application.
4812	TERMINALIA ARJUNA	A	<p>Only for use in oral medicines.</p> <p>Only for use when the plant part is bark.</p> <p>The maximum recommended daily dose must be no more than 6 grams of Terminalia arjuna dried bark or its extract equivalents.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)</p> <p>- (CHILD2) 'Not suitable for children'.</p>
4813	TERMINALIA BELLIRICA	A	Only for use when the preparation is as an aqueous

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			extract of the fruit pericarp.
4814	TERMINALIA CATAPPA	A, H	
4815	TERMINALIA CHEBULA	A, H	
4816	TERMINALIA FERDINANDIANA	A, E, H	<p>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.</p> <p>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.</p> <p>When used as an excipient, the concentration in the medicine must be no more than 0.3%.</p>
4817	TERMINALIA SERICEA	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>Only for use when the plant part is root bark.</p> <p>Only methanol/water (90:10; V/V) extract of Terminalia sericea bark of the root is</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			approved.  The concentration in the medicine must be no more than 0.1%.
4818	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%.
4819	TERPINEOL	E	
4820	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4821	TERPINOLENE	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>
4822	TERPINYL 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>
4823	TERPINYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
4824	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%.
4825	TERT-BUTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
4826	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%.
4827	TERT-BUTYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4828	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%.
4829	TETRACLINIS ARTICULATA	A, E, H	
4830	TETRADECYL AMINO BUTYROYL VALYLAMINE 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%.
4831	TETRADIUM RUTICARPUM	A, H	When for internal use, oxe-drine is a mandatory component of Tetradium ruticarpum.



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.
4832	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%.
4833	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 medicine must be no more than 1%.
4834	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
4835	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%.
4836	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%.
4837	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

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			medicine must be no more 1%.
4838	TETRAHYDROGERANYL 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%.
4839	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%.
4840	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%.

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4841	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%.
4842	TETRAHYDROXYPROPYL ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
4843	TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	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%.
4844	TETRAPANAX PAPYRIFER	A, H	
4845	TETRASODIUM ETIDRONATE	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4846	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).
4847	TEUCRIUM CHAMAEDRYS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium chamaedrys</i> .
4848	TEUCRIUM MARUM	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium marum</i> .
4849	TEUCRIUM SCORODONIA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Teucrium</i>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			scorodonia.
4850	THAPSIA GARGANICA	A, H	
4851	THAUMATIN	E	
4852	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%.
4853	THEMEDA TRIANDRA	A, H	
4854	THEOBROMA CACAO	A, E, H	Caffeine is a mandatory component of Theobroma cacao.  When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 1 mg but no more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:  - (CAFFR) 'The recommended dose of this medicine provides

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>small amounts of caffeine.’</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of more than 10 mg of caffeine in the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) ‘Contains caffeine [state quantity per dosage unit or per mL or per gram of product]’.</p>
4855	THEOBROMA OIL	A, E, H	
4856	THIAMINE	A, E	
4857	THIAMINE HYDROCHLORIDE	A, E	
4858	THIAMINE NITRATE	A, E	
4859	THIOCINEOLE	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>

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4860	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%.
4861	THLASPI ARVENSE	A, E, H	
4862	THREONINE	A, E	
4863	THUJA OCCIDENTALIS	A, H	
4864	THUJA PLICATA	A, E, H	
4865	THYME HERB DRY	A, E, H	
4866	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).
4867	THYMOL	A, E	When used as an active ingredient, the medicine must



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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be medicated space spray or medicated throat lozenges.  When used as an excipient, only for use in topical medicines for dermal applications.
4868	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).
4869	THYMUS GLAND	H	Only for use as an active homoeopathic ingredient.
4870	THYMUS MASTICHINA	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
4871	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).
4872	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			warning statement on the medicine label:  - (CHILD) 'Keep out of reach of children' (or words to that effect)
4873	THYMUS VULGARIS MIS	A, E, H	When the plant preparation is an oil or distillate, the nominal capacity of the container must be no more than 25 millilitres.  When the concentration of Thymus vulgaris 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:  - (CHILD) 'Keep out of reach of children' (or words to that effect)
4874	THYMUS ZYGIS	A, H	When the plant preparation is an oil or a distillate, the nominal capacity of the container must be no more than 25 millilitres.  When the concentration of Thymus zygis oil or distillate in the preparation is greater

