



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

This instrument is in 6 volumes:

Volume 1:	Sections 1–7	
	Schedule 1	(1,7,7-TRIMETHYLBICYCLO(2.2.1)HEPT-2-YL)- CYCLOHEXANOL)–AZULENE
<b>Volume 2:</b>	<b>Schedule 1</b>	<b>BACKHOUSIA CITRIODORA–EVERNIA</b> <b>PRUNASTRA EXTRACT</b>
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## **Schedule 1—Specified permissible ingredients and requirements applying to these ingredients when contained in a medicine**

Note: See sections 5 and 6.

<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
731	BACKHOUSIA CITRIODORA	A, E, H	The herbal substance must be derived from leaf oil only. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%. The medicine requires the following warning statements on the medicine label: - (IRRIT) 'If irritation develops - discontinue use' - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
732	BACOPA MONNIERI	A, H	
733	BALLOTA NIGRA	A, H	
734	BALM OF GILEAD BUD DRY	A, H	
735	BALM OF GILEAD BUD POWDER	A, H	
736	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

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			medicine must be no more than 1%.
737	BAMBUSA BREVIFLORA	A, E, H	
738	BAMBUSA TEXTILIS	A, H	
739	BANANA	E	
740	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%.
741	BAPTISIA CONFUSA	A, H	
742	BAPTISIA TINCTORIA	A, H	
743	BARBAREA VULGARIS	A, H	
744	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
745	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
746	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
747	BARLEY	E	Gluten is a mandatory component of Barley 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:

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			- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.
748	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 label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
749	BARLEY GERM	E	<p>Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
750	BARLEY LEAF	E	
751	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
752	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.

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753	BASIC RED 1	E	<p>Only for use as a colour 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 0.1%.</p>
754	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>
755	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>

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756	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>
757	BASSIA SCOPARIA	A, H	
758	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
759	BAY LEAF	E	
760	BAY OIL	A, E, H	<p>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.</p> <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</p>

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			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. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
761	BEESWAX 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%.
762	BEET RED	E	Permitted for use only as a colour for oral and topical use.
763	BEETROOT	E, H	
764	BEGONIA FIMBRISTIPULA	A, H	
765	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

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			level of detection.
766	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
767	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
768	BEHENOYL STEARIC ACID	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 2.4%.
769	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
770	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%.



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

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			10%.
			When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
			When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:
			- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and
			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
775	BENINCASA HISPIDA	A, E, H	
776	BENTONITE	E	
777	BENZALDEHYDE	E	
778	BENZALDEHYDE GLYCERYL 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%.

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779	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>
780	BENZETHONIUM CHLORIDE	E	<p>Only for use as a preservative in topical medicines for dermal application.</p>
781	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>
782	BENZOIN	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>
783	BENZOIN SIAM	A, E, H	
784	BENZOIN SUMATRA	A, E, H	
785	BENZOPHENONE	E	<p>Permitted for use only in combination with other</p>

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
786	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 medicine must be no more 1%.
787	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%.
788	BENZYL ALCOHOL	E	
789	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

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			or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.
790	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 no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
791	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%.
792	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%.
793	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

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			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%.
794	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%.
795	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%.
796	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 medicine must be no more 1%.
797	BENZYL LAURATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
798	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%.
799	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 medicine must be no more 1%.
800	BENZYL 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

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			medicine must be no more 1%.
801	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>
802	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 fragrance concentration in a medicine must be no more than 1%.</p>
803	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> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p>



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			<p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
804	BERBERIS AQUIFOLIUM	A, H	
805	BERBERIS ARISTATA	A	<p>Only for use in oral medicines. The medicine requires the following warning statement on the medicine label:</p> <p>- (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).</p>
806	BERBERIS VULGARIS	A, E, H	
807	BERGAMOT 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</p>

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			medicine must be no more 1%. The medicine requires the following warning statement on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
808	BERGAMOT OIL BERGAPTEN-FREE	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%.
809	BERGAMOT OIL COLDPRESSED	A, E, H	When for internal use oxedrine is a mandatory component of bergamot oil coldpressed. The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine. 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 0.4 per cent or less of bergamot oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.

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810	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%.
811	BERTHOLLETIA EXCELSA	A, E, H	
812	BETA RAPA	A, E, H	
813	BETA VULGARIS	A, E, H	
814	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%.
815	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 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%.
816	BETA-CARYOPHYLLENE ALCOHOL	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

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			medicine must be no more than 5%.
817	BETA-DAMASCENONE	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%.
818	BETA-DAMASCONE	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%.
819	BETA-HOMO CYCLOCITRAL	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%.
820	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
821	BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
822	BETA-IONONE EPOXIDE	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>
823	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>
824	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>
825	BETA-N-METHYL IONONE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
826	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>
827	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>
828	BETA-NAPHTHYL ANTHRANILATE	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</p>

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			5%.
829	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 1%.
830	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%.
831	BETA-TOCOPHEROL	E	
832	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

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				for men.’
833	BETADEX	E		
834	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%.
835	BETAINE	E		Only for use in topical medicines for dermal application.
836	BETAINE HYDROCHLORIDE	E		
837	BETULA LENTA	A, H		Methyl salicylate is a mandatory component of <i>Betula lenta</i> . Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:



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- the delivery device is engaged into the container in such a way that prevents it from being readily removed;

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application, 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:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

- (IRRIT) 'If irritation develops, discontinue use.'; and

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).

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838	BETULA NIGRA	A, H	<p>Cresol, eugenol and methyl salicylate are mandatory components of <i>Betula nigra</i>.</p> <p>For external use only when the total concentration of cresols, xyenols 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> <ul style="list-style-type: none"><li>a) the nominal capacity of the container must be no more than 25 mL;</li><li>b) the medicine must be fitted with a restricted flow insert;</li><li>c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and</li><li>d) the medicine requires the following warning statements on the medicine label:<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></li></ul> <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</p>
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than spray, the medicine requires child resistant packaging.

When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
- direct suction through the delivery device results in delivery of no more than one dosage unit; and
- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application, 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:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
  - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
  - (SENS) 'Application to skin
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			may increase sensitivity to sunlight.' (or words to that effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
839	BETULA PENDULA	A, E, H	Methyl salicylate is a mandatory component of Betula pendula.  Not to be included in medicines for use in the eye or on damaged skin.  When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.  When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.  When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish.

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In addition, when the ingredient is included in a medicine that is listed in the Register:

- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);

- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or

- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).

a) The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

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:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);

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			- (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
840	BETULA PUBESCENS	A, E, H	
841	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	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	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%.
843	BIFIDOBACTERIUM ADOLESCENTIS	A	
844	BIFIDOBACTERIUM ANIMALIS	A	
845	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
846	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
847	BIFIDOBACTERIUM BIFIDUM	A	
848	BIFIDOBACTERIUM BREVE	A	
849	BIFIDOBACTERIUM INFANTIS	A	
850	BIFIDOBACTERIUM LACTIS	A	
851	BIFIDOBACTERIUM LONGUM	A	
852	BILBERRY	E	

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853	BIOSACCHARIDE GUM-1	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.</p> <p>The concentration in the medicine must be no more than 5%.</p>
854	BIOTA ORIENTALIS	A, H	
855	BIOTIN	A, E	
856	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 device results in delivery of no more than one dosage unit; and</li> </ul>

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- actuation of the spray device is ergonomically difficult for young children to accomplish.

In addition, when the ingredient is included in a medicine that is listed in the Register:

- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);

- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or

- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).

a) The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

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:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to

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			<p>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>
857	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, xlenols and other phenol homologues in the medicine is greater than 3%.</p>
858	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 must be no more than 1.5%.</p>
859	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	<p>Only for use in topical medicines for dermal application.</p>
860	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE	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>

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861	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%.
862	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%.
863	BIS-STEARYL ETHYLENEDIAMINE/NEOPENTY L GLYCOL/STEARYL HYDROGENATED 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.  The concentration in the medicine must be no more than 7%.
864	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 1%.
865	BISABOLOL	E	If used as an excipient, the medicine is only for use in

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			topical medicines for dermal application.
866	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 medicine must be declared.
867	BIXA ORELLANA	A, E, H	
868	BLACK BONED CHICKEN POWDER	A	
869	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.'
870	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

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			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.'
871	BLACK CURRANT	E	
872	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%.
873	BLACK CURRANT FRESH	A, E, H	
874	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%.
875	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
876	BLACK PEPPER OIL	A, E, H	
877	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

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			medicine must be no more than 5%.
878	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
879	BLACKBERRY	E	
880	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%.
881	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%.
882	BLACKCURRANT 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%.
883	BLACKCURRANT JUICE	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

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			medicine must be no more than 5%.
884	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> <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>
885	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</p>

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			dose.
886	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 recommended daily dose.</p>
887	BLAINVILLEA ACMELLA	A, E, H	<p>When used as an excipient, 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>
888	BLETILLA STRIATA	A, H	
889	BLUE FLAG RHIZOME DRY	A, H	
890	BLUE FLAG RHIZOME POWDER	A, H	
891	BLUEBERRY	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>
892	BLUEBERRY JUICE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or 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>
893	BLUMEA LACERA	A, H	
894	BOEHMERIA NIVEA	A, H	
895	BOERHAVIA DIFFUSA	A, H	
896	BOERHAVIA REPENS	A, H	
897	BOGBEAN LEAF DRY	A, H	
898	BOGBEAN LEAF POWDER	A, H	
899	BOIS DE ROSE OIL	A, E, H	
900	BOMBAX CEIBA	A, H	
901	BORAGO OFFICINALIS	A, E, H	<p>Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of <i>Borago officinalis</i>.</p>
902	BORAX	A, E, H	<p>Boron is a mandatory component of Borax.</p> <p>The percentage of Boron from Borax should be calculated based on the molecular weight of Borax.</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</p>



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			0.35%.
903	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>
904	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 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>

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905	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>
906	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>
907	BORON NITRIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
908	BORONIA 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>

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909	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%.
910	BOSWELLIA CARTERII	A, E, H	
911	BOSWELLIA SERRATA	A, E, H	
912	BOSWELLIA THURIFERA	A, H	
913	BOVINE CALCIUM CHONDROITIN SULFATE	A	
914	BOVINE CHONDROITIN SULFATE	A	
915	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.'
916	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label:  - (COWMK) 'Derived from cow's milk.'
917	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
918	BOVINE SODIUM CHONDROITIN SULFATE	A	

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919	BOVINE WHEY IG-RICH FRACTION	A	<p>Only for use in oral medicines. 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>
920	BRANDY	E	
921	BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p>
922	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>
923	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</p>

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10 mg/L or 0.001%.			
924	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>
925	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>
926	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>
927	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</p>

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			isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
928	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>
929	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 10 mg/kg or 10 mg/L or 0.001%.</p>
930	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>
931	BRASSICA PEKINENSIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica pekinensis when the

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			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%.
932	BRASSICA RAPA	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica rapa 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%.
933	BRAZIL NUT	E	
934	BRILLIANT BLACK BN	E	Permitted for use only as a colour for oral and topical use.
935	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
936	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
937	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
938	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour for oral and topical use.
939	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.

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940	BRIZA MEDIA	A, H	
941	BROCCOLI	E	
942	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>
943	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>
944	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>
945	BROMUS CATHARTICUS	A, H	
946	BROMUS INERMIS	A, H	
947	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
948	BRONOPOL	E	<p>Only for use in topical medicines for dermal application.</p>



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949	BROUSSONETIA PAPYRIFERA	A, H	
950	BROWN FK	E	Permitted for use only as a colour for topical use.
951	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
952	BRUSSEL SPROUT	E	
953	BRYONIA ALBA	A, H	
954	BRYONIA DIOICA	A, H	
955	BUCHU LEAF DRY	A, H	
956	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 medicine must be no more 1%.
957	BUCHU LEAF POWDER	A, E, H	
958	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
959	BUDDLEJA OFFICINALIS	A, H	
960	BULNESIA SARMIENTI	A, E, H	
961	BUNIAS ORIENTALIS	A, H	
962	BUPLEURUM FALCATUM	A, H	
963	BURDOCK LEAF DRY	A, H	

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964	BURDOCK LEAF POWDER	A, H	
965	BURDOCK ROOT DRY	A, H	
966	BURDOCK ROOT POWDER	A, H	
967	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
968	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%.
969	BUTANE	E	Only for use as an excipient propellant ingredient.
970	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%.
971	BUTTER	E	
972	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%.
973	BUTTER ESTERS	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
974	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%.
975	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%.
976	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%.
977	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

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			fragrance concentration in a medicine must be no more 1%.
978	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>
979	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>
980	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 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>
981	BUTYL FORMATE	E	Permitted for use only in combination with other

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			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 HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. 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.
983	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%.
984	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%.

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985	BUTYL LACTATE	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>
986	BUTYL 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>
987	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</p>

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			<p>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>
988	BUTYL PROPIONATE	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>
989	BUTYL STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
990	BUTYL UNDECYLENATE	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>
991	BUTYLATED HYDROXYANISOLE	E	

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992	BUTYLATED HYDROXYTOLUENE	E	
993	BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE	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%.
994	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%.
995	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%.
996	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 medicine must be no more 1%.



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997	BUTYRALDEHYDE	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>
998	BUTYRIC 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>
999	C1-8 ALKYL TETRAHYDROXYCYCLOHEXAN OATE	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 0.012%.</p>
1000	C10-12 ALKANE/CYCLOALKANE	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>
1001	C10-30 CHOLESTEROL/LANOSTEROL	E	<p>Only for use in topical medicines for dermal</p>

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1002	C11-13 ALKANE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p>
1003	C11-14-ISO-ALCOHOL C-13 RICH	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>
1004	C12-13 PARETH-23	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>
1005	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</p>

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			and ethylene oxide (and related substances) are to be kept below the level of detection.
1006	C12-15 ALKYL LACTATE	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 1.2%.
1007	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1008	C12-20 ACID PEG-8 ESTER	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%.
1009	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%.
1010	C12-22 ALKYL ACRYLATE/HYDROXYETHYL ACRYLATE 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.

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			The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.
1011	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1012	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%.
1013	C15-19 ALKANE	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%.
1014	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1015	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1016	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

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			medicine must be no more than 5%.
1017	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1018	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%.
1019	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%.
1020	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%.
1021	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

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1%.			
1022	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1023	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1024	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%
1025	CABBAGE	E	
1026	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%.
1027	CADE OIL	A, E, H	
1028	CAESALPINIA SAPPAN	A, H	
1029	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

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	<p>prescribed in Schedule 14 to the Regulations (other than caffeine); and contains no more than 100 mg of caffeine per 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>
<p>1030 CAJUPUT OIL A, E, H</p>	<p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, the 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</p>

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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.

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.

When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or word to that effect)
- (NTAKEN) 'Not to be taken'.

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.

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 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:

- (CHILD) 'Keep out of reach of children' (or word to that effect)
- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is

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

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1036	CALCIUM ASCORBATE	A, E, H	
1037	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1038	CALCIUM ASPARTATE	A	
1039	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1040	CALCIUM BEHENATE	E	Behenic acid is a mandatory component of Calcium behenate.  When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 mg of Behenic acid.
1041	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1042	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1043	CALCIUM CARBONATE	A, E, H	
1044	CALCIUM CASEINATE	E	
1045	CALCIUM CHLORIDE DIHYDRATE	E	
1046	CALCIUM CITRATE	A, E, H	
1047	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1048	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1049	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

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			than 10mg/kg or 10mg/L or 0.1%.
1050	CALCIUM FOLINATE	A	<p>Folinic acid is a mandatory component of calcium folinate. 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: - (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>
1051	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1052	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1053	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1054	CALCIUM GLYCINATE DIHYDRATE	A	

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1055	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1056	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1057	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1058	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1059	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.
1060	CALCIUM HYDROXYCITRATE	A, H	
1061	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1062	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1063	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%
1064	CALCIUM L-THREONATE	A	Only for use in oral medicines.

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1065	CALCIUM LACTATE	A, E, H	
1066	CALCIUM LACTATE GLUCONATE	A, E, H	
1067	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1068	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1069	CALCIUM LYSINATE	A	Only for use in oral medicines.
1070	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1071	CALCIUM OROTATE	A, E, H	
1072	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1073	CALCIUM PANTOTHENATE	A, E, H	
1074	CALCIUM PHOSPHATE	A, E, H	
1075	CALCIUM PYRUVATE	A	
1076	CALCIUM SACCHARATE	E	
1077	CALCIUM SILICATE	E	
1078	CALCIUM SODIUM CASEINATE	A, H	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk'.
1079	CALCIUM SODIUM LACTATE	A, E, H	
1080	CALCIUM STEARATE	E	
1081	CALCIUM SUCCINATE	A, E, H	
1082	CALCIUM SULFATE	A, E, H	

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1083	CALCIUM SULFATE DIHYDRATE	A, E, H	
1084	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1085	CALCIUM THREONINATE	A	
1086	CALENDULA FLOWER DRY	A, E, H	
1087	CALENDULA FLOWER POWDER	A, H	
1088	CALENDULA OFFICINALIS	A, E, H	
1089	CALLERYA RETICULATA	A, H	
1090	CALLICARPA PEDUNCULATA	A, H	
1091	CALLISTEMON CITRINUS	A, H	
1092	CALLISTEPHUS CHINENSIS	A, H	
1093	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%.
1094	CALLITRIS RHOMBOIDEA	A, H	
1095	CALLUNA VULGARIS	A, E, H	
1096	CALOCHORTUS TOLMIEI	A, H	
1097	CALTHA PALUSTRIS	A, H	
1098	CALUMBA ROOT DRY	A, H	
1099	CALUMBA ROOT POWDER	A, H	
1100	CALVATIA GIGANTEA	A, E, H	
1101	CALYCANTHUS FLORIDUS	A, H	
1102	CALYCANTHUS PRAECOX	A, H	
1103	CAMELLIA JAPONICA	A, H	
1104	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is

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			restricted to topical or sunscreen preparations for dermal application only.
1105	CAMELLIA SINENSIS	A, E, H	<p>Caffeine is a mandatory component of Camellia sinensis for oral use.</p> <p>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:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine require 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 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 Camellia sinensis) is only permitted for use as a component when the plant part is leaf.</p>
1106	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</p>

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			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%.
1107	CAMPHOLENIC ALDEHYDE	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%.
1108	CAMPHOR	A, E, H	In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the concentration of camphor must be no more than 2.5%.
1109	CAMPHOR BENZALKONIUM METHOSULFATE	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 preparation must be no more than 6%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and



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			<p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
1110	CAMPHOR OIL BROWN	A, H	<p>camphor, cineole and saftrole 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 label:</p> <p>- (CHILD) 'Keep out of reach</p>

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of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

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:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is 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:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

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.

When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the

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	<p>container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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 children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <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>		
1111	CAMPHOR OIL WHITE	A, E, H	Camphor and safrole are mandatory components of

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camphor oil white.

In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.

In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is 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:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15

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			<p>millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>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>
1112	CAMPSIS GRANDIFLORA	A, H	
1113	CANADA BALSAM	A, H	
1114	CANANGA ODORATA	A, E, H	
1115	CANANGA OIL	A, E, H	
1116	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> <ul style="list-style-type: none"> <li>- (DERIVED) 'This product contains material derived from nuts' (or words to that effect).</li> </ul>
1117	CANARIUM LUZONICUM	A, H	
1118	CANDELILLA WAX	A, E, H	

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1119	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1120	CANDIDA UTILIS	A, H	
1121	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1122	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%.
1123	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1124	CANTHAXANTHIN	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1125	CAPRIC 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%.
1126	CAPROIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<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>
1127	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 fragrance concentration in a medicine must be no more 1%.</p>
1128	CAPRYLIC/CAPRIC GLYCERIDES	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>
1129	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1130	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC TRIGLYCERIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the</p>

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			medicine is not to exceed 3%
1131	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1132	CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER	E	<p>Only to be used in a medicine where A S Harrison &amp; Co Pty Ltd (Client ID 50284), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020.</p> <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p>
1133	CAPRYLOYL GLYCINE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 2%</p>
1134	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



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			damaged skin. The concentration in the medicine must not be more than 0.3%.
1135	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%
1136	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%.
1137	CAPSELLA BURSA-PASTORIS	A, H	
1138	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1139	CAPSICUM ANNUUM	A, E, H	
1140	CAPSICUM DRY	A, E, H	
1141	CAPSICUM FRUIT OLEORESIN	A, E	
1142	CAPSICUM FRUTESCENS	A, E, H	
1143	CAPSICUM POWDER	A, E, H	
1144	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1145	CARAMEL	E	Permitted as an excipient

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			ingredient as a colour for oral and topical use.
1146	CARAPICHEA IPECACUANHA	A, H	<p>Emetine is a mandatory component of Carapichea ipecacuanha.</p> <p>The concentration of emetine in the medicine must be no more than 0.2%.</p> <p>Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.</p>
1147	CARAWAY DRY	A, H	
1148	CARAWAY OIL	A, E, H	
1149	CARAWAY POWDER	A, H	
1150	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1151	CARBOMER 2001	E	<p>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.</p> <p>The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.</p>
1152	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1153	CARBOMER 934P	E	Only for use in topical medicines for dermal application.

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1154	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1155	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1156	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1157	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1158	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1159	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1160	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1161	CARBOMER U-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1162	CARBON	E, H	Only for use as an active

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			homoeopathic or excipient ingredient.
1163	CARBON BLACK	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1164	CARBON DIOXIDE	E	
1165	CARDAMOM FRUIT DRY	A, H	
1166	CARDAMOM FRUIT POWDER	A, E, H	
1167	CARDAMOM OIL	A, E, H	
1168	CARDIOSPERMUM HALICACABUM	A, H	
1169	CARICA PAPAYA	A, E, H	
1170	CARLINA ACAULIS	A, H	
1171	CARMELLOSE	E	
1172	CARMELLOSE CALCIUM	E	
1173	CARMELLOSE SODIUM	E	
1174	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1175	CARMOISINE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1176	CARMOISINE ALUMINIUM LAKE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1177	CARNAUBA WAX	A, E, H	
1178	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

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			0.2%.
1179	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%.
1180	CAROB GUM	E	
1181	CAROB POD	E	
1182	CAROTENES	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1183	CARPINUS BETULUS	A, H	
1184	CARPINUS CORDATA	A, H	
1185	CARRAGEENAN	E	
1186	CARROT	E	
1187	CARROT SEED OIL	A, E, H	
1188	CARTHAMUS TINCTORIUS	A, E, H	Carthamus tinctorius (sunflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only. If for oral use, the medicine requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).
1189	CARUM CARVI	A, H	

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1190	CARVACROL	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%.
1191	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%.
1192	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%.
1193	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 1%.

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1194	CARVYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1195	CARYA ILLINOINENSIS	A, H	
1196	CARYA OVATA	A, H	
1197	CARYOPHYLLENE OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1198	CASCARA DRY	A, H	<p>Hydroxyanthracene derivatives calculated as cascarioside A is a 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> <p>- (CHILD3) 'Use in children under 12 years is not</p>

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recommended’;

- (LAX2) ‘Prolonged use may cause serious bowel problems’;  
and

- (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product’ [or words to that effect].

When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

- (LAX1) ‘Drink plenty of water’ [or words to that effect].

When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

- (LAX5) ‘This product contains [name of the herb(s) or the chemical component(s)]’; and

- (LAX4) ‘This product may have laxative effect’.

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:

- (CHILD3) ‘Use in children under 12 years is not recommended’;

- (LAX1) ‘Drink plenty of

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			<p>water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
1199	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 medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'; and</p> <p>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' (or words to that effect).</p> <p>When not promoted or marketed as laxative, the</p>

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			<p>medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) ‘This product contains [name of the herb(s) or the chemical component(s)]’; and</li> <li>- (LAX4) ‘This product may have laxative effect’.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) ‘Use in children under 12 years is not recommended’;</li> <li>- (LAX1) ‘Drink plenty of water’ (or words to that effect); and</li> <li>- (LAX2) ‘Prolonged use may cause serious bowel problems’.</li> </ul>
1200	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1201	CASEIN	E	
1202	CASHEW NUT	E	
1203	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>

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			The concentration in the medicine must be no more than 0.0275%.
1204	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%.
1205	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.
1206	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 abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that</li> </ul>

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			<p>effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX1) 'Drink plenty of water' (or words to that effect).</li> </ul> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</li> <li>- (LAX4) 'This product may have laxative effect'.</li> </ul> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD3) 'Use in children under 12 years is not recommended';</li> <li>- (LAX1) 'Drink plenty of water' (or words to that effect); and</li> <li>- (LAX2) 'Prolonged use may cause serious bowel problems'.</li> </ul>
1207	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</p>

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			be no more than 5%.
1208	CASSIE 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%.
1209	CASTANEA MOLLISSIMA	A, H	
1210	CASTANEA SATIVA	A, H	
1211	CASTOR OIL	A, E	
1212	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1213	CASUARINA EQUISITIFOLIA	A, H	
1214	CATALPA BIGNONIOIDES	A, H	
1215	CATALPA OVATA	A, H	
1216	CATECHU	A, H	
1217	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%.

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1218	CAULIFLOWER	E	
1219	CAULOPHYLLUM THALICTROIDES	A, E, H	
1220	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1221	CEANOTHUS AMERICANUS	A, H	
1222	CEDAR LEAF OIL	A, E, H	
1223	CEDARWOOD 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%.
1224	CEDARWOOD OIL ATLAS	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	CEDARWOOD OIL TERPENES	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%.
1226	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%.
1227	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%.
1228	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%.
1229	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%.
1230	CEDRUS ATLANTICA	A, E, H	
1231	CEDRUS DEODARA	A, H	

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1232	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1233	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%.
1234	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%.
1235	CELERY LEAF	E, H	
1236	CELERY SEED DRY	A, E, H	
1237	CELERY SEED OIL	A, E, H	
1238	CELERY SEED POWDER	A, H	
1239	CELLACEFATE	E	
1240	CELLULASE	A	Must be derived from <i>Trichoderma longibrachiatum</i> only. If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram. If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.



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1241	CELLULOSE	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%.
1242	CELOSIA ARGENTEA	A, H	
1243	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1244	CENTAUREA CYANUS	A, E, H	
1245	CENTAURIUM ERYTHRAEA	A, H	
1246	CENTELLA ASIATICA	A, E, H	
1247	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 use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.05%.
1248	CENTIPEDA CUNNINGHAMII	A, E, H	
1249	CENTIPEDA MINIMA	A, H	
1250	CEPHALANOPSIS SEGETUM	A, H	
1251	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1252	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

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			medicine must be no more than 0.05%.
1253	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1254	CERATONIA SILIQUA	A, E, H	
1255	CERATOSTIGMA WILLMOTTIANUM	A, H	
1256	CERESIN	E	Only for use in topical medicines for dermal application.
1257	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%.
1258	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1259	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1260	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1261	CETEARETH-25	E	Only for use in topical medicines for dermal

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			application.
1262	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1263	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.
1264	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1265	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1266	CETEARYL NONANOATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must not be more than 5%.
1267	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.

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1268	CETETH-10	E	Only for use in topical medicines for dermal application.
1269	CETETH-2	E	Only for use in topical medicines for dermal application.
1270	CETETH-24	E	Only for use in topical medicines for dermal application.
1271	CETETH-5	E	Only for use in topical medicines for dermal application.
1272	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1273	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%.
1274	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%.

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1275	CETOSTEARYL ALCOHOL	E	
1276	CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE COMPLEX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 5.0 %
1277	CETRARIA ISLANDICA	A, H	
1278	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1279	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1280	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1281	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1282	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1283	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1284	CETYL DIMETICONE/BIS- VINYLDIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be

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			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%.
1285	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1286	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%.
1287	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1288	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1289	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1290	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1291	CETYL-PG HYDROXYETHYL PALMITAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 8%.
1292	CETYLPIRIDINIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1293	CHAENOMELES LAGENARIA	A, H	
1294	CHAENOMELES SPECIOSA	A, H	
1295	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.
1296	CHAMAECYPARIS LAWSONIANA	A, H	
1297	CHAMAELIRIUM LUTEUM	A, H	
1298	CHAMAEMELUM NOBILE	A, E, H	
1299	CHAMOMILE FLOWER DRY	A, E, H	
1300	CHAMOMILE OIL ENGLISH	A, E, H	
1301	CHAMOMILE OIL GERMAN	A, E, H	
1302	CHANGIUM SMYRNOIDES	A, H	
1303	CHEIRANTHUS CHEIRI	A, H	
1304	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

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			only under the supervision of a healthcare professional'.
1305	CHELONE GLABRA	A, H	
1306	CHENOPODIUM ALBUM	A, H	
1307	CHENOPODIUM VULVARIA	A, H	
1308	CHERRY	E	
1309	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%.
1310	CHESTNUT SWEET	E, H	
1311	CHICKEN COMB EXTRACT	A	
1312	CHILLI	E, H	
1313	CHIMAPHILA UMBELLATA	A, H	Arbutin is a mandatory component of Chimaphila umbellata. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
1314	CHIONANTHUS VIRGINICA	A, H	
1315	CHLORELLA	E	Iodine is a mandatory component of Chlorella. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is



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			2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1316	CHLORELLA PYRENOIDOSA	E	
1317	CHLORELLA VULGARIS	A, E	Iodine is a mandatory component of <i>Chlorella vulgaris</i> . 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.
1318	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1319	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1320	CHLOROACETAMIDE	E	Only for use in topical medicines for dermal application.
1321	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than

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			0.5%.
1322	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1323	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%.
1324	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1325	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1326	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1327	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1328	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1329	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.

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1330	CHOCOLATE BROWN HT	E	Permitted for use only as a colour for oral and topical use.
1331	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1332	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1333	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1334	CHOLESTERYL/BEHENYL/OCTYL DODECYL 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%.
1335	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1336	CHOLINE BITARTRATE	A, E	
1337	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1338	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

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0.001%.			
1339	CHONDRUS CRISPUS	A, E, H	<p>Iodine is a mandatory component of Chondrus crispus.</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>
1340	CHONDRUS DRY	A, E, H	<p>Iodine is a mandatory component of Chondrus 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>
1341	CHONDRUS EXTRACT	A, E, H	<p>Iodine is a mandatory component of Chondrus extract.</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</p>

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			dose.
1342	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>
1343	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>
1344	CHROMIUM PICOLINATE	A	<p>Chromium is a mandatory component of Chromium picolinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of</p>

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			chromium from organic sources. Chromium picolinate is considered to be an organic form of chromium.
1345	CHRYSANTHEMUM BALSAMITA	A, H	
1346	CHRYSANTHEMUM INDICUM	A, H	
1347	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1348	CHRYSANTHEMUM MARSHALLII	A, H	
1349	CHRYSANTHEMUM SINENSE	A, H	
1350	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1351	CHRYSOSPORIUM PRUINOSUM	A, H	
1352	CIBOTIUM BAROMETZ	A, H	
1353	CICHORIUM INTYBUS	A, E, H	
1354	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1355	CINCHONA BARK DRY	A, H	Quinidine and quinine are mandatory components of Cinchona bark dry. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1356	CINCHONA BARK POWDER	A, H	Quinidine and quinine are mandatory components of Cinchona bark powder. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of

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			quinidine per g or mL.
1357	CINCHONA OFFICINALIS	A, H	<p>Quinidine and quinine are mandatory components of <i>Cinchona officinalis</i>.</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>
1358	CINCHONA PUBESCENS	A, H	<p>Quinidine and quinine are mandatory components of <i>Cinchona pubescens</i>.</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>
1359	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> <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 in the preparation is more than 25% and the nominal capacity of the container is more than</p>

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			15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1360	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>
1361	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>
1362	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 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</p>

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more than 25 millilitres and the following warning statements must be included on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);
- (NTAKEN) 'Not to be taken'; and
- Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.

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.

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 fitted on the container.

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.

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is

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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:

- (CHILD) 'Keep out of reach of children' (or words to that effect); and
- (NTAKEN) 'Not to be taken'.

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container.

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.

When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.

When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.

When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.

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			If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.
1363	CINNAMOMUM CASSIA	A, E	<p>Cassia oil is a mandatory component of Cinnamomum cassia if the plant preparation is an essential oil, distillate, fixed oil or 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>
1364	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</p>

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			<p>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>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>
1365	CINNAMON BARK OIL	A, E, H	<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>
1366	CINNAMON DRY	A, H	<p>Cinnamon bark oil is a mandatory component of</p>

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			<p>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>
1367	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> <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 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> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that</li> </ul>

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			effect). - (NTAKEN) 'Not to be taken'. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1368	CINNAMON POWDER	A, E, H	Cinnamon bark oil is a mandatory component of cinnamon powder. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1369	CINNAMYL 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%.
1370	CINNAMYL ALCOHOL	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%.

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1371	CINNAMYL 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%.
1372	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%.
1373	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%.
1374	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%.
1375	CINNAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used as a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
1376	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>
1377	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>

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			<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>
1378	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>
1379	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>
1380	CIS-3-HEXENAL	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>

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1381	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%.
1382	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 1%.
1383	CIS-3-HEXENYL BENZOATE	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%.
1384	CIS-3-HEXENYL 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 1%.

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1385	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>
1386	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 no more than 5%.</p>
1387	CIS-3-HEXENYL ISOBUTYRATE	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>
1388	CIS-3-HEXENYL 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>
1389	CIS-3-HEXENYL LACTATE	E	<p>Permitted for use only in combination with other</p>

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1390	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%.
1391	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%.
1392	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%.

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1393	CIS-4-HEPTENAL	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>
1394	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 1%.</p>
1395	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 1%.</p>
1396	CIS-BETA-OCIMENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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1397	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%.
1398	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%.
1399	CISTANCHE DESERTICOLA	A, H	
1400	CISTANCHE SALSA	A, H	
1401	CISTUS LADANIFERUS	A, E, H	
1402	CITRAL	E	
1403	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%.
1404	CITRAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
1405	CITRIC ACID	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> <ul style="list-style-type: none"> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)</li> <li>- (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect)</li> <li>- (IRRIT) 'If irritation develops, discontinue use.'</li> <li>- (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.'</li> <li>- (CHILD3) 'Use in children under 12 years is not recommended'</li> </ul>
1406	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>

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			<p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"><li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)</li><li>- (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect)</li><li>- (IRRIT) 'If irritation develops, discontinue use.'</li><li>- (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.'</li><li>- (CHILD3) 'Use in children under 12 years is not recommended'</li></ul>
1407	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> <ul style="list-style-type: none"><li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)</li><li>- (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or</li></ul>

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			<p>words to that effect)</p> <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use.'</li> <li>- (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.'</li> <li>- (CHILD3) 'Use in children under 12 years is not recommended.'</li> </ul>
1408	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	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>
1409	CITROL	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>
1410	CITRON	E	
1411	CITRONELLA OIL	A, E, H	<p>Medicines for topical use containing citronella oil require the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CITRON) 'Contains citronella oil'.</li> </ul>
1412	CITRONELLA TERPENES	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1413	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>
1414	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>
1415	CITRONELLOL	E	<p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than</p>

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			5%.
1416	CITRONELLYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1417	CITRONELLYL 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>
1418	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 1%.</p>
1419	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</p>

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1420	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>
1421	CITRONELLYL OXYACETALDEHYDE	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>
1422	CITRONELLYL 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 no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1423	CITRONELLYL TIGLATE	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>

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			medicine must be no more than 1%.
1424	CITRULLUS COLOCYNTHIS	H	Only for use as an active homoeopathic ingredient. When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).
1425	CITRULLUS VULGARIS	A, H	
1426	CITRUS AURANTIFOLIA	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 0.5% or less of citrus aurantifolia oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1427	CITRUS AURANTIUM	A, E, H	Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. 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

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			<p>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>
1428	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1429	CITRUS CHACHIENSIS	A, H	
1430	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>
1431	CITRUS FIBRE	E	
1432	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 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>
1433	CITRUS LIMON	A, E, H	Oxedrine is a mandatory component of Citrus limon

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			<p>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 shower gels that are washed off the skin.</p>
1434	CITRUS MAXIMA	A, H	
1435	CITRUS MEDICA	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 0.05% or less of citrus medica oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1436	CITRUS OIL DISTILLED	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1437	CITRUS RETICULATA	A, E, H	<p>Oxedrine is a mandatory component of Citrus reticulata when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p>
1438	CITRUS SINENSIS	A, E, H	<p>Oxedrine is a mandatory component of Citrus sinensis when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p>
1439	CITRUS SINENSIS PEEL MOLASSES 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>
1440	CITRUS UNSHIU	A, E, H	<p>Oxedrine is a mandatory component of Citrus unshiu when intended for internal use.</p> <p>The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.</p>
1441	CITRUS X PARADISI	A, E, H	
1442	CITRUS X WILSONII	A, H	
1443	CIVET	E	<p>Permitted for use only in combination with other</p>



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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1444	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%.
1445	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%.
1446	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%.
1447	CLARY OIL	A, E, H	
1448	CLEMATIS ARMANDII	A, H	
1449	CLEMATIS CHINENSIS	A, E, H	
1450	CLEMATIS RECTA	A, H	
1451	CLEMATIS VITALBA	A, H	

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1452	CLERODENDRUM TRICHOTOMUM	A, H	
1453	CLINOPODION POLYCEPHALUM	A, H	
1454	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1455	CLIVER HERB DRY	A, H	
1456	CLIVER HERB POWDER	A, H	
1457	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 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> </ul>

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- (NTAKEN) 'Not to be taken'

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1458	CLOVE DRY	A, E, H	
1459	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 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 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:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect)</p> <p>- (NTAKEN) 'Not to be taken'</p>
1460	CLOVE OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1461	CLOVE POWDER	A, E, H	
1462	CLOVE STEM OIL	A, E, H	<p>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 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>

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1463	CLUPEA HARENGUS LIPID EXTRACT	A	Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.
1464	CNICUS BENEDICTUS	A, H	
1465	CNICUS JAPONICUS	A, H	
1466	CNIDIUM MONNIERI	A, H	
1467	CNIDIUM OFFICINALE	A, H	
1468	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1469	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1470	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1471	COCAMIDOPROPYL BETAINE 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%.
1472	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the

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			<p>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>
1473	COCCOLOBIA UVIFERA	A, H	
1474	COCCULUS ORBICULATUS	A, H	
1475	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1476	COCHLEARIA OFFICINALIS	A, H	
1477	COCILLANA DRY	A, H	
1478	COCILLANA POWDER	A, H	
1479	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1480	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.
1481	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%
1482	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.
1483	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 no more than 5%.
1484	COCOA POWDER	A, E, H	
1485	COCOLYCIDES	E	
1486	COCONUT	E	
1487	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1488	COCONUT OIL	A, E, H	
1489	COCOS NUCIFERA	A, E, H	
1490	COD-LIVER OIL	A, E	Vitamin A and colecalciferol are mandatory components of Cod-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be

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		<p>no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.</p>
1491	CODONOPSIS LANCEOLATA	A, H
1492	CODONOPSIS PILOSULA	A, H

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1493	CODONOPSIS TANGSHEN	A, H	
1494	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>
1495	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 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</p>

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			the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1496	COFFEE	E, H	Caffeine is a mandatory component of coffee. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.
1497	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%.
1498	COFFEE SOLID EXTRACT	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1499	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%.
1500	COGNAC OIL GREEN	A, E, H	
1501	COGNAC OIL WHITE	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%.
1502	COIX LACHRYMA-JOBI	A, H	
1503	COLA ACUMINATA	A, E, H	Caffeine is a mandatory component of Cola acuminata. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'

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			<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>
1504	COLA NITIDA	A, E, H	<p>Caffeine is a mandatory component of Cola nitida.</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>
1505	COLCHICUM AUTUMNALE	H	Only for use as an active homeopathic ingredient.
1506	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1507	COLLAGEN	E	
1508	COLLINSONIA CANADENSIS	A, H	

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1509	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1510	COLOPHONY	A, E, H	
1511	COMMIPHORA HABESSINICA	A, H	
1512	COMMIPHORA KATAF	A, H	
1513	COMMIPHORA MYRRHA	A, E, H	
1514	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1515	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1516	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'.
1517	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).
1518	CONIFER PHYTOSTEROL	A	

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COMPLEX			
1519	CONIOSELIUM UNIVITTATUM	A, H	
1520	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.
1521	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry Convallaria majalis in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1522	CONYZA CANADENSIS	A, H	
1523	COPAIBA OIL	A, E, H	
1524	COPAIFERA LANGSDORFFII	A, E, H	
1525	COPERNICIA CERIFERA	A, E, H	
1526	COPOVIDONE	E	
1527	COPPER	H	Only for use as an active homoeopathic ingredient. 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%.
1528	COPPER (II) ASPARTATE	A, H	Copper is a mandatory component of copper (II) aspartate. The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II)

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			<p>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>
1529	COPPER (II) GLYCINATE	A, H	<p>Copper is a mandatory component 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>
1530	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>

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1531	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1532	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%.
1533	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1534	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%.
1535	COPPER TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.



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1536	COPTIS CHINENSIS	A, H	
1537	COPTIS JAPONICA	A, H	
1538	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%.
1539	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1540	CORIANDER DRY	A, H	
1541	CORIANDER OIL	A, E, H	
1542	CORIANDER POWDER	A, H	
1543	CORIANDRUM SATIVUM	A, E, H	
1544	CORN GLYCERIDES	E	
1545	CORN SILK DRY	A, H	
1546	CORN SILK POWDER	A, H	
1547	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%.
1548	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

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5%.			
1549	CORNUS FLORIDA	A, H	
1550	CORNUS OFFICINALIS	A, H	
1551	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1552	CORYDALIS AMBIGUA	A, E, H	
1553	CORYDALIS BUNGEANA	A, H	
1554	CORYDALIS CAVA	A, H	
1555	CORYDALIS FABACEA	A, H	
1556	CORYDALIS FORMOSA	A, H	
1557	CORYDALIS TURTSCHANINOVII	A, H	
1558	CORYLUS AMERICANA	A, H	
1559	CORYLUS AVELLANA	A, H	
1560	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</p>

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			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.
1561	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>

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1562	COSMOS BIPINNATUS	A, H	
1563	COSTUS ROOT OIL	A, H	
1564	COSTUS SPICATUS	A, H	
1565	COTTONSEED OIL	A, E, H	
1566	COUCH GRASS RHIZOME DRY	A, H	
1567	COUCH GRASS RHIZOME POWDER	A, H	
1568	COUMARIN	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
1569	CRANBERRY	E	
1570	CRATAEGUS CUNEATA	A, E, H	
1571	CRATAEGUS LAEVIGATA	A, E, H	
1572	CRATAEGUS MONOGYNA	A, E, H	
1573	CRATAEGUS PINNATIFIDA	A, E, H	
1574	CRATEVA MAGNA	A, E, H	
1575	CREATINE	A, E	
1576	CREATINE MONOHYDRATE	A, E	
1577	CREATINE PHOSPHATE	A, E	
1578	CREATININE	E	Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1579	CREOSOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<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>
1580	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1581	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>
1582	CRESYL ISOBUTYRATE	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>
1583	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	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 0.00341%.</p>
1584	CROCUS SATIVUS	A, H	

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1585	CROSCARMELOSE 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).'
1586	CROSPROVIDONE	E	
1587	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1588	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1589	CRYPTOMERIA JAPONICA	A, H	
1590	CUBEB OIL	A, H	
1591	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%.
1592	CUCUMBER	E	
1593	CUCUMIS MELO	A, H	
1594	CUCUMIS SATIVUS	A, E, H	

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1595	CUCURBITA MAXIMA	A, E, H	
1596	CUCURBITA MOSCHATA	A, H	
1597	CUCURBITA PEPO	A, E, H	
1598	CULLEN CORYLIFOLIUM	A, H	
1599	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%.
1600	CUMIN OIL	A, E, H	
1601	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 1%.
1602	CUMINUM CYMINUM	A, H	
1603	CUMINYL NITRILE	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%.
1604	CUPRESSUS ARIZONICA	A, H	
1605	CUPRESSUS FUNEBRIS	A, E, H	

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1606	CUPRESSUS MACROCARPA	A, H	
1607	CUPRESSUS SEMPERVIRENS	A, E, H	
1608	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1609	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1610	CUPRIC CITRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric citrate.</p> <p>The percentage of copper from cupric citrate should be calculated based on the molecular weight of cupric citrate.</p> <p>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 dose.</p>
1611	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</p>



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			per the recommended daily dose.
1612	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, the concentration of copper compounds must be no more than 5%.</p>
1613	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>
1614	CUPRIC SULFATE MONOHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory

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			<p>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> <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>
1615	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 should be</p>

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			calculated based on the molecular weight of cupric sulfate pentahydrate.
1616	CURCULIGO ORCHIOIDES	A, H	
1617	CURCUMA AROMATICA	A, H	
1618	CURCUMA LONGA	A, E, H	
1619	CURCUMA XANTHORRHIZA	A, H	
1620	CURCUMA ZEDOARIA	A, H	
1621	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1622	CUSCUTA EPITHYMUM	A, H	
1623	CUSCUTA EUROPAEA	A, H	
1624	CUSCUTA HYGROPHILAE	A, H	
1625	CUSCUTA RACEMOSA	A, H	
1626	CUSPARIA FEBRIFUGA	A, H	
1627	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1628	CYANOCOBALAMIN	A, E, H	
1629	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. 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%.
1630	CYATHULA OFFICINALIS	A, H	
1631	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.

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1632	CYCLAMEN PURPURASCENS	A, H	
1633	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%.
1634	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%.
1635	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%.
1636	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%.
1637	CYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1638	CYCLOHEXYL BUTYRATE	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> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1639	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>
1640	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>

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1641	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> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1642	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1643	CYCLOPENTADECANONE	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>
1644	CYDONIA OBLONGA	A, H	
1645	CYMBOPOGON FLEXUOSUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1646	CYMBOPOGON MARTINI	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1647	CYMBOPOGON NARDUS	A, H	The concentration or

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			Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1648	CYMBOPOGON SCHOENANTHUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1649	CYNANCHUM ATRATUM	A, H	
1650	CYNANCHUM STAUNTONII	A, E, H	
1651	CYNARA SCOLYMUS	A, E, H	
1652	CYNODON DACTYLON	A, E, H	
1653	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1654	CYPERUS LONGUS	A, H	
1655	CYPERUS ROTUNDUS	A, H	
1656	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%.
1657	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1658	CYSTEINE	A	When the ingredient is included in a medicine for internal use that is listed in the Register:  - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must

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			<p>comply with all requirements under (a) &amp; (b); or</p> <ul style="list-style-type: none"><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>
1659	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 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 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</p>

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			total of 450 mg cysteine per maximum recommended daily dose.
1660	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> <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 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>

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1661	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 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 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>
1662	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>
1663	D-ALPHA-TOCOPHEROL	A, E	
1664	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1665	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	

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1666	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 must be no more than 3%.</p>
1667	D-BORNEOL	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>
1668	D-CARVONE	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>
1669	D-FENCHONE	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>
1670	D-LIMONENE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1671	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>
1672	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>
1673	DACTYLIS GLOMERATA	A, H	
1674	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1675	DAEMONOROPS DRACO	A, E, H	
1676	DAHLIA PINNATA	A, H	
1677	DALBERGIA ODORIFERA	A, H	
1678	DAMIANA LEAF POWDER	A	

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1679	DANDELION LEAF DRY	A, H	
1680	DANDELION LEAF POWDER	A, H	
1681	DANDELION ROOT DRY	A, H	
1682	DANDELION ROOT POWDER	A, H	
1683	DAPHNE GENKWA	A, H	
1684	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1685	DATE	E	
1686	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 calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1687	DAUCUS CAROTA	A, E, H	
1688	DAVANA 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%.
1689	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal

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			<p>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 eyes' (or words to that effect).</li> </ul>
1690	DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN	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>
1691	DECAHYDRO-BETA-NAPHTHYLACETATE	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>
1692	DECAHYDRO-BETA-NAPHTHYLFORMATE	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>
1693	DECAHYDROSPIRO(FURAN-	E	Permitted for use only in

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	2(3H),5'-(4,7)METHANO(5H)INDENE)		combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%.
1694	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 1%.
1695	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 1%.
1696	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%.
1697	DECARBOXY CARNOISINE DIHYDROCHLORIDE	E	Only for use in topical medicines for dermal

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			<p>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>
1698	DECENAL	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>
1699	DECYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1700	DECYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1701	DECYL GLUCOSIDE	E	<p>Only for use in topical medicines for dermal</p>



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			application.
1702	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1703	DECYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.5%.
1704	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1705	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; 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; c) the deer are sourced only from farmed stock bred and raised in New Zealand; 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

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			force or existing from time to time; 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.
1706	DEER VELVET ANTLER SLICE	A	Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; 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; c) the deer are sourced only from farmed stock bred and raised in New Zealand; 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; 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.

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1707	DEERTONGUE 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%.
1708	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1709	DEHYDROMENTHOFUROLACT ONE	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%.
1710	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%.
1711	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1712	DELTA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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			fragrance concentration in a medicine must be no more than 1%.
1713	DELTA-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 1%.
1714	DELTA-DODECALACTONE	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%.
1715	DELTA-NONALACTONE	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%.
1716	DELTA-OCTALACTONE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1717	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%.
1718	DELTA-TOCOPHEROL	E	
1719	DELTA-UNDECALACTONE	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%.
1720	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1721	DENATONIUM BENZOATE	E	
1722	DENDROBIUM NOBILE	A, H	
1723	DESCURAINIA SOPHIA	A, H	
1724	DESMODIUM STYRACIFOLIUM	A, H	

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1725	DESMODIUM TRIQUETUM	A, H	
1726	DEVIL'S CLAW TUBER DRY	A, H	
1727	DEVIL'S CLAW TUBER POWDER	A, H	
1728	DEXPANTHENOL	A, E	
1729	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>
1730	DEXTRAN 40	A, E	
1731	DEXTRATES	E	
1732	DEXTRIN	E	
1733	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>
1734	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>
1735	DI-C12-13 ALKYL MALATE	E	Only for use in topical

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			<p>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>
1736	DI-C12-15 ALKYL FUMARATE	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>
1737	DI-N-PROPYL ISOCINCHOMERONATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 25%.</p>
1738	DI-PPG-3 MYRISTYL ETHER ADIPATE	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>
1739	DIACETIN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1740	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%.
1741	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%.
1742	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1743	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1744	DIANTHUS SUPERBUS	A, H	
1745	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1746	DIBASIC MAGNESIUM CITRATE	A	Only for use in oral medicines.



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TETRAHYDRATE			
1747	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	<p>Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.</p> <p>The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.</p>
1748	DIBASIC POTASSIUM PHOSPHATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium 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 preparation must not exceed 11.5.</p>
1749	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</p>

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			semi-solid preