

## 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
730	BACKHOUSIA CITRIODORA	A, E, H	<p>The herbal substance must be derived from leaf oil only.</p> <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops - discontinue use'</li> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> <li>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</li> </ul>
731	BACOPA MONNIERI	A, H	

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Table 1 **Part 2**

Volume 2

<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>
732	BALLOTA NIGRA	A, H	
733	BALM OF GILEAD BUD DRY	A, H	
734	BALM OF GILEAD BUD POWDER	A, H	
735	BALSAM COPAIBA	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%.
736	BAMBUSA BREVIFLORA	A, E, H	
737	BAMBUSA TEXTILIS	A, H	
738	BANANA	E	
739	BANANA DISTILLATE	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%.
740	BAPTISIA CONFUSA	A, H	
741	BAPTISIA TINCTORIA	A, H	
742	BARBAREA VULGARIS	A, H	
743	BARIUM CARBONATE	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			homoeopathic ingredient.
744	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
745	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
746	BARLEY	E	<p>Gluten is a mandatory component of Barley 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>
747	BARLEY BRAN	E	<p>Gluten is a mandatory component of Barley 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</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:  - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
748	BARLEY GERM	E	Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal.  When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:  - (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
749	BARLEY LEAF	E	
750	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
751	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
752	BASIC RED 1	E	Only for use as a colour in topical medicines for dermal application and not to be included in 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>intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
753	BASIC VIOLET 11:1	E	<p>Only for use as a colour 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 0.1%.</p>
754	BASIL OIL COMOROS	A, E, H	<p>Methyl chavicol is a mandatory component of Basil oil Comoros.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (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
755	BASIL OIL EUROPEAN	A, E, H	<p>Methyl chavicol is a mandatory component of Basil oil European.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
756	BASSIA SCOPARIA	A, H	
757	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
758	BAY LEAF	E	
759	BAY OIL	A, E, H	When the concentration of Bay oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.

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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>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is no more than 15 mL, there must be a restricted flow insert fitted on the container.</p> <p>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is more than 15 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>
760	BEESWAX ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total 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
761	BEET RED	E	Permitted for use only as a colour for oral and topical use.
762	BEETROOT	E, H	
763	BEGONIA FIMBRISTIPULA	A, H	
764	BEHENETH-10	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 1.5%.  Residual levels of ethylene oxide are to be kept below the level of detection.
765	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
766	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
767	BEHENOYL STEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical 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
			intended for use in the eye.  The concentration in the medicine must be no more than 2.4%.
768	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
769	BELLADONNA HERB DRY	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb dry.  The concentration of alkaloids calculated as hyoscyamine in the medicine and must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.  The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
770	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb powder.  The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300

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			micrograms/L or 0.00003%.  The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
771	BELLADONNA HERB PREPARED	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application.  The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.  The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
772	BELLIS PERENNIS	A, H	
773	BEMOTRIZINOL	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

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			<p>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>
774	BENINCASA HISPIDA	A, E, H	
775	BENTONITE	E	
776	BENZALDEHYDE	E	
777	BENZALDEHYDE GLYCERYL	E	Permitted for use only in combination with other permitted

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	ACETAL		<p>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>
778	BENZALKONIUM CHLORIDE	E	<p>Only for use in topical medicines for dermal application and nasal sprays.</p> <p>The concentration in the medicine must be no more than 5%.</p>
779	BENZETHONIUM CHLORIDE	E	<p>Only for use as a preservative in topical medicines for dermal application.</p>
780	BENZOIC ACID	E, H	<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 used] (or words to this effect)' if product contains one benzoate source.</p>

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781	BENZOIN	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%.
782	BENZOIN SIAM	A, E, H	
783	BENZOIN SUMATRA	A, E, H	
784	BENZOPHENONE	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%.
785	BENZYL 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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			medicine must be no more 1%.
786	BENZYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
787	BENZYL ALCOHOL	E	
788	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application.  Medicines containing benzoates require the warning statement:  - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.
789	BENZYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
790	BENZYL CINNAMATE	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%.
791	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	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%.
792	BENZYL 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

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			medicine must be no more 1%.
793	BENZYL ISOAMYL 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%.
794	BENZYL 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%.
795	BENZYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a



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			medicine must be no more 1%.
796	BENZYL LAURATE	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%.
797	BENZYL PHENYLACETATE	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%.
798	BENZYL 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

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			medicine must be no more 1%.
799	BENZYL SALICYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
800	BENZYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
801	BENZYLIDENE ACETONE	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</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
			fragrance concentration in a medicine must be no more than 1%.
802	BENZYLIDENE CAMPHOR 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 6% (as acid).</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).
803	BERBERIS AQUIFOLIUM	A, H	
804	BERBERIS ARISTATA	A	Only for use in oral medicines.  The medicine requires the following warning statement on the medicine label:  - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
805	BERBERIS VULGARIS	A, E, H	
806	BERGAMOT 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%.  The medicine requires the following warning statement on the medicine label:  - (SENS) 'Application to skin may

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			increase sensitivity to sunlight.' (or words to that effect)
807	BERGAMOT OIL BERGAPTEN-FREE	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>
808	BERGAMOT OIL COLDPRESSED	A, E, H	<p>When for internal use oxedrine is a mandatory component of bergamot oil coldpressed.</p> <p>The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine.</p> <p>The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.4 per cent or less of bergamot 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
			coldpressed; or  c) for use in soaps or bath or shower gels that are washed off the skin.
809	BERGAMOT OIL TERPENELESS	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%.
810	BERTHOLLETIA EXCELSA	A, E, H	
811	BETA RAPA	A, E, H	
812	BETA VULGARIS	A, E, H	
813	BETA,4-DIMETHYLCYCLOHEX-3-ENE-1-PROPAN-1-AL	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%.
814	BETA-CARYOPHYLLENE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>concentration 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>
815	BETA-CARYOPHYLLENE ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
816	BETA-DAMASCENONE	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>
817	BETA-DAMASCONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</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>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>
818	BETA-HOMO CYCLOCITRAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
819	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
820	BETA-IONONE	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>
821	BETA-IONONE EPOXIDE	E	Permitted for use only in combination with other permitted



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			<p>ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
822	BETA-ISO-METHYL IONONE	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>
823	BETA-METHYL NAPHTHYL KETONE	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>
824	BETA-N-METHYL IONONE	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</p>

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			<p>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>
825	BETA-NAPHTHOL ETHYLETHER	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>
826	BETA-NAPHTHOL METHYL ETHER	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>

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**Schedule 1**

Table 1 **Part 2**

Volume 2

<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>
827	BETA-NAPHTHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.  The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
828	BETA-NAPHTHYL ISOBUTYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
829	BETA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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%.

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830	BETA-TOCOPHEROL	E	
831	BETACAROTENE	A, E	When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or sublingual use in adults the medicine requires the following warning statement on the medicine label:  - (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.'
832	BETADEX	E	
833	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 0.01%.
834	BETAINE	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
835	BETAINE HYDROCHLORIDE	E	
836	BETULA LENTA	A, H	<p>Methyl salicylate is a mandatory component of Betula lenta.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement 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
			<p>required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (IRRIT) 'If irritation develops, discontinue use.'; and</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</li> </ul>
837	BETULA NIGRA	A, H	<p>Cresol, eugenol and methyl salicylate are mandatory components of Betula nigra.</p> <p>For external use only when the total concentration of cresols, xylenols</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>and other phenol homologues in the medicine is greater than 3%.</p> <p>When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%.</p> <p>When the concentration of eugenol in the medicine is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 mL;</p> <p>b) the medicine must be fitted with a restricted flow insert;</p> <p>c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and</p> <p>d) the medicine requires 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>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</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>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) ‘Contains methyl salicylate’ (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p>



Column 1	Column 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>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (IRRIT) 'If irritation develops, discontinue use.'; and</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</p>
838	BETULA PENDULA	A, E, H	<p>Methyl salicylate is a mandatory component of Betula pendula.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is</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>more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> <li>- on or after 1 July 2018, the medicine must comply with all requirements under (a) &amp; (b);</li> <li>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</li> <li>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</li> </ul> <p>a) The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl</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>salicylate' (or words to that effect).</p> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (IRRIT) 'If irritation develops, discontinue use.'; and</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</li> </ul>
839	BETULA PUBESCENS	A, E, H	
840	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	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</p>

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

Table 1 **Part 2**

Volume 2

<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 than 1%.
841	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)-	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%.
842	BIFIDOBACTERIUM ADOLESCENTIS	A	
843	BIFIDOBACTERIUM ANIMALIS	A	
844	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
845	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
846	BIFIDOBACTERIUM BIFIDUM	A	
847	BIFIDOBACTERIUM BREVE	A	
848	BIFIDOBACTERIUM INFANTIS	A	
849	BIFIDOBACTERIUM LACTIS	A	
850	BIFIDOBACTERIUM LONGUM	A	
851	BILBERRY	E	
852	BIOSACCHARIDE GUM-1	E	Only for use in topical medicines for dermal application and not to be included in topical 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
			intended for use in the eye.  The concentration in the medicine must be no more than 5%.
853	BIOTA ORIENTALIS	A, H	
854	BIOTIN	A, E	
855	BIRCH LEAF DRY	A, E, H	<p>Methyl salicylate is a mandatory component of birch leaf dry.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery</li> </ul>

<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>device results in delivery of no more than one dosage unit; and</p> <ul style="list-style-type: none"> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> <li>- on or after 1 July 2018, the medicine must comply with all requirements under (a) &amp; (b);</li> <li>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</li> <li>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</li> </ul> <p>a) The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if</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>pregnant or likely to become pregnant' (or words to that effect);</p> <ul style="list-style-type: none"> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (IRRIT) 'If irritation develops, discontinue use.'; and</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</li> </ul>
856	BIRCH TAR OIL RECTIFIED	A, E, H	<p>Cresol is a mandatory component of birch tar oil rectified.</p> <p>For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%.</p>
857	BIS-BUTYLDIMETICONE POLYGLYCERYL-3	E	<p>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.</p> <p>The concentration in 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
			must be no more than 1.5%.
858	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
859	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE	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%.
860	BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE	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 2.5%.
861	BIS-PEG-12 DIMETHICONE BEESWAX	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%.
862	BIS-STEARYL	E	Only for use in topical 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
	ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE COPOLYMER		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%.
863	BISABOLENE	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%.
864	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
865	BITTER ALMOND OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  The absence of amygdalin in the

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

Table 1 **Part 2**

Volume 2

<b>Column 1</b>	<b>Column 2 Ingredient Name</b>	<b>Column 3 Purpose of the ingredient in the medicine</b>	<b>Column 4 Specific requirements(s) applying to the ingredient in Column 2</b>
			medicine must be declared.
866	BIXA ORELLANA	A, E, H	
867	BLACK BONED CHICKEN POWDER	A	
868	BLACK COHOSH DRY	A, H	The medicine requires the following warning statement on the medicine label:  - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
869	BLACK COHOSH POWDER	A, H	The medicine requires the following warning statement on the medicine label:  - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			product and see your doctor.'
870	BLACK CURRANT	E	
871	BLACK CURRANT ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
872	BLACK CURRANT FRESH	A, E, H	
873	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
874	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
875	BLACK PEPPER OIL	A, E, H	

<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>
876	BLACK RASPBERRY	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%.
877	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
878	BLACKBERRY	E	
879	BLACKBERRY OILS	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%.
880	BLACKBERRY WINE	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%.
881	BLACKCURRANT ESTERS	E	Permitted for use only in combination with other permitted

Column 1	Column 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>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>
882	BLACKCURRANT JUICE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
883	BLACKSTRAP MOLASSES	E	<p>When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap.</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>

Column 1	Column 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>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>
884	BLADDERWRACK DRY	A, H	<p>Iodine is a mandatory component of Bladderwrack dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
885	BLADDERWRACK POWDER	A, H	<p>Iodine is a mandatory component of Bladderwrack powder.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum</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.
886	BLAINVILLEA ACMELLA	A, E, H	When used as an excipient, 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%.
887	BLETILLA STRIATA	A, H	
888	BLUE FLAG RHIZOME DRY	A, H	
889	BLUE FLAG RHIZOME POWDER	A, H	
890	BLUEBERRY	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%.
891	BLUEBERRY JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
892	BLUMEA LACERA	A, H	
893	BOEHMERIA NIVEA	A, H	
894	BOERHAVIA DIFFUSA	A, H	
895	BOERHAVIA REPENS	A, H	
896	BOGBEAN LEAF DRY	A, H	
897	BOGBEAN LEAF POWDER	A, H	
898	BOIS DE ROSE OIL	A, E, H	
899	BOMBAX CEIBA	A, H	
900	BORAGO OFFICINALIS	A, E, H	Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of Borago officinalis.
901	BORAX	A, E, H	Boron is a mandatory component of Borax.  The percentage of Boron from Borax should be calculated based on the molecular weight of Borax.  The maximum recommended daily dose must provide no more than 6mg of Boron.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of Boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.
902	BORAX PENTAHYDRATE	A, E	<p>Boron is a mandatory component of Borax Pentahydrate.</p> <p>The percentage of Boron from Borax pentahydrate should be calculated based on the molecular weight of Borax Pentahydrate.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron from Borax pentahydrate.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 g/L or 0.35%.</p>
903	BORIC ACID	A, H	<p>Boron is a mandatory component of Boric acid.</p> <p>The percentage of Boron from Boric acid 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>Boric acid.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
904	BORNEOL	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>
905	BORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 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
906	BORON NITRIDE	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%.
907	BORONIA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
908	BORONIA MEGASTIGMA	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%.
909	BOSWELLIA CARTERII	A, E, H	

<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>
910	BOSWELLIA SERRATA	A, E, H	
911	BOSWELLIA THURIFERA	A, H	
912	BOVINE CALCIUM CHONDROITIN SULFATE	A	
913	BOVINE CHONDROITIN SULFATE	A	
914	BOVINE COLOSTRUM POWDER	A	The medicine requires the warning statement:  - (BOVCOL) 'Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'
915	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label:  - (COWMK) 'Derived from cow's milk.'
916	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
917	BOVINE SODIUM CHONDROITIN SULFATE	A	
918	BOVINE WHEY IG-RICH	A	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
	FRACTION		<p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (COWMK) 'Derived from cows milk'</li> <li>- (BABY3) 'Not suitable for use in children under the age of 12 months - except on the advice of a health professional)'.</li> </ul>
919	BRANDY	E	
920	BRASSICA CHINENSIS	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica chinensis when the plant part is seed.</p> <p>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%.</p>
921	BRASSICA JUNCEA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica juncea when the plant part is seed.</p> <p>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%.</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
922	BRASSICA NAPUS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed.</p> <p>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%.</p>
923	BRASSICA NIGRA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed.</p> <p>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%.</p>
924	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed.</p> <p>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%.</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
925	BRASSICA OLERACEA VAR. CAPITATA	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata when the plant part is seed.</p> <p>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%.</p>
926	BRASSICA OLERACEA VAR. GEMMIFERA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var gemmifera when the plant part is seed.</p> <p>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%.</p>
927	BRASSICA OLERACEA VAR. ITALICA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than</p>

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

Table 1 **Part 2**

Volume 2

<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>
			10 mg/kg or 10 mg/L or 0.001%.
928	BRASSICA OLERACEA VAR. VIRIDIS	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed.</p> <p>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%.</p>
929	BRASSICA PEKINENSIS	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica pekinensis when the plant part is seed.</p> <p>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%.</p>
930	BRASSICA RAPA	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica rapa when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product 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
			10 mg/kg or 10 mg/L or 0.001%.
931	BRAZIL NUT	E	
932	BRILLIANT BLACK BN	E	Permitted for use only as a colour for oral and topical use.
933	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral and topical use.
934	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
935	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
936	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour for oral and topical use.
937	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
938	BRIZA MEDIA	A, H	
939	BROCCOLI	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
940	BROMELAINS	A	<p>May be derived from either the stem or fruit of the pineapple (<i>Ananas comosus</i>).</p> <p>If used in a divided preparation, the allowed units are papain units and million papain units.</p> <p>If used in an undivided preparation, the allowed units are million papain units per gram.</p>
941	BROMINE	H	<p>Only for use as an active homoeopathic ingredient. The concentration of bromine in the preparation must be no more than 14mg/Kg or 14mg/L or 0.0014% for oral and sublingual use.</p>
942	BROMOSTYROL	E	<p>Not for use in infants</p> <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>
943	BROMUS CATHARTICUS	A, H	
944	BROMUS INERMIS	A, H	

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

Table 1 **Part 2**

Volume 2

<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>
945	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
946	BRONOPOL	E	Only for use in topical medicines for dermal application.
947	BROUSSONETIA POPYRIFERA	A, H	
948	BROWN FK	E	Permitted for use only as a colour for topical use.
949	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
950	BRUSSEL SPROUT	E	
951	BRYONIA ALBA	A, H	
952	BRYONIA DIOICA	A, H	
953	BUCHU LEAF DRY	A, H	
954	BUCHU LEAF 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

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

Table 1 **Part 2**

Volume 2

<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%.
955	BUCHU LEAF POWDER	A, E, H	
956	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
957	BUDDLEJA OFFICINALIS	A, H	
958	BULNESIA SARMIENTI	A, E, H	
959	BUNIAS ORIENTALIS	A, H	
960	BUPLEURUM FALCATUM	A, H	
961	BURDOCK LEAF DRY	A, H	
962	BURDOCK LEAF POWDER	A, H	
963	BURDOCK ROOT DRY	A, H	
964	BURDOCK ROOT POWDER	A, H	
965	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
966	BUTAN-1-OL	E	The residual solvent limit for Butan-1-ol is 50 mg per maximum recommended daily dose.  The concentration in the medicine must be no more than 0.5%.

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
967	BUTANE	E	Only for use as an excipient propellant ingredient.
968	BUTOXYETHANOL	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%.
969	BUTTER	E	
970	BUTTER ACIDS	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%.
971	BUTTER ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
972	BUTTER STARTER DISTILLATE	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%.
973	BUTYL 2-METHYLBUTYRATE	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%.
974	BUTYL ACETATE	E	The residual solvent limit for Butyl acetate is 50 mg per maximum recommended daily dose.  The concentration in the medicine must be no more than 0.5%.
975	BUTYL 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%.  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%.
976	BUTYL BUTYRYL LACTATE	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>
977	BUTYL CAPROATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
978	BUTYL ESTER OF PVM/MA 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 15%.</p> <p>The medicine requires the following warning statements on</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 medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) 'Avoid contact with eyes' (or words to that effect)</li> <li>- (EYE2) 'May be irritant to the eyes' (or words to that effect).</li> </ul>
979	BUTYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
980	BUTYL HYDROXYBENZOATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (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.</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
981	BUTYL ISOBUTYRATE	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%.
982	BUTYL ISOVALERATE	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%.
983	BUTYL LACTATE	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%.
984	BUTYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
985	BUTYL METHOXYDIBENZOYLMETHAN E	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 preparation must be no more than 5%.</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
986	BUTYL PROPIONATE	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%.
987	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
988	BUTYL UNDECYLENATE	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%.
989	BUTYLATED HYDROXYANISOLE	E	
990	BUTYLATED HYDROXYTOLUENE	E	
991	BUTYLENE GLYCOL	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
	DICAPRYLATE/DICAPRATE		included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 10%.
992	BUTYLIDENE PHTHALIDE	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%.
993	BUTYLOCTYL 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 7%.
994	BUTYLPHENYL METHYLPROPIONAL	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%.
995	BUTYRALDEHYDE	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%.
996	BUTYRIC 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%.
997	C1-8 ALKYL TETRAHYDROXYCYCLOHEXAN OATE	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 0.012%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
998	C10-12 ALKANE/CYCLOALKANE	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%.
999	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.
1000	C11-14-ISO-ALCOHOL C-13 RICH	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%.
1001	C12-13 PARETH-23	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 0.125%.  Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to 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
1002	C12-13 PARETH-3	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 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
1003	C12-15 ALKYL LACTATE	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 1.2%.</p>
1004	C12-15 ALKYL OCTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
1005	C12-20 ACID PEG-8 ESTER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1006	C12-20 ALKYL GLUCOSIDE	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 0.75%.
1007	C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE 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 C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.
1008	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1009	C14-22 ALCOHOLS	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 2.55%.
1010	C15-19 ALKANE	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 7%.
1011	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1012	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1013	C2-OCTENAL	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%.
1014	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1015	C20-40 ALKYL 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 2%.

<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>
1016	C20-40 PARETH-24	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.25%.
1017	C20-40 PARETH-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 2%.
1018	C30-45 ALKYL CETEARYL DIMETICONE 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 1%.
1019	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1020	C9-11 PARETH-3	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
1021	C9-15 ALKYL 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 0.12%
1022	CABBAGE	E	
1023	CABREUVA 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%.
1024	CADE OIL	A, E, H	
1025	CAESALPINIA SAPPAN	A, H	
1026	CAFFEINE	A, E	When used as an excipient, only for use in topical medicines for dermal application.  Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and contains no more than 100 mg of caffeine per

Column 1	Column 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.</p> <p>Medicines for oral use containing caffeine as an active ingredient require the following warning statement on the medicine label:</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine 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>b) more than 10 mg of caffeine 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>
1027	CAJUPUT OIL	A, E, H	<p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, 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>nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container.</p> <p>When the concentration in the medicine is more than 25%, 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> <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 mL.</p> <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, 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>must have a child resistant closure and restricted flow insert fitted on the container and 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> <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the medicine must have the restricted flow insert fitted on the container and 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>
1028	CALAMINE	A, E	<p>Only for use as an active or excipient ingredient for dermal application.</p> <p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or</p>

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
			existing from time to time.
1029	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1030	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1031	CALCIUM ALGINATE	E	
1032	CALCIUM AMINO ACID CHELATE	A, H	Calcium is a mandatory component of calcium amino acid chelate.  The concentration of calcium in the calcium amino acid chelate must be no more than 25% w/w.
1033	CALCIUM ASCORBATE	A, E, H	
1034	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1035	CALCIUM ASPARTATE	A	
1036	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1037	CALCIUM BEHENATE	E	Behenic acid is a mandatory component of Calcium behenate.

Column 1	Column 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 for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 mg of Behenic acid.
1038	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1039	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1040	CALCIUM CARBONATE	A, E, H	
1041	CALCIUM CASEINATE	E	
1042	CALCIUM CHLORIDE DIHYDRATE	E	
1043	CALCIUM CITRATE	A, E, H	
1044	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1045	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1046	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular weight of Calcium fluoride.  The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.



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
1047	CALCIUM FOLINATE	A	<p>Folinic acid is a mandatory component of calcium folinate.</p> <p>The maximum daily dose must not provide more than 500 micrograms of folinic acid.</p> <p>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.</p> <p>When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following warning statement is required on the medicine label:</p> <p>- (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect).'</p>
1048	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	

<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>
1049	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1050	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1051	CALCIUM GLYCINATE DIHYDRATE	A	
1052	CALCIUM HEXAFLUROSILICATE	H	Only for use as an active homoeopathic ingredient.
1053	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1054	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1055	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1056	CALCIUM HYDROXIDE	A, E, H	When used as a standard 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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1057	CALCIUM HYDROXYCITRATE	A, H	
1058	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1059	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1060	CALCIUM KETOGLUCONATE	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 must be no more than 1%
1061	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1062	CALCIUM LACTATE	A, E, H	
1063	CALCIUM LACTATE GLUCONATE	A, E, H	
1064	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1065	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1066	CALCIUM LYSINATE	A	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
1067	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1068	CALCIUM OROTATE	A, E, H	
1069	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1070	CALCIUM PANTOTHENATE	A, E, H	
1071	CALCIUM PHOSPHATE	A, E, H	
1072	CALCIUM PYRUVATE	A	
1073	CALCIUM SACCHARATE	E	
1074	CALCIUM SILICATE	E	
1075	CALCIUM SODIUM CASEINATE	A, H	The medicine requires the following warning statement on the medicine label:  - (COWMK) 'Derived from cow's milk'.
1076	CALCIUM SODIUM LACTATE	A, E, H	
1077	CALCIUM STEARATE	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
1078	CALCIUM SUCCINATE	A, E, H	
1079	CALCIUM SULFATE	A, E, H	
1080	CALCIUM SULFATE DIHYDRATE	A, E, H	
1081	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1082	CALCIUM THREONINATE	A	
1083	CALENDULA FLOWER DRY	A, E, H	
1084	CALENDULA FLOWER POWDER	A, H	
1085	CALENDULA OFFICINALIS	A, E, H	
1086	CALLERYA RETICULATA	A, H	
1087	CALLICARPA PEDUNCULATA	A, H	
1088	CALLISTEMON CITRINUS	A, H	
1089	CALLISTEPHUS CHINENSIS	A, H	
1090	CALLITRIS INTRATROPICA	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%.
1091	CALLITRIS RHOMBOIDEA	A, H	

<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>
1092	CALLUNA VULGARIS	A, E, H	
1093	CALOCHORTUS TOLMIEI	A, H	
1094	CALTHA PALUSTRIS	A, H	
1095	CALUMBA ROOT DRY	A, H	
1096	CALUMBA ROOT POWDER	A, H	
1097	CALVATIA GIGANTEA	A, E, H	
1098	CALYCANTHUS FLORIDUS	A, H	
1099	CALYCANTHUS PRAECOX	A, H	
1100	CAMELLIA JAPONICA	A, H	
1101	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only.
1102	CAMELLIA SINENSIS	A, E, H	Caffeine is a mandatory component of Camellia sinensis for oral use.  Medicines for oral or sublingual administration that contain caffeine as a component of a herbal substance and that provide a maximum recommended daily dose of:  a) more than 1 mg but no more than 10 mg of caffeine require the following warning statement on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine require 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> <p>Polyphenols calculated as gallic acid (of <i>Camellia sinensis</i>) is only permitted for use as a component when the plant part is leaf.</p>
1103	CAMPHENE	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution, 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>
1104	CAMPHOLENIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary</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
			excipient formulation in a medicine must be no more than 5%.
1105	CAMPHOR	A, E, H	<p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations, the concentration of camphor must be no more than 2.5%.</p>
1106	CAMPHOR BENZALKONIUM METHOSULFATE	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 preparation must be no more than 6%.</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</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>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>
1107	CAMPHOR OIL BROWN	A, H	<p>camphor, cineole and safrole are mandatory components of camphor oil brown.</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</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>- (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> <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);</li> </ul>

<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>and</p> <ul style="list-style-type: none"> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <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>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> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect);</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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 the 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</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>children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.</p>
1108	CAMPHOR OIL WHITE	A, E, H	<p>Camphor and safrole are mandatory components of camphor oil white.</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</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 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> <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>

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

Table 1 **Part 2**

Volume 2

Column 1	Column 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>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.</p>
1109	CAMPSIS GRANDIFLORA	A, H	
1110	CANADA BALSAM	A, H	
1111	CANANGA ODORATA	A, E, H	
1112	CANANGA OIL	A, E, H	
1113	CANARIUM INDICUM	A, H	<p>The plant part must be seed and the plant preparation is oil.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (DERIVED) 'This product contains material derived from nuts'</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  (or words to that effect).
1114	CANARIUM LUZONICUM	A, H	
1115	CANDELILLA WAX	A, E, H	
1116	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1117	CANDIDA UTILIS	A, H	
1118	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1119	CANOLA OIL	A, E, H	Allyl isothiocyanate is a mandatory component of canola oil when the plant part is seed.  The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1120	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1121	CANTHAXANTHIN	E	Permitted as an excipient ingredient 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
1122	CAPRIC 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 than 1%.</p>
1123	CAPROIC 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 than 1%.</p>
1124	CAPRYLIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution, 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</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
			fragrance concentration in a medicine must be no more 1%.
1125	CAPRYLIC/CAPRIC GLYCERIDES	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%.
1126	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1127	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC TRIGLYCERIDE	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 is not to exceed 3%
1128	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1129	CAPRYLOYL GLYCINE	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 not be more than 2%
1130	CAPRYLOYL SALICYLIC 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 not be more than 0.3%.
1131	CAPRYLYL 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 2%
1132	CAPRYLYL METHICONE	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%.
1133	CAPSELLA BURSA-PASTORIS	A, H	

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

Table 1 **Part 2**

Volume 2

<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>
1134	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1135	CAPSICUM ANNUUM	A, E, H	
1136	CAPSICUM DRY	A, E, H	
1137	CAPSICUM FRUIT OLEORESIN	A, E	
1138	CAPSICUM FRUTESCENS	A, E, H	
1139	CAPSICUM POWDER	A, E, H	
1140	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1141	CARAMEL	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1142	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha.  The concentration of emetine in the medicine must be no more than 0.2%.  Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.

<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>
1143	CARAWAY DRY	A, H	
1144	CARAWAY OIL	A, E, H	
1145	CARAWAY POWDER	A, H	
1146	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1147	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.
1148	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1149	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1150	CARBOMER 940	E	Only for use in topical medicines for dermal application.

<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>
1151	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1152	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1153	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1154	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1155	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1156	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1157	CARBOMER U-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 5%.
1158	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1159	CARBON BLACK	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1160	CARBON DIOXIDE	E	
1161	CARDAMOM FRUIT DRY	A, H	
1162	CARDAMOM FRUIT POWDER	A, E, H	
1163	CARDAMOM OIL	A, E, H	
1164	CARDIOSPERMUM HALICACABUM	A, H	
1165	CARICA PAPAYA	A, E, H	
1166	CARLINA ACAULIS	A, H	
1167	CARMELLOSE	E	
1168	CARMELLOSE CALCIUM	E	
1169	CARMELLOSE SODIUM	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>
1170	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1171	CARMOISINE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1172	CARMOISINE ALUMINIUM LAKE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1173	CARNAUBA WAX	A, E, H	
1174	CARNOSINE	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%.
1175	CAROB BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1176	CAROB GUM	E	
1177	CAROB POD	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
1178	CAROTENES	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1179	CARPINUS BETULUS	A, H	
1180	CARPINUS CORDATA	A, H	
1181	CARRAGEENAN	E	
1182	CARROT	E	
1183	CARROT SEED OIL	A, E, H	
1184	CARTHAMUS TINCTORIUS	A, E, H	<p>Carthamus tinctorius (sunflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only.</p> <p>If for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).</p>
1185	CARUM CARVI	A, H	
1186	CARVACROL	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</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
			no more than 5%.
1187	CARVACRYL 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%.
1188	CARVEOL	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%.
1189	CARVONE	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

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

Table 1 **Part 2**

Volume 2

<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%.
1190	CARVYL 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%.
1191	CARYA ILLINOINENSIS	A, H	
1192	CARYA OVATA	A, H	
1193	CARYOPHYLLENE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1194	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is 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>mandatory component of cascara dry when the route of administration is oral.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' [or words to that effect].</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on</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 medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
1195	CASCARA POWDER	A, H	<p>Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara powder 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 derivatives 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>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</li> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>maximum recommended daily dose 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>
1196	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1197	CASEIN	E	
1198	CASHEW NUT	E	
1199	CASSIA ALATA LEAF EXTRACT	E	<p>Only for use as an excipient ingredient in sunscreens for dermal application and not to be intended for use in the eye.</p> <p>The extraction ratio of the Cassia alata can only be 1:3 in 62.5% glycerine:water.</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 in the medicine must be no more than 0.0275%.
1200	CASSIA CINNAMON BARK DRY	A, H	When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1201	CASSIA CINNAMON BARK POWDER	A, H	When used as an active ingredient, the maximum daily dose of the medicine must contain no more than 0.001% of coumarin.
1202	CASSIA FISTULA	A, H	<p>Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia fistula when the route of administration is oral.</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</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>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> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under</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>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>
1203	CASSIA OIL	A, E, H	<p>The concentration of Cassia oil in the product must be no more than 2% unless the preparation is for dermal use as a rubefacient, in which case the concentration of cassia oil must be no more than 5%.</p>
1204	CASSIE ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total 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>
1205	CASTANEA MOLLISSIMA	A, H	
1206	CASTANEA SATIVA	A, H	
1207	CASTOR OIL	A, E	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
1208	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1209	CASUARINA EQUISITIFOLIA	A, H	
1210	CATALPA BIGNONIOIDES	A, H	
1211	CATALPA OVATA	A, H	
1212	CATECHU	A, H	
1213	CATHARANTHUS ROSEUS	A, H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus.  The concentration of vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1214	CAULIFLOWER	E	
1215	CAULOPHYLLUM THALICTROIDES	A, E, H	
1216	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1217	CEANOTHUS AMERICANUS	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
1218	CEDAR LEAF OIL	A, E, H	
1219	CEDARWOOD 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 than 1%.</p>
1220	CEDARWOOD OIL ATLAS	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>
1221	CEDARWOOD OIL TERPENES	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
1222	CEDARWOOD OIL VIRGINIA	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%.
1223	CEDRENOL	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%.
1224	CEDRENYLACETATE	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%.
1225	CEDROL	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
1226	CEDRUS ATLANTICA	A, E, H	
1227	CEDRUS DEODARA	A, H	
1228	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1229	CEDRYL 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%.
1230	CEDRYL 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%.
1231	CELERY LEAF	E, H	
1232	CELERY SEED DRY	A, E, H	
1233	CELERY SEED OIL	A, E, H	
1234	CELERY SEED POWDER	A, H	
1235	CELLACEFATE	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
1236	CELLULASE	A	<p>Must be derived from <i>Trichoderma longibrachiatum</i> only.</p> <p>If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram.</p> <p>If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.</p>
1237	CELLULOSE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1238	CELOSIA ARGENTEA	A, H	
1239	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1240	CENTAUREA CYANUS	A, E, H	
1241	CENTAURIUM ERYTHRAEA	A, H	
1242	CENTELLA ASIATICA	A, E, H	
1243	CENTELLA ASIATICA MERISTEM CELL CULTURE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended 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
			use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.05%.
1244	CENTIPEDA CUNNINGHAMII	A, E, H	
1245	CENTIPEDA MINIMA	A, H	
1246	CEPHALANOPSIS SEGETUM	A, H	
1247	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1248	CERAMIDE 2	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.05%.
1249	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1250	CERATONIA SILIQUA	A, E, H	
1251	CERATOSTIGMA WILLMOTTIANUM	A, H	
1252	CERESIN	E	Only for use in topical medicines for dermal application.

<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>
1253	CESTRUM LATIFOLIUM	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 plant part must be leaf and must be a water extract.  The concentration must be no more than 0.5%.
1254	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1255	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1256	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1257	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1258	CETEARETH-30	E	Only for use in topical medicines for dermal application.



<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>
1259	CETEARETH-33	E	Only for use as an excipient ingredient 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%.  Residual levels of 1,4-dioxane oxide (and related substances) are to be kept below the level of detection.
1260	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1261	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1262	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1263	CETETH-10	E	Only for use in topical medicines for dermal application.
1264	CETETH-2	E	Only for use in topical medicines for dermal application.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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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>
1265	CETETH-24	E	Only for use in topical medicines for dermal application.
1266	CETETH-5	E	Only for use in topical medicines for dermal application.
1267	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1268	CETOMACROGOL 1000 PHOSPHATE	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%.
1269	CETOMACROGOL 500 PHOSPHATE	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%.
1270	CETOSTEARYL ALCOHOL	E	
1271	CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended 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
	COMPLEX		use in the eye or on damaged skin.  The concentration in the medicine must be no more than 5.0 %
1272	CETRARIA ISLANDICA	A, H	
1273	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1274	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1275	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1276	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1277	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1278	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1279	CETYL DIMETICONE/BIS-VINYLDIMETICONE	E	Only for use in topical medicines for dermal application and not to be

<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>
	CROSSPOLYMER		included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.1%.
1280	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1281	CETYL HYDROXYETHYLCELLULOSE	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%.
1282	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1283	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1284	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1285	CETYL PHOSPHATE	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
1286	CETYL-PG HYDROXYETHYL PALMITAMIDE	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 8%.
1287	CETYLPYRIDINIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1288	CHAENOMELES LAGENARIA	A, H	
1289	CHAENOMELES SPECIOSA	A, H	
1290	CHALK	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
1291	CHAMAECYPARIS LAWSONIANA	A, H	
1292	CHAMAELIRIUM LUTEUM	A, H	
1293	CHAMAEMELUM NOBILE	A, E, H	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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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>
1294	CHAMOMILE FLOWER DRY	A, E, H	
1295	CHAMOMILE OIL ENGLISH	A, E, H	
1296	CHAMOMILE OIL GERMAN	A, E, H	
1297	CHANGIUM SMYRNIOIDES	A, H	
1298	CHEIRANTHUS CHEIRI	A, H	
1299	CHELIDONIUM MAJUS	A, E, H	When for oral or sublingual use, the medicine requires the following warning statement on the medicine label:  - (CELAND) 'WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a healthcare professional'.
1300	CHELONE GLABRA	A, H	
1301	CHENOPODIUM ALBUM	A, H	
1302	CHENOPODIUM VULVARIA	A, H	
1303	CHERRY	E	
1304	CHERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1305	CHESTNUT SWEET	E, H	
1306	CHICKEN COMB EXTRACT	A	
1307	CHILLI	E, H	
1308	CHIMAPHILA UMBELLATA	A, H	<p>Arbutin is a mandatory component of Chimaphila umbellata.</p> <p>When for internal use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001%.</p> <p>When for topical use, the concentration of arbutin in the medicine must not be more than 10 mg/Kg or 10 mg/L or 0.001% unless used on the hair.</p> <p>When for use on hair, the concentration of arbutin in the medicine must not be more than 0.3%.</p>
1309	CHIONANTHUS VIRGINICA	A, H	
1310	CHLORELLA	E	<p>Iodine is a mandatory component of Chlorella.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1311	CHLORELLA PYRENOIDOSA	E	
1312	CHLORELLA VULGARIS	A, E	<p>Iodine is a mandatory component of <i>Chlorella vulgaris</i>.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
1313	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1314	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1315	CHLOROACETAMIDE	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
1316	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application.  The concentration in the medicine must be no more than 0.5%.
1317	CHLOROCRESOL	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 3%.
1318	CHLOROFORM	E	The residual solvent limit must be no more than 0.6 mg per recommended daily dose and the concentration in the medicine must be no more than 0.006%.
1319	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1320	CHLOROPHYLL-COPPER	E	Only for use as a colour in oral and

<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>
	COMPLEXES		topical medicines.
1321	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1322	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1323	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1324	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1325	CHOCOLATE BROWN HT	E	Permitted for use only as a colour for oral and topical use.
1326	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1327	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
1328	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1329	CHOLESTERYL/BEHENYL/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 0.5%.
1330	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1331	CHOLINE BITARTRATE	A, E	
1332	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1333	CHONDRODENDRON TOMENTOSUM	A, H	The concentration of equivalent dry Chondrodendron tomentosum in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1334	CHONDRUS CRISPUS	A, E, H	Iodine is a mandatory component of Chondrus crispus.  Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% 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
			less.  Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1335	CHONDRUS DRY	A, E, H	Iodine is a mandatory component of Chondrus dry.  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.
1336	CHONDRUS EXTRACT	A, E, H	Iodine is a mandatory component of Chondrus extract.  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

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

Table 1 **Part 2**

Volume 2

Column 1	Column 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.
1337	CHROMIC CHLORIDE HEXAHYDRATE	A, H	<p>When used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic chloride hexahydrate.</p> <p>The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate.</p> <p>The maximum recommended daily dose must provide 50 micrograms or less of chromium from organic sources (i.e. chromium picolinate, chromium nicotinate and high chromium yeast).</p>
1338	CHROMIUM NICOTINATE	A	<p>Chromium is a mandatory component of chromium nicotinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.</p> <p>Chromium nicotinate is considered to be an organic form of chromium.</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
1339	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate.  The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.  Chromium picolinate is considered to be an organic form of chromium.
1340	CHRYSANTHEMUM BALSAMITA	A, H	
1341	CHRYSANTHEMUM INDICUM	A, H	
1342	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1343	CHRYSANTHEMUM MARSHALLII	A, H	
1344	CHRYSANTHEMUM SINENSE	A, H	
1345	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1346	CHRYSOSPORIUM PRUINOSUM	A, H	
1347	CIBOTIUM BAROMETZ	A, H	
1348	CICHORIUM INTYBUS	A, E, H	
1349	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			material.
1350	CINCHONA BARK DRY	A, H	<p>Quinidine and quinine are mandatory components of Cinchona bark dry.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1351	CINCHONA BARK POWDER	A, H	<p>Quinidine and quinine are mandatory components of Cinchona bark powder.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1352	CINCHONA OFFICINALIS	A, H	<p>Quinidine and quinine are mandatory components of Cinchona officinalis.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</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
1353	CINCHONA PUBESCENS	A, H	<p>Quinidine and quinine are mandatory components of Cinchona pubescens.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1354	CINEOLE	E	<p>In liquid preparations when the concentration of cineole in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, 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 also</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
			have a child resistant closure.
1355	CINNAMALDEHYDE	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>
1356	CINNAMIC 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>
1357	CINNAMOMUM CAMPHORA	A, E, H	<p>Camphor, cineole and safrole are mandatory components of Cinnamomum camphora.</p> <p>In solid and semi solid preparations, the concentration of camphor must</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>be no more than 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>In essential oil preparations or distillates, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect);</li> <li>- (NTAKEN) 'Not to be taken'; and</li> <li>- Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.</li> </ul> <p>In essential oil preparations or distillates, 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.</p> <p>In essential oil preparations or distillates, 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</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>fitted on the container.</p> <p>In essential oil preparations or distillates, 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.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more 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:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is 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</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>container.</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.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.</p>
1358	CINNAMOMUM CASSIA	A, E	Cassia oil is a mandatory component of Cinnamomum cassia if the plant preparation is an essential oil, distillate, fixed oil 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
			<p>infused oil.</p> <p>The concentration of Cassia oil in the medicine must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1359	CINNAMOMUM VERUM	A, E, H	<p>When used as an active ingredient coumarin is a mandatory component of Cinnamomum verum and the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is essential oil, distillate, fixed oil or infused oil.</p> <p>The concentration of cinnamon bark oil in the medicine must be no more than 2%.</p> <p>Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the plant part is leaf.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 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
			<p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must 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>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but no more than 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the container must be fitted with a restricted flow insert.</p>
1360	CINNAMON BARK OIL	A, E, H	The concentration of cinnamon bark oil in the product must be no

Column 1	Column 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>more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1361	CINNAMON DRY	A, H	<p>Cinnamon bark oil is a mandatory component of cinnamon dry.</p> <p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1362	CINNAMON LEAF OIL	A, E, H	<p>When the concentration of cinnamon leaf oil in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and 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>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1363	CINNAMON POWDER	A, E, H	<p>Cinnamon bark oil is a mandatory component of cinnamon powder.</p> <p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</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
1364	CINNAMYL 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 than 1%.</p>
1365	CINNAMYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1366	CINNAMYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1367	CINNAMYL CINNAMATE	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%.
1368	CINNAMYL FORMATE	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%.
1369	CINNAMYL ISOBUTYRATE	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%.
1370	CINNAMYL ISOVALERATE	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
1371	CINNAMYL PROPIONATE	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>
1372	CINOXATE	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 6%.</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>

Column 1	Column 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>- (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>
1373	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	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>
1374	CIS-3-HEXEN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</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
1375	CIS-3-HEXENAL	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%.
1376	CIS-3-HEXENYL 2-METHYLBUTYRATE	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%.
1377	CIS-3-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%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1378	CIS-3-HEXENYL BENZOATE	E	Permitted for use only in combination with other permitted

Column 1	Column 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>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>
1379	CIS-3-HEXENYL BUTYRATE	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>
1380	CIS-3-HEXENYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1381	CIS-3-HEXENYL HEXANOATE	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</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
			no more than 5%.
1382	CIS-3-HEXENYL 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%.
1383	CIS-3-HEXENYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a 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%.
1384	CIS-3-HEXENYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1385	CIS-3-HEXENYL METHYL CARBONATE	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%.
1386	CIS-3-HEXENYL SALICYLATE	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%.
1387	CIS-3-HEXENYL TIGLATE	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 medicine must be no more than 1%.
1388	CIS-4-HEPTENAL	E	Permitted for use only in combination with other permitted



Column 1	Column 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>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>
1389	CIS-6-NONEN-1-AL	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>
1390	CIS-6-NONENOL	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>
1391	CIS-BETA-OCIMENE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1392	CIS-HEXAHYDROCUMINYL ALCOHOL	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%.
1393	CIS-JASMONE	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%.
1394	CISTANCHE DESERTICOLA	A, H	
1395	CISTANCHE SALSA	A, H	
1396	CISTUS LADANIFERUS	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
1397	CITRAL	E	
1398	CITRAL DIETHYL ACETAL	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%.
1399	CITRAL DIMETHYL ACETAL	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%.
1400	CITRIC ACID	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.  When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:  - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)  - (SUNPRO) 'Wear protective

Column 1	Column 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>clothing, hats and eyewear when exposed to the sun.' (or words to that effect)</p> <p>- (IRRIT) 'If irritation develops, discontinue use.'</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>- (CHILD3) 'Use in children under 12 years is not recommended'</p>
1401	CITRIC ACID DIHYDRATE	A, E	<p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)</p> <p>- (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect)</p> <p>- (IRRIT) 'If irritation develops,</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>discontinue use.'</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>- (CHILD3) 'Use in children under 12 years is not recommended'</p>
1402	CITRIC ACID MONOHYDRATE	A, E	<p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)</p> <p>- (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect)</p> <p>- (IRRIT) 'If irritation develops, discontinue use.'</p> <p>- (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to 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
			large area.'  - (CHILD3) 'Use in children under 12 years is not recommended.'
1403	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	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%.
1404	CITROL	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%.
1405	CITRON	E	
1406	CITRONELLA OIL	A, E, H	Medicines for topical use containing citronella oil require the following warning statement on the medicine label:  - (CITRON) 'Contains citronella oil'.
1407	CITRONELLA TERPENES	E	Permitted for use only 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>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>
1408	CITRONELLAL	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>
1409	CITRONELLIC 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>

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

Table 1 **Part 2**

Volume 2

<b>Column 1</b>	<b>Column 2 Ingredient Name</b>	<b>Column 3 Purpose of the ingredient in the medicine</b>	<b>Column 4 Specific requirements(s) applying to the ingredient in Column 2</b>
1410	CITRONELLOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
1411	CITRONELLYL 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 than 1%.
1412	CITRONELLYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1413	CITRONELLYL FORMATE	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>
1414	CITRONELLYL 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> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1415	CITRONELLYL NITRILE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1416	CITRONELLYL OXYACETALDEHYDE	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%.
1417	CITRONELLYL 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%.
1418	CITRONELLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1419	CITRULLUS COLOCYNTHIS	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
			When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).
1420	CITRULLUS VULGARIS	A, H	
1421	CITRUS AURANTIFOLIA	A, E, H	<p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1422	CITRUS AURANTIUM	A, E, H	<p>Oxedrine is a mandatory component of Citrus aurantium when intended for internal use.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.</p> <p>When the plant preparation is oil 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
			<p>distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1423	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1424	CITRUS CHACHIENSIS	A, H	
1425	CITRUS 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 flavour concentration in a medicine must be no more than 5%.</p>
1426	CITRUS FIBRE	E	
1427	CITRUS LIMETTA	A, H	<p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (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
			<p>words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1428	CITRUS LIMON	A, E, H	<p>Oxedrine is a mandatory component of Citrus limon when intended for internal use.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus limon oil or distillate; or</p> <p>c) for use in soaps or bath 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
			shower gels that are washed off the skin.
1429	CITRUS MAXIMA	A, H	
1430	CITRUS MEDICA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:  a) for internal use; or  b) in preparations containing 0.05% or less of citrus medica oil or distillate; or  c) for use in soaps or bath or shower gels that are washed off the skin.
1431	CITRUS OIL DISTILLED	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%.
1432	CITRUS RETICULATA	A, E, H	Oxedrine is a mandatory component of Citrus reticulata

Column 1	Column 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 intended for internal use.  The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1433	CITRUS SINENSIS	A, E, H	Oxedrine is a mandatory component of Citrus sinensis when intended for internal use.  The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1434	CITRUS SINENSIS PEEL MOLASSES EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1435	CITRUS UNSHIU	A, E, H	Oxedrine is a mandatory component of Citrus unshiu when intended for internal use.  The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1436	CITRUS X PARADISI	A, E, H	

<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>
1437	CITRUS X WILSONII	A, H	
1438	CIVET	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%.
1439	CIVET ABSOLUTE	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%.
1440	CIVET SYNTHETIC	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%.
1441	CIVETONE	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%.



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

Table 1 **Part 2**

Volume 2

<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>
1442	CLARY OIL	A, E, H	
1443	CLEMATIS ARMANDII	A, H	
1444	CLEMATIS CHINENSIS	A, E, H	
1445	CLEMATIS RECTA	A, H	
1446	CLEMATIS VITALBA	A, H	
1447	CLERODENDRUM TRICHOTOMUM	A, H	
1448	CLINOPODION POLYCEPHALUM	A, H	
1449	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1450	CLIVER HERB DRY	A, H	
1451	CLIVER HERB POWDER	A, H	
1452	CLOVE BUD OIL	A, E, H	<p>When the concentration of Clove Bud Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration of Clove Bud Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statement on the medicine</p>

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

Column 1	Column 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>- (CHILD) 'Keep out of reach of children' (or words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul> <p>When the concentration of clove bud oil in the preparation 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 and requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul>
1453	CLOVE DRY	A, E, H	
1454	CLOVE LEAF OIL	A, E, H	<p>When the concentration of Clove Leaf Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration of Clove Leaf Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and 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: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'  When the concentration of clove leaf oil in the preparation 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 and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1455	CLOVE OIL TERPENES	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%.
1456	CLOVE POWDER	A, E, H	
1457	CLOVE STEM OIL	A, E, H	When the concentration of Clove Stem Oil in the preparation is more than 25%, 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
			<p>25 mL.</p> <p>When the concentration of Clove Stem Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul> <p>When the concentration of Clove Stem oil in the preparation 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 and 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul>
1458	CLUPEA HARENGUS LIPID EXTRACT	A	<p>Only for use in oral medicines.</p> <p>The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in</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
			combination with other sources of omega-3 fatty acids.
1459	CNICUS BENEDICTUS	A, H	
1460	CNICUS JAPONICUS	A, H	
1461	CNIDIUM MONNIERI	A, H	
1462	CNIDIUM OFFICINALE	A, H	
1463	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1464	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1465	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1466	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye.  The concentration in the medicine must be no more than 1%.
1467	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and

Column 1	Column 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>not to be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be:</p> <p>a) no more than 1% in leave on medicines</p> <p>b) no more than 15% in wash on /wash off medicines</p> <p>c) 1.2% for buccal mucosa and dental medicines.</p> <p>Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection.</p>
1468	COCCOLOBIA UVIFERA	A, H	
1469	COCCULUS ORBICULATUS	A, H	
1470	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1471	COCHLEARIA OFFICINALIS	A, H	
1472	COCILLANA DRY	A, H	

<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>
1473	COCILLANA POWDER	A, H	
1474	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1475	COCO-CAPRYLATE	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 is to be no more than 12.5% in the medicine.
1476	COCO-GLUCOSIDE	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%
1477	COCO-OCTANOATE/DECANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.
1478	COCOA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.
1479	COCOA POWDER	A, E, H	
1480	COCOLYCIDES	E	
1481	COCONUT	E	
1482	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1483	COCONUT OIL	A, E, H	
1484	COCOS NUCIFERA	A, E, H	
1485	COD-LIVER OIL	A, E	<p>Vitamin A and colecalciferol are mandatory components of Cod-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine 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>statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</li> <li>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</li> </ul> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.</p>
1486	CODONOPSIS LANCEOLATA	A, H	
1487	CODONOPSIS PILOSULA	A, H	
1488	CODONOPSIS TANGSHEN	A, H	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1489	COFFEA ARABICA	A, E, H	<p>Caffeine is a mandatory component of Coffea arabica.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine 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>b) more than 10 mg of caffeine 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>
1490	COFFEA CANEPHORA	A, E, H	<p>Caffeine is a mandatory component of Coffea canephora.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine 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>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine 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>
1491	COFFEE	E, H	<p>Caffeine is a mandatory component of coffee.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine 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>b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state</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
			quantity per dosage unit or per mL or per gram of product]¹.
1492	COFFEE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1493	COFFEE SOLID EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1494	COGNAC OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1495	COGNAC OIL GREEN	A, E, H	
1496	COGNAC OIL WHITE	E	Permitted for use only in combination with other permitted

Column 1	Column 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>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>
1497	COIX LACHRYMA-JOBI	A, H	
1498	COLA ACUMINATA	A, E, H	<p>Caffeine is a mandatory component of Cola acuminata.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1499	COLA NITIDA	A, E, H	<p>Caffeine is a mandatory component of Cola nitida.</p> <p>When the route of administration 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
			<p>oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1500	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.
1501	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1502	COLLAGEN	E	
1503	COLLINSONIA CANADENSIS	A, H	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
1504	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1505	COLOPHONY	A, E, H	
1506	COMMIPHORA HABESSINICA	A, H	
1507	COMMIPHORA KATAF	A, H	
1508	COMMIPHORA MYRRHA	A, E, H	
1509	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1510	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1511	CONCENTRATED SQUID OMEGA-3 TRIGLYCERIDES	A	Only for oral use.  'Concentrated squid omega-3-triglycerides' must be obtained from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the preparation AND be presented in a therapeutic dosage form for therapeutic use.  The medicine requires the following warning statement on the medicine label:  - (SFOOD) 'Derived from seafood'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1512	CONIFER GREEN NEEDLE COMPLEX	A	Only for topical and oral use. Must be made by petroleum ether extraction of needles of the conifer species <i>Pinus sylvestris</i> (Scotch Pine) and <i>Picea abies</i> (Norwegian Spruce).
1513	CONIFER PHYTOSTEROL COMPLEX	A	
1514	CONIOSELIMUM UNIVITTATUM	A, H	
1515	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient.  The concentration must be no more than exceed 12X homoeopathic dilution.
1516	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry <i>Convallaria majalis</i> in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1517	CONYZA CANADENSIS	A, H	
1518	COPAIBA OIL	A, E, H	
1519	COPAIFERA LANGSDORFFII	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
1520	COPERNICIA CERIFERA	A, E, H	
1521	COPOVIDONE	E	
1522	COPPER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>
1523	COPPER (II) ASPARTATE	A, H	<p>Copper is a mandatory component of copper (II) aspartate.</p> <p>The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1524	COPPER (II) GLYCINATE	A, H	Copper is a mandatory component

Column 1	Column 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 copper (II) glycinate.</p> <p>The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1525	COPPER (II) LYSINATE	A, H	<p>Copper is a mandatory component of copper (II) lysinate.</p> <p>The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1526	COPPER ACETYL TYROSINATE METHYLSILANOL	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
1527	COPPER CHLOROPHYLL	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%.
1528	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1529	COPPER GLUCONATE	A, E	Copper is a mandatory component of copper gluconate.  The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate.  When for internal use the maximum daily dose must not contain more than 5 mg of copper.  When for other than internal use, the concentration of copper compounds must be no more than 5%.
1530	COPPER TRIPEPTIDE-1	E	Only for use in topical 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
			for dermal application.  The concentration in the medicine must be no more than 3%.
1531	COPTIS CHINENSIS	A, H	
1532	COPTIS JAPONICA	A, H	
1533	CORALLINA OFFICINALIS	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 is to be no more than 1%.
1534	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1535	CORIANDER DRY	A, H	
1536	CORIANDER OIL	A, E, H	
1537	CORIANDER POWDER	A, H	
1538	CORIANDRUM SATIVUM	A, E, H	
1539	CORN GLYCERIDES	E	
1540	CORN SILK DRY	A, H	
1541	CORN SILK POWDER	A, H	

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

Table 1 **Part 2**

Volume 2

<b>Column 1</b>	<b>Column 2 Ingredient Name</b>	<b>Column 3 Purpose of the ingredient in the medicine</b>	<b>Column 4 Specific requirements(s) applying to the ingredient in Column 2</b>
1542	CORN SYRUP	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%.
1543	CORN SYRUP SOLIDS	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%.
1544	CORNUS FLORIDA	A, H	
1545	CORNUS OFFICINALIS	A, H	
1546	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1547	CORYDALIS AMBIGUA	A, E, H	
1548	CORYDALIS BUNGEANA	A, H	
1549	CORYDALIS CAVA	A, H	
1550	CORYDALIS FABACEA	A, H	
1551	CORYDALIS FORMOSA	A, H	
1552	CORYDALIS TURTSCHANINOVII	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
1553	CORYLUS AMERICANA	A, H	
1554	CORYLUS AVELLANA	A, H	
1555	CORYMBIA CITRIODORA	A, E, H	<p>Cineole is a mandatory component of <i>Corymbia citriodora</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</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
1556	CORYMBIA FICIFOLIA	A, H	<p>Cineole is a mandatory component of <i>Corymbia ficifolia</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>

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

Table 1 **Part 2**

Volume 2

<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>
1557	COSMOS BIPINNATUS	A, H	
1558	COSTUS ROOT OIL	A, H	
1559	COSTUS SPICATUS	A, H	
1560	COTTONSEED OIL	A, E, H	
1561	COUCH GRASS RHIZOME DRY	A, H	
1562	COUCH GRASS RHIZOME POWDER	A, H	
1563	COUMARIN	H	Only for use as an active homoeopathic ingredient.  The concentration in the medicine must be no more than 0.001%.
1564	CRANBERRY	E	
1565	CRATAEGUS CUNEATA	A, E, H	
1566	CRATAEGUS LAEVIGATA	A, E, H	
1567	CRATAEGUS MONOGYNA	A, E, H	
1568	CRATAEGUS PINNATIFIDA	A, E, H	
1569	CRATEVA MAGNA	A, E, H	
1570	CREATINE	A, E	
1571	CREATINE MONOHYDRATE	A, E	
1572	CREATINE PHOSPHATE	A, 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
1573	CREATININE	E	<p>Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1574	CREOSOL	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>
1575	CREOSOTE	H	<p>Only for use as an active homoeopathic ingredient.</p>
1576	CRESOL	E	<p>Only for use as a preservative in topical medicines.</p> <p>The concentration of phenols (including cresols and xylenols and any other homologue of phenol) boiling below 220 degrees centigrade must be no more than 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
1577	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%.
1578	CRITHMUM MARITIMUM WHOLE PLANT 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 0.00341%.
1579	CROCUS SATIVUS	A, H	
1580	CROSCARMELLOSE SODIUM	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
1581	CROSPVIDONE	E	
1582	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1583	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1584	CRYPTOMERIA JAPONICA	A, H	
1585	CUBEB OIL	A, H	
1586	CUBEBENE	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%.
1587	CUCUMBER	E	
1588	CUCUMIS MELO	A, H	
1589	CUCUMIS SATIVUS	A, E, H	
1590	CUCURBITA MAXIMA	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
1591	CUCURBITA MOSCHATA	A, H	
1592	CUCURBITA PEPO	A, E, H	
1593	CULLEN CORYLIFOLIUM	A, H	
1594	CUMIC ALCOHOL	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%.
1595	CUMIN OIL	A, E, H	
1596	CUMINALDEHYDE	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%.
1597	CUMINUM CYMINUM	A, H	
1598	CUMINYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total

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

Table 1 **Part 2**

Volume 2

<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>
			fragrance concentration in a medicine must be no more than 1%.
1599	CUPRESSUS ARIZONICA	A, H	
1600	CUPRESSUS FUNEBRIS	A, E, H	
1601	CUPRESSUS MACROCARPA	A, H	
1602	CUPRESSUS SEMPERVIRENS	A, E, H	
1603	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1604	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1605	CUPRIC CITRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate.  The percentage of copper from cupric citrate should be calculated based on the molecular weight of cupric citrate.  The medicine must not contain more than 750 micrograms of copper from cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dose.
1606	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate.</p> <p>The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate.</p> <p>The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.</p>
1607	CUPRIC OXIDE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric oxide.</p> <p>The percentage of copper from cupric oxide should be calculated based on the molecular weight of cupric oxide.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal 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
			the concentration of copper compounds must be no more than 5%.
1608	CUPRIC SULFATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate.</p> <p>The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>
1609	CUPRIC SULFATE MONOHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate.</p> <p>The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate.</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 for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.</p>
1610	CUPRIC SULFATE PENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of cupric sulfate from cupric sulfate pentahydrate</p>



Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
			should be calculated based on the molecular weight of cupric sulfate pentahydrate.
1611	CURCULIGO ORCHIOIDES	A, H	
1612	CURCUMA AROMATICA	A, H	
1613	CURCUMA LONGA	A, E, H	
1614	CURCUMA XANTHORRHIZA	A, H	
1615	CURCUMA ZEDOARIA	A, H	
1616	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1617	CUSCUTA EPITHYMUM	A, H	
1618	CUSCUTA EUROPAEA	A, H	
1619	CUSCUTA HYGROPHILAE	A, H	
1620	CUSCUTA RACEMOSA	A, H	
1621	CUSPARIA FEBRIFUGA	A, H	
1622	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1623	CYANOCOBALAMIN	A, E, H	
1624	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients.

Column 1	Column 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 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%.
1625	CYATHULA OFFICINALIS	A, H	
1626	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1627	CYCLAMEN PURPURASCENS	A, H	
1628	CYCLOHEXADECENONE-8	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%.
1629	CYCLOHEXANE	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%.

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
1630	CYCLOHEXANE, 1-ETHENYL-1-METHYL-2-(1-METHYLETHENYL)-4-(1-METHYLETHYL)-, DIDEHYDRO DERIV.	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%.
1631	CYCLOHEXANEETHANOL	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%.
1632	CYCLOHEXYL 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%.
1633	CYCLOHEXYL BUTYRATE	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

Column 1	Column 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>no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1634	CYCLOHEXYL PHENETHYL ETHER	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>
1635	CYCLOHEXYL SALICYLATE	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>
1636	CYCLOHEXYLETHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>

Column 1	Column 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 used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1637	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1638	CYCLOPENTADECANONE	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%.
1639	CYDONIA OBLONGA	A, H	
1640	CYMBOPOGON FLEXUOSUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1641	CYMBOPOGON MARTINI	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1642	CYMBOPOGON NARDUS	A, H	The concentration or Aldehydes calculated as citral in the medicine

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

Table 1 **Part 2**

Volume 2

<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>
			must be no more than 5% for topical use.
1643	CYMBOPOGON SCHOENANTHUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1644	CYNANCHUM ATRATUM	A, H	
1645	CYNANCHUM STAUNTONII	A, E, H	
1646	CYNARA SCOLYMUS	A, E, H	
1647	CYNODON DACTYLON	A, E, H	
1648	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1649	CYPERUS LONGUS	A, H	
1650	CYPERUS ROTUNDUS	A, H	
1651	CYPRESS 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%.
1652	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	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
1653	CYSTEINE	A	<p>When the ingredient is included in a medicine for internal use that is listed in the Register:</p> <ul style="list-style-type: none"> <li>- on or after 1 July 2018, the medicine must comply with all requirements under (a) &amp; (b);</li> <li>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</li> <li>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</li> </ul> <p>a) The maximum recommended daily dose must contain no more than 450 mg of cysteine.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1654	CYSTEINE HYDROCHLORIDE	A	<p>When the ingredient is included in a medicine for internal use 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</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>on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</p> <p>a) The maximum recommended daily dose must contain no more than 585 mg of cysteine hydrochloride.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1655	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	<p>When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient and the total flavour proprietary excipient formulation concentration in a medicine must not be more than 5%.</p> <p>In addition, when the ingredient is included in a medicine for internal use 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) &amp; (b);</p> <ul style="list-style-type: none"> <li>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) &amp; (b); or</li> <li>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</li> </ul> <p>a) The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1656	CYSTINE	A	<p>When the ingredient is included in a medicine for internal use 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</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>before 1 January 2020, the medicine may comply with the requirements under (a) &amp; (b).</p> <p>a) The maximum recommended daily dose must contain no more than 450 mg of cystine.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1657	CYTISUS SCOPARIUS	A, H	<p>Sparteine is a mandatory component of Cytisus scoparius.</p> <p>The concentration of Sparteine in the medicine must be no more than 0.001%.</p>
1658	D-ALPHA-TOCOPHEROL	A, E	
1659	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1660	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1661	D-ALPHA-TOCOPHERYL PHOSPHATES	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine</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
			must be no more than 3%.
1662	D-BORNEOL	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%.
1663	D-CARVONE	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%.
1664	D-FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1665	D-LIMONENE	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>
1666	D-PULEGONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>The concentration of d-pulegone in the medicine must not be more than 4%.</p>
1667	D-RIBOSE-L-CYSTEINE	A	<p>Only for use in oral medicines.</p> <p>Cysteine is a mandatory component of D-Ribose-L-Cysteine.</p> <p>The medicine must provide no more than 450 mg of cysteine per maximum recommended daily dose.</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
1668	DACTYLIS GLOMERATA	A, H	
1669	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1670	DAEMONOROPS DRACO	A, E, H	
1671	DAHLIA PINNATA	A, H	
1672	DALBERGIA ODORIFERA	A, H	
1673	DAMIANA LEAF POWDER	A	
1674	DANDELION LEAF DRY	A, H	
1675	DANDELION LEAF POWDER	A, H	
1676	DANDELION ROOT DRY	A, H	
1677	DANDELION ROOT POWDER	A, H	
1678	DAPHNE GENKWA	A, H	
1679	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1 mg of the dry herbal material.
1680	DATE	E	
1681	DATURA STRAMONIUM	A, H	Only for use in oral medicines.  Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium.  The concentration of alkaloids

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1682	DAUCUS CAROTA	A, E, H	
1683	DAVANA 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 than 1%.</p>
1684	DEA-OLETH-3 PHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (EYE) 'Avoid contact with eyes'</li> <li>- (EYE2) 'May be irritant to the</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
			eyes' (or words to that effect).
1685	DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN	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%.
1686	DECAHYDRO-BETA-NAPHTHYLACETATE	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%.
1687	DECAHYDRO-BETA-NAPHTHYLFORMATE	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%.
1688	DECAHYDROSPIRO(FURAN-2(3H),5'-(4,7)METHANO(5H)INDENE)	E	Permitted for use only in combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%.

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

Table 1 **Part 2**

Volume 2

<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>
1689	DECALACTONE	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%.
1690	DECANAL	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%.
1691	DECANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1692	DECARBOXY CARNOISINE DIHYDROCHLORIDE	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 0.05.
1693	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%.
1694	DECYL 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%.
1695	DECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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>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>
1696	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1697	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1698	DECYLENE GLYCOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
1699	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1700	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to 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>following conditions:</p> <p>a) the medicines are for oral use only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p>
1701	DEER VELVET ANTLER SLICE	A	<p>Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions:</p> <p>a) the medicines are for oral 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
			<p>only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p>
1702	DEERTONGUE ABSOLUTE	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>

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

Table 1 **Part 2**

Volume 2

<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>
1703	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1704	DEHYDROMENTHOFUROLACTONE	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%.
1705	DEHYDROXANTHAN GUM	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%.
1706	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1707	DELTA-DAMASCONE	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
1708	DELTA-DECALACTONE	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>
1709	DELTA-DODECALACTONE	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>
1710	DELTA-NONALACTONE	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</p>

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

Table 1 **Part 2**

Volume 2

<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>
			no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1711	DELTA-OCTALACTONE	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%.
1712	DELTA-TETRADECALACTONE	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%.
1713	DELTA-TOCOPHEROL	E	
1714	DELTA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 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>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>
1715	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1716	DENATONIUM BENZOATE	E	
1717	DENDROBIUM NOBILE	A, H	
1718	DESCURAINIA SOPHIA	A, H	
1719	DESMODIUM STYRACIFOLIUM	A, H	
1720	DESMODIUM TRIQUETUM	A, H	
1721	DEVIL'S CLAW TUBER DRY	A, H	
1722	DEVIL'S CLAW TUBER POWDER	A, H	
1723	DEXPANTHENOL	A, E	
1724	DEXTRAN 20	E	<p>Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.3%.</p>



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1725	DEXTRAN 40	A, E	
1726	DEXTRATES	E	
1727	DEXTRIN	E	
1728	DEXTRIN PALMITATE	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 3%.</p>
1729	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A	<p>Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil.</p> <p>Only for use in oral medicines when in combination with other active or excipient ingredients.</p> <p>The ratio of DHA to EPA must be 2:1.</p>
1730	DI-C12-13 ALKYL MALATE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1731	DI-C12-15 ALKYL FUMARATE	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%.
1732	DI-N-PROPYL ISOCINCHOMERONATE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 25%.
1733	DI-PPG-3 MYRISTYL ETHER ADIPATE	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 15%.
1734	DIACETIN	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

Column 1	Column 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%.
1735	DIACETYL	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%.
1736	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	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%.
1737	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1738	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical 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
1739	DIANTHUS SUPERBUS	A, H	
1740	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1741	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1742	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.  The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.
1743	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate.  When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 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
			When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1744	DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE	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 dibasic potassium phosphate trihydrate.</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>
1745	DIBASIC SODIUM PHOSPHATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.</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</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>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>
1746	DIBASIC SODIUM PHOSPHATE DIHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.</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> <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
			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1747	DIBASIC SODIUM PHOSPHATE DODECAHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate.</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> <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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1748	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate.</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> <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>
1749	DIBASIC SODIUM PHOSPHATE MONOHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution</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>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>
1750	DIBENZYL KETONE	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>
1751	DIBUTYL ADIPATE	E	Only for use in topical 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
			for dermal application.
1752	DIBUTYL PHTHALATE	E	Only for use in topical medicines for dermal application.
1753	DIBUTYL SEBACATE	E	
1754	DIBUTYLAMINE	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%.
1755	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 34%.
1756	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1757	DICAPRYLYL MALEATE	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

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

Table 1 **Part 2**

Volume 2

<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>
			must be no more than 10%.
1758	DICETYL PHOSPHATE	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%.
1759	DICHLOROBENZYL ALCOHOL	E	
1760	DICHLOROMETHANE	E	The concentration in the medicine must be no more than 0.06%.  The residual solvent limit for Dichloromethane is 6 mg per recommended daily dose.
1761	DICTAMNUS ALBUS	A, H	
1762	DICTAMNUS DESYCARPUS	A, H	
1763	DICYCLOHEXYL DISULFIDE	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%.
1764	DIEFFENBACHIA SEGUINE	H	Only for use as an active

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

Table 1 **Part 2**

Volume 2

<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>
			homoeopathic ingredient.
1765	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 5%.
1766	DIETHYL CITRACONATE	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%.
1767	DIETHYL MALONATE	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%.
1768	DIETHYL PHTHALATE	E	
1769	DIETHYLAMINE	E	Permitted for use only 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>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>
1770	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</li> <li>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</li> </ul> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if</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>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>
1771	DIETHYLAMINOMETHYLCOUMARIN	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
1772	DIETHYLDIMETHYL-2-CYCLOHEXENONE	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>
1773	DIETHYLENE GLYCOL	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1774	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1775	DIETHYLHEXYL CARBONATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 3%.
1776	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1777	DIETHYLHEXYL SYRINGYLIDENEMALONATE	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%.
1778	DIETHYLHEXYL-2,6- NAPHTHALATE	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%.

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

Table 1 **Part 2**

Volume 2

Column 1	Column 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 statement on the medicine label:</p> <p>- (EYE2) 'May be irritant to the eyes' (or words to that effect).</p>
1779	DIETHYLTOLUAMIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 20%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.'</p>
1780	DIGITALIS LEAF DRY	A, H	<p>The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.</p>
1781	DIGITALIS LEAF POWDER	A, H	<p>The concentration of Digitalis leaf powder in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.</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
1782	DIGITALIS PURPUREA	A, H	The concentration of equivalent dry Digitalis purpurea in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
1783	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1784	DIHEXYL FUMARATE	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%.
1785	DIHYDRO JASMONE	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%.
1786	DIHYDRO TERPINYLACETATE	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%.
1787	DIHYDRO-ALPHA-TERPINEOL	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%.
1788	DIHYDRO-BETA-IONONE	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%.
1789	DIHYDRO-ISOJASMONE	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
1790	DIHYDROACTINIDIOLIDE	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%.
1791	DIHYDROAMBRETTOLIDE	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%.
1792	DIHYDROCARVYL ACETATE	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%.
1793	DIHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total

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

Table 1 **Part 2**

Volume 2

<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>
			fragrance concentration in a medicine must be no more 1%.
1794	DIHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.  The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1795	DIHYDROEUGENOL	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%.
1796	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	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%.
1797	DIHYDROINDENYL-2,4-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Column 1	Column 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 fragrance the total fragrance concentration in a medicine must be no more than 1%.
1798	DIHYDROLINALOOL	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%.
1799	DIHYDROMYRCENOL	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%.
1800	DIHYDROMYRCENYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1801	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1802	DIISOPROPYL ADIPATE	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 15%.
1803	DIISOPROPYL SEBACATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 10%.
1804	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1805	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1806	DILL HERB OIL	A, E, H	
1807	DILL SEED OIL	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
1808	DILL WEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1809	DIMER DISTEARYLTRICARBONATE	E	Only for use in topical medicines for dermal application and not to be used in medicines intended for use in the eye.  The concentration in the medicine must be no more than 4%.
1810	DIMETHICONE 12500	E	
1811	DIMETHICONE 4000	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%.
1812	DIMETHICONE 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 15%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1813	DIMETHICONE 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 10%.
1814	DIMETHICONE/METHICONE 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 4%.
1815	DIMETHICONE/VINYL DIMETHICONE 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 1.5%.
1816	DIMETHYL 3-CYCLOHEXENE-1-CARBOXALDEHYDE	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
1817	DIMETHYL ANTHRANILATE	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>
1818	DIMETHYL BENZYL CARBINOL	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>
1819	DIMETHYL BENZYL CARBINYL 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 than 1%.</p>

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

Table 1 **Part 2**

Volume 2

<b>Column 1</b>	<b>Column 2 Ingredient Name</b>	<b>Column 3 Purpose of the ingredient in the medicine</b>	<b>Column 4 Specific requirements(s) applying to the ingredient in Column 2</b>
1820	DIMETHYL BENZYL CARBINYL 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%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1821	DIMETHYL BENZYL CARBINYL 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%.
1822	DIMETHYL PHENYLETHYL CARBINOL	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%.
1823	DIMETHYL PHTHALATE	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1824	DIMETHYL POLYSILOXANE	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%.
1825	DIMETHYL SUCCINATE	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%.
1826	DIMETHYL SULFATE	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%.
1827	DIMETHYL SULFIDE	E	Permitted for use only in combination with other permitted

Column 1	Column 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>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>
1828	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1829	DIMETHYL SULFOXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1830	DIMETHYLACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1831	DIMETHYLCYCLOHEXYLETHO	E	Permitted for use only in combination with other permitted

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	XY ISOBUTYLPROPANOATE		ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1832	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1833	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1834	DIMETICONE 1.5	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 not be more than 23%.
1835	DIMETICONE 10	E	
1836	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1837	DIMETICONE 1000	E	
1838	DIMETICONE 1510	E	Permitted for use only in combination with other permitted

Column 1	Column 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>ingredients as a printing ink.</p> <p>If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%</p>
1839	DIMETICONE 2	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 9.602%.</p>
1840	DIMETICONE 20	E	<p>Only for use in topical medicines for dermal application.</p>
1841	DIMETICONE 200	E	<p>Only for use in topical medicines for dermal application.</p>
1842	DIMETICONE 30	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 4%.</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>
1843	DIMETICONE 350	E	Only for use in topical and oral medicines.  When used orally, the maximum daily dose must be no more than 7.5mg.
1844	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1845	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1846	DIMETICONE 5	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 10%.
1847	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1848	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1849	DIMETICONE 6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended 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
			use in the eye.  The concentration in the medicine must be no more than 10%.
1850	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1851	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1852	DIMETICONE CROSSPOLYMER-3	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 15%.
1853	DIMETICONE/PEG-10/15 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 1%.
1854	DIMETICONOL	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
1855	DIMETICONOL 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 2%.
1856	DIMOCARPUS LONGAN	A, H	
1857	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1858	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1859	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1860	DIOCTYL TEREPHTHALATE	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

<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%.
1861	DIOLAMINE C8-18 PERFLUOROALKYLETHYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.7%
1862	DIOLAMINE CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye.
1863	DIOSCOREA COLLETTII	A, H	
1864	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1865	DIOSCOREA JAPONICA	A, H	
1866	DIOSCOREA OPPOSITIFOLIA	A, H	
1867	DIOSCOREA POLYSTACHYA	A, H	
1868	DIOSCOREA SEPTEMLOBA	A, H	
1869	DIOSCOREA VILLOSA	A, E, H	
1870	DIOSPYROS KAKI	A, E, H	
1871	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal

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Table 1 **Part 2**

Volume 2

Column 1	Column 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>The concentration in the medicine must be no more than 3%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the 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>
1872	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
1873	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSTEARATE	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1874	DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE	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%.
1875	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1876	DIPHENYL METHANE	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%.
1877	DIPHENYL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

<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>
1878	DIPOTASSIUM GLYCYRRHIZATE	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%.
1879	DIPROPIONYL	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%.
1880	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1881	DIPROPYLENE GLYCOL DIBENZOATE	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 4.2%.
1882	DIPROPYLENE GLYCOL SALICYLATE	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
1883	DIPSACUS ASPER	A, H	
1884	DIPSACUS JAPONICUS	A, H	
1885	DIPTERYX ODORATA	A, E, H	When used as an active ingredient coumarin is a mandatory component of Dipteryx odorata and the concentration of coumarin in the medicine must be no more than 0.001%.
1886	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1887	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1888	DISODIUM COCOAMPHODIPROPIONATE	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%.
1889	DISODIUM DIMETICONE COPOLYOL SULFOSUCCINATE	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 14%.
1890	DISODIUM EDETATE	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).'
1891	DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE	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%.
1892	DISODIUM GUANYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1893	DISODIUM INOSINATE	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%.
1894	DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES	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%.
1895	DISODIUM NADH	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.02%.
1896	DISODIUM OLEAMIDO PEG-2 SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye.  The concentration in the medicine must be no more than 1%.
1897	DISODIUM PHENYL DIBENZIMIDAZOLE	A	Only for use as an active ingredient in sunscreens 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
	TETRASULFONATE		<p>application.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the 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>
1898	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	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 3%.</p>
1899	DISODIUM RUTINYL DISULFATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.05%.</p>

<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>
1900	DISODIUM STEAROYL 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 1%.
1901	DISPERSIBLE CELLULOSE	E	
1902	DISTARCH 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 4%.
1903	DISTEARDIMONIUM HECTORITE	E	Only for use in topical medicines for dermal application and not to be included for medicines intended for use in the eye.  The concentration in the medicine must be no more than 2%.
1904	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.

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Table 1 **Part 2**

Volume 2

<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>
1905	DISTEARYL PHTHALIC ACID AMIDE	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%.
1906	DISTEARYLDIMONIUM CHLORIDE	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%.
1907	DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 1.5%.
1908	DL-ALPHA-TOCOPHEROL	A, E	
1909	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1910	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1911	DL-BORNEOL	E	

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Table 1 **Part 2**

Volume 2

<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>
1912	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1913	DL-THREONINE	A, E	
1914	DOCOSAHEXAENOIC ACID (DHA)-RICH OIL DERIVED FROM MICROALGAE SCHIZOCHYTRIUM SP.	A	Only for use in oral medicines and must be present in combination with other ingredients.
1915	DOCUSATE SODIUM	E	
1916	DODECAHYDRO-3A,6,6,9A-TETRAMETHYLNAPHTHO(2,1-B)FURAN	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%.
1917	DODECANENITRILE	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%.
1918	DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 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>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>
1919	DODECENE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1920	DODECYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1921	DODECYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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

Table 1 **Part 2**

Volume 2

<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>
1922	DOLICHOS LABLAB	A, H	
1923	DOLOMITE	A, E, H	
1924	DRACAENA DRACO	A, H	
1925	DRIED BUTTERMILK	E	
1926	DRIED CALCIUM SULFATE	A, E, H	
1927	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
1928	DRIMIA INDICA	A, H	
1929	DRIMIA MARITIMA	A, H	
1930	DROMETRIZOLE TRISILOXANE	A	<p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in a medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the 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</li> </ul>

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

Table 1 **Part 2**

Volume 2

<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>
			exposed to the sun' (or words to this effect).
1931	DROSERANGLICA	A, H	
1932	DROSERABURMANNI	A, H	
1933	DROSERAINTERMEDIA	A, H	
1934	DROSERARAMENTACIA	A, H	
1935	DROSERAROTUNDIFOLIA	A, E, H	
1936	DROSERAROTUNDIFOLIAMIS	A, H	
1937	DRYNARIAFORTUNEI	A, H	
1938	DRYOBALANOPSAROMATICA	A, H	
1939	DRYOPTERISFILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1940	DULACIAINOIFLORA	A, H	
1941	DUNALIELLASALINA	A, E, H	
1942	DUPICAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
1943	DURVILLAEA ANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.1%.
1944	DWARF PINE-NEEDLE 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%.
1945	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of <i>Dysphania ambrosioides</i> ) are mandatory components of <i>Dysphania ambrosioides</i> .
1946	ECAMSULE	A	Only for use as an active ingredient in sunscreens for dermal application.  The concentration in the medicine



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

Table 1 **Part 2**

Volume 2

<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 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the 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>
1947	ECHINACEA ANGUSTIFOLIA	A, E, H	
1948	ECHINACEA PALLIDA	A, E, H	
1949	ECHINACEA PURPUREA	A, E, H	
1950	ECHINOPA SPINOSISSIMUS	A, H	
1951	ECLIPTA PROSTRATA	A, H	
1952	ECTOIN	E	<p>Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 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
1953	EDETATE SODIUM	E	Only for use in topical medicines for dermal application and nasal medicines.  The concentration in the medicine must be no more than 0.2%.
1954	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1955	EGG LECITHIN	A, E	
1956	EGGSHELL MEMBRANE HYDROLYSATE	A	
1957	EGGSHELL MEMBRANE POWDER	A	
1958	EICHHORNIA CRASSIPES	A, H	
1959	ELAEAGNUS ANGUSTIFOLIA	A, H	
1960	ELAEIS GUINEENSIS	A, E, H	
1961	ELASTIN	E	Only for use in topical medicines for dermal application.
1962	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total 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
			concentration in a medicine must be no more than 5%.
1963	ELDER FLOWER BLACK DRY	A, E, H	
1964	ELDER FLOWER BLACK POWDER	A, H	
1965	ELECAMPANE RHIZOME DRY	A, H	
1966	ELECAMPANE RHIZOME POWDER	A, H	
1967	ELEMI 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%.
1968	ELEMI RESINOID	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%.
1969	ELEMOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total

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

Table 1 **Part 2**

Volume 2

<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>
			fragrance concentration in a medicine must be no more than 1%.
1970	ELEOCHARIS DULCIS	A, H	
1971	ELETTARIA CARDAMOMUM	A, E, H	
1972	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1973	ELEUTHEROCOCCUS ROOT DRY	A, H	
1974	ELEUTHEROCOCCUS ROOT POWDER	A, H	
1975	ELEUTHEROCOCCUS SENTICOSUS	A, H	
1976	ELSHOLTZIA SPLENDENS	A, H	
1977	ELYMUS REPENS	A, E, H	
1978	EMU OIL	A, E	<p>Emu oil ingredients must meet the following two requirements:</p> <p>1) the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and</p> <p>2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw</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
			material was extracted were healthy and fit for human consumption.
1979	EMULSIFYING WAX	E	
1980	ENOXOLONE	E	Only for use in topical medicines for dermal application.
1981	ENZYME MODIFIED CREAM	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%.
1982	EPHEDRA DISTACHYA	A, H	Ephedrine and Pseudoephedrine (of Ephedra distachya) are mandatory components of Ephedra distachya and must be declared in the application.  The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1983	EPHEDRA SINICA	A, H	Ephedrine and Pseudoephedrine (of Ephedra sinica) are mandatory components of Ephedra sinica.  The concentration of ephedrine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1984	EPIGAEA REPENS	A, H	
1985	EPILOBIUM ANGUSTIFOLIUM	E	<p>Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The extract must be processed from the flower, leaf and stem (herb top flowering) of the plant.</p> <p>The extracts used must be: 1:20 in 100% water or 1:2 in 100% water.</p> <p>The concentrations of Epilobium angustifolium must be no more than 0.75% for a 1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.</p>
1986	EPILOBIUM PALUSTRE	A, H	
1987	EPILOBIUM PARVIFLORUM	A, H	
1988	EPIEDIUM BREVICORNU	A, H	
1989	EPIEDIUM GRANDIFLORUM	A, H	
1990	EPIEDIUM SAGITTATUM	A, H	
1991	EPOXY CEDRENE	E	Permitted for use only in combination with other permitted

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

Table 1 **Part 2**

Volume 2

<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>
			ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1992	EQUISETUM ARVENSE	A, E, H	
1993	EQUISETUM HIEMALE	A, H	
1994	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
1995	ERGOTHIONEINE	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%.
1996	ERIGERON BREVISCAPUS	A, H	
1997	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components.  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

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

Table 1 **Part 2**

Volume 2

<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>
			microgram/L or 0.0000001%.
1998	ERIOCAULON BUERGERIANUM	A, H	
1999	ERIODICTYON CRASSIFOLIUM	A, H	
2000	ERIODICTYON GLUTINOSUM	A, H	
2001	ERODIUM CICUTARIUM	A, H	
2002	ERUCA SATIVA	A, H	
2003	ERYTHORBIC ACID	E	
2004	ERYTHRITOL	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%.
2005	ERYTHROSINE	E	Only for use as a colour for oral and topical use.
2006	ERYTHROSINE ALUMINIUM LAKE	E	Only for use as a colour for oral and topical use.
2007	ERYTHRULOSE	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
			<p>The concentration in the medicine must be no more than 2%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (EYE) 'Avoid contact with eyes'.</p>
2008	ESCHSCHOLZIA CALIFORNICA	A, H	
2009	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2010	ETHANOL	A, E	<p>When used as an active ingredient, can only be supplied as an un compounded medicine substance packed for retail sale and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p> <p>When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:</p> <p>- (ETHAN) 'Contains ethanol or contains alcohol'.</p>
2011	ETHANOL ABSOLUTE	A, E	When used as an active ingredient, can only be supplied as an

Column 1	Column 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>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 concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:</p> <p>- (ETHAN) 'Contains ethanol or contains alcohol'</p>
2012	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2013	ETHOHEXADIOL	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>- (EHEXAD) 'Contains ethohexadiol' (or words to that effect).</p>
2014	ETHOXYLATED HYDROGENATED CASTOR OIL	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
2015	ETHOXYLATED NONYLPHENOL	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%.
2016	ETHOXYMETHOXY CYCLODODECANE	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%.
2017	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) 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%.
2018	ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE	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%.
2019	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	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%.
2020	ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-CARBOXYLATE	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%.
2021	ETHYL 2-BUTENOATE	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%.
2022	ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE	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%.
2023	ETHYL 2-HEXYL ACETOACETATE	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%.
2024	ETHYL 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%.
2025	ETHYL 2-METHYLPENTANOATE	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

Column 1	Column 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%.
2026	ETHYL 3-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%.
2027	ETHYL 3-HYDROXYBUTYRATE	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%.
2028	ETHYL 3-HYDROXYHEXANOATE	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%.
2029	ETHYL 3-MERCAPTOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total 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
			concentration in a medicine must be no more than 5%.
2030	ETHYL 3-METHYLTHIOPROPIONATE	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%.
2031	ETHYL 4,7-OCTADIENOATE	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%.
2032	ETHYL ACETATE	E	The residual solvent limit for ethyl acetate is 50 mg per recommended daily dose.  The concentration in the medicine must be no more than 0.5%.
2033	ETHYL ACETOACETATE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			<p>concentration 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>
2034	ETHYL ACRYLATE	E	
2035	ETHYL AMYL KETONE	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>
2036	ETHYL ANTHRANILATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2037	ETHYL BENZOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or 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>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>
2038	ETHYL BENZOYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2039	ETHYL BUTYLACETYLAMINOPROPIONATE	E	<p>Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%.</p> <p>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>
2040	ETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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
			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%.
2041	ETHYL CAPRATE	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%.
2042	ETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a 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
2043	ETHYL CAPRYLATE	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%.
2044	ETHYL CINNAMATE	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%.
2045	ETHYL CROTONATE	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%.
2046	ETHYL ENANTATE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2047	ETHYL FORMATE	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%.
2048	ETHYL 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.
2049	ETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 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>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>
2050	ETHYL 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>
2051	ETHYL LACTATE	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
2052	ETHYL LAURATE	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>
2053	ETHYL LEVULATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2054	ETHYL LEVULINATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2055	ETHYL LINALOOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</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>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>
2056	ETHYL LINALYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2057	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2058	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2059	ETHYL MACADAMIATE	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 10%.</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
2060	ETHYL MALTOL	E	
2061	ETHYL MENTHANE CARBOXAMIDE	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%.
2062	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2063	ETHYL METHYLPHENYLGLYCIDATE	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%.
2064	ETHYL METICONE	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%.



Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2065	ETHYL MYRISTATE	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>
2066	ETHYL OLEATE	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>
2067	ETHYL ORTHO-METHOXYBENZYL ETHER	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>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2068	ETHYL OXYHYDRATE	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>
2069	ETHYL PALMITATE	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>
2070	ETHYL PARA-ANISATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2071	ETHYL PELARGONATE	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>
2072	ETHYL 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 than 1%.</p>
2073	ETHYL PROPIONATE	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</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
			no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2074	ETHYL RICINOLEATE	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%.
2075	ETHYL SALICYLATE	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%.
2076	ETHYL SEBACATE	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 5%.
2077	ETHYL STEARATE	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%.
2078	ETHYL SUCCINATE	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%.
2079	ETHYL TARTRATE	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%.
2080	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total 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
			concentration in a medicine must be no more than 5%.
2081	ETHYL TRANS-3-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%.
2082	ETHYL UNDECYLENATE	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%.
2083	ETHYL VALERATE	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%.
2084	ETHYL VANILLIN	E	
2085	ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>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>
2086	ETHYL-2-METHYL-4-PENTENOATE	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>
2087	ETHYL-2-METHYLPENTENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2088	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.002%.</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
2089	ETHYLCELLULOSE	E	
2090	ETHYLENE BRASSYLATE	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%.
2091	ETHYLENE GLYCOL	E	The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose.  The concentration in the medicine must be no more than 0.062%.
2092	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2093	ETHYLENE/ACRYLIC ACID COPOLYMER	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%.
2094	ETHYLENE/VINYL ACETATE	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
	COPOLYMER		included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 16%.
2095	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2096	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	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%.
2097	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	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 6%.
2098	ETHYLHEXYL BENZOATE	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

Column 1	Column 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 be no more than 3.5%.
2099	ETHYLHEXYL METHOXYCRYLENE	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 10%.</p>
2100	ETHYLHEXYL TRIAZONE	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 5%.</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</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 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>
2101	ETHYLHEXYLGLYCERIN	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>
2102	ETIDRONIC ACID	E	<p>Only for use in topical medicines for dermal application only.</p> <p>The concentration in the medicine must be no more than 1%.</p>
2103	EUCALYPTUS DIVES	A, E, H	<p>Cineole is a mandatory component of Eucalyptus dives.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in</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 preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2104	EUCALYPTUS FRUTICETORUM	A, E, H	<p>Cineole is a mandatory component of Eucalyptus fruticetorum.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of 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>container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2105	EUCALYPTUS GLOBULUS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus globulus.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) 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
			<p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2106	EUCALYPTUS MACRORHYNCHA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus macrorhyncha.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than 25 millilitres;</li> <li>b) a restricted flow insert must be fitted on the container; 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>c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2107	EUCALYPTUS OIL	A, E, H	<p>Cineole is a mandatory component of Eucalyptus oil.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow</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>insert must be fitted on the container. 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul> <p>When the concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert must be fitted on the container. 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul>
2108	EUCALYPTUS RADIATA	A, E, H	<p>Cineole is a mandatory component of <i>Eucalyptus radiata</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than 25 millilitres;</li> <li>b) a restricted flow insert must be</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>fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2109	EUCALYPTUS ROSTRATA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus rostrata.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than 25 millilitres;</li> <li>b) a restricted flow insert must be fitted on the container; and</li> <li>c) the container must include the</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>following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2110	EUCALYPTUS TERETICORNIS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus tereticornis.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> <li>a) the nominal capacity of the container must be no more than 25 millilitres;</li> <li>b) a restricted flow insert must be fitted on the container; and</li> <li>c) the container must include the following warning statements on the medicine label:</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>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate 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 also have a child resistant closure.</p>
2111	EUCOMMIA ULMOIDES	A, H	
2112	EUGENOL	E	<p>When for oral ingestion, eugenol must not comprise more than 0.06% of the formulation.</p> <p>When used in topical medicines for dermal application, the following apply:</p> <p>a) When the concentration of Eugenol in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>b) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child</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>resistant closure and restricted flow insert must be fitted on the container. 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul> <p>c) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15mL, a restricted flow insert must be fitted on the container. 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 words to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul>
2113	EUGENYL 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</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
			fragrance concentration in a medicine must be no more 1%.
2114	EUONYMUS ATROPURPUREUS	A, H	
2115	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2116	EUPATORIUM FORTUNEI	A, H	
2117	EUPATORIUM JAPONICUM	A, H	
2118	EUPATORIUM PERFOLIATUM	A, H	
2119	EUPATORIUM PURPUREUM	A, H	
2120	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.  The medicine requires the following warning statement on the medicine label:  - (SFOOD) 'Derived from seafood'  or  - (SHELL) 'Contains crustacean shellfish'.
2121	EUPHORBIA CYPARISSIAS	A, H	
2122	EUPHORBIA DRY	A, H	

Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine  
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Table 1 **Part 2**

Volume 2

<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>
2123	EUPHORBIA HETERODOXA	A, H	
2124	EUPHORBIA HIRTA	A, H	
2125	EUPHORBIA LATHYRIS	A, H	Levodopa (of Euphorbia lathyris) is a mandatory component of Euphorbia lathyris.  The concentration of Levodopa (of Euphorbia lathyris) in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%.
2126	EUPHORBIA PEKINENSIS	A, H	
2127	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2128	EUPHORBIA POWDER	A, H	
2129	EUPHORBIA RESINIFERA	A, H	
2130	EUPHORBIA SIEBOLDIANA	A, H	
2131	EUPHRASIA OFFICINALIS	A, H	
2132	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2133	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.

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

Table 1 **Part 2**

Volume 2

<b>Column 1</b>	<b>Column 2 Ingredient Name</b>	<b>Column 3 Purpose of the ingredient in the medicine</b>	<b>Column 4 Specific requirements(s) applying to the ingredient in Column 2</b>
2134	EURYALE FEROX	A, H	
2135	EUTERPE OLERACEA	A	The herbal substance must be derived from the fruit only.
2136	EVENING PRIMROSE OIL	A, E, H	
2137	EVERNIA PRUNASTRA EXTRACT	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%.