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4875	TIGER SNAKE	H	Only for use as an active homoeopathic ingredient.
4876	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 units' and 'thousand acid lactase units' are permitted.</p>
4877	TILIA CORDATA	A, E, H	
4878	TILIA PLATYPHYLLOS	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4879	TILIA TOMENTOSA	A, H	
4880	TILIA X VULGARIS	A, E, H	
4881	TILIA TOL	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%.
4882	TIN	H	Only for use as an active homoeopathic ingredient.
4883	TINOSPORA CORDIFOLIA	A, H	
4884	TINOSPORA SINENSIS	A, H	
4885	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>the eye.</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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4886	TOCOCYSTEAMIDE	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%.
4887	TOCOFERSOLAN	E	Only for oral and topical use.  When for oral use, the concentration in the medicine must be no more than 10% w/w.  When used in topical medicines for dermal application, it is 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 0.1%
4888	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4889	TOCOPHERYL GLUCOSIDE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.05%</p>
4890	TOCOPHERYL LINOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
4891	TOCOPHERYL NICOTINATE	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 must not exceed 0.3%.</p>



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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
4892	TOLU BALSAM	A, E, H	
4893	TOLUENE	E	<p>The residual solvent limit for toluene is 8.9 mg per maximum recommended daily dose.</p> <p>The concentration in the medicine must be no more than 0.089%.</p>
4894	TOLYL ALDEHYDE	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>
4895	TOLYLALDEHYDE GLYCERYLACETAL	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</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			5%.
4896	TOMATO	E	
4897	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%.
4898	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%.
4899	TONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
4900	TOXICODENDRON DIVERSILOBUM	H	Only for use as an active homoeopathic ingredient.
4901	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.
4902	TOXICODENDRON RADICANS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Toxicodendron radicans.
4903	TOXICODENDRON SUCCEDANEUM	H	Only for use as an active homoeopathic ingredient.
4904	TRACHELOSPERMUM JASMINOIDES	A, E, H	

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4905	TRACHYSPERMUM AMMI	A, E	<p>Only for use in oral medicines when the plant part is fruit or seed.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect)</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).</p> <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>
4906	TRAGACANTH	A, E	
4907	TRAMETES VERSICOLOR	A, H	
4908	TRAMETES VERSICOLOR PROTEOGLYCAN CONCENTRATE	A, H	Only for use in oral medicines.
4909	TRANS,TRANS-2,4-DECADIEN-1-	E	Permitted for use only in combination with other

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	AL		permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
4910	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.
4911	TRANS-1-(2,4,4-TRIMETHYL-2-CYCLOHEXEN-1-YL)-2-BUTEN-1-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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
4912	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%.
4913	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%.
4914	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
4915	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 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
4916	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%.
4917	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

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
4918	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%.
4919	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%.
4920	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



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
4921	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%.
4922	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%.
4923	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4924	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%.
4925	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%.
4926	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%.
4927	TREACLE	E	When for oral or sublingual use, sucrose is a mandatory component of Treacle.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>When the 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>
4928	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4929	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4930	TREHALOSE DIHYDRATE	E	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.
4931	TREMELLA FUCIFORMIS	A, H	
4932	TRIACETIN	E	
4933	TRIACONTANYL PVP	E	Only for use in topical medicines for dermal application.
4934	TRIADICA SEBIFERA	A, H	
4935	TRIBASIC POTASSIUM PHOSPHATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of tribasic potassium phosphate.</p> <p>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.</p> <p>When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than</p>

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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			11.5.
4936	TRIBASIC SODIUM PHOSPHATE	E	<p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</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>
4937	TRIBEHENIN	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</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			6%.
4938	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%.
4939	TRIBULUS TERRESTRIS	A, E, H	
4940	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%.
4941	TRICALCIUM PHOSPHATE	E	
4942	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

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
4943	TRICAPRYLYL 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 7%.
4944	TRICETEARETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4945	TRICHLOROMETHYLPHENYL CARBINYL 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%.
4946	TRICHODERMA VIRIDE	A, E, H	
4947	TRICHOSANTHES KIRILOWII	A, E, H	
4948	TRICLOSAN	E	The concentration in the medicine must be no more than



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<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			1%.
4949	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%.
4950	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 1%.
4951	TRIDECETH-4 PHOSPHATE	E	Only for use in topical medicines for dermal application.
4952	TRIDECETH-6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.5%.
4953	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%.
4954	TRIDECYL BEHENATE	E	Behenic acid is a mandatory component of Tridecyl behenate.  Only for use in topical medicines for dermal application.
4955	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			23%.
4956	TRIDECYL SALICYLATE	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%.
4957	TRIDECYL STEARATE	E	Only for use in topical medicines for dermal application.
4958	TRIDECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application.
4959	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
4960	TRIETHYL CITRATE	E	
4961	TRIETHYLENE GLYCOL	E	
4962	TRIFOLIUM PRATENSE	A, E, H	
4963	TRIFOLIUM REPENS	A, H	
4964	TRIGONELLA FOENUM- GRAECUM	A, E, H	
4965	TRIHIDROXYPALMITAMIDOH 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%.
4966	TRIHIDROXYSTEARIN	E	Only for use in topical medicines for dermal application.
4967	TRISOCETYL CITRATE	E	Only for use in topical medicines for dermal application.
4968	TRISODECYL TRIMELLITATE	E	Only for use in topical medicines for dermal application and not to be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 5%.
4969	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%.
4970	TRIISOSTEARIN	E	Only for use in topical medicines for dermal application.
4971	TRILAURIN	E	Only for use in topical medicines for dermal application.
4972	TRILISA ODORATISSIMA	A, H	
4973	TRILLIUM ERECTUM	A, H	
4974	TRIMETHOXYCAPRYLYL SILANE	E	Only for use in topical medicines for dermal application and not to be

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.25%.
4975	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%.
4976	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%.
4977	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 1%.
4978	TRIMETHYLBENZENEPROPANOL	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%.
4979	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 1%.
4980	TRIMETHYLOPROPANE TRIOCTANOATE	E	Only for use in topical medicines for dermal application.
4981	TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye.  The concentration in the medicine must be no more than 5%.
4982	TRIMETHYLSILOXYSILICATE	E	Only for use in topical medicines for dermal application.
4983	TRINITROPHENOL	H	Only for use as an active homoeopathic ingredient.
4984	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%.
4985	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



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			12%.
4986	TRIOLEIN	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%.
4987	TRIOSTEUM PERFOLIATUM	A, H	
4988	TRIOXAUNDECANEDIOIC ACID	E	
4989	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%.
4990	TRIPLEPTIDE-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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 0.002%.
4991	TRIS-BIPHENYL TRIAZINE	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 topically, the dosage form must not be spray.</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</p>

Table 1 Part 2

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
4992	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>
4993	TRISODIUM EDETATE	E	Only for use in topical medicines for dermal application.
4994	TRISODIUM ETHYLENEDIAMINE DISUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Table 1 **Part 2**

Volume 5

<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
			The concentration in the medicine must be no more than 0.2%.
4995	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%.
4996	TRISTEARIN	E	
4997	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.  When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:  - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).

Table 1 **Part 2**

Volume 5

<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
4998	TRITICUM DURUM	A, E, H	<p>Gluten is a mandatory component when the plant part is seed and the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).</p>
4999	TRIUNDECANOIN	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 11.2%.</p>
5000	TROLAMINE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5001	TROLAMINE LAURIL SULFATE	E	Only for use in topical medicines for dermal application.
5002	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</p>

Table 1 Part 2

Volume 5

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>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>
5003	TROLLIUS CHINENSIS	A, H	
5004	TROMETAMOL	E	
5005	TROMETAMOL HYDROCHLORIDE	E	
5006	TROPAEOLUM MAJUS	A, E, H	
5007	TROPICAL RATTLESNAKE	H	Only for use as an active homoeopathic ingredient.
5008	TROPOLONE	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>

Table 1 Part 2

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Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
5009	TSUGA CANADENSIS	A, H	
5010	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%.
5011	TURMERIC	E	Permitted for use only in combination with other permitted ingredients as a colour.
5012	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 %.
5013	TURNIP	E	



<b>Column 1</b>	<b>Column 2</b> <b>Ingredient Name</b>	<b>Column 3</b> <b>Purpose of the ingredient in the medicine</b>	<b>Column 4</b> <b>Specific requirements(s) applying to the ingredient in Column 2</b>
5014	TURPENTINE OIL	A, E	The concentration in the medicine must be no more than 25%.
5015	TYPHA ANGUSTIFOLIA	A, H	
5016	TYPHA LATIFOLIA	A, H	
5017	TYPHONIUM GIGANTEUM	A, H	
5018	TYROSINE	A, E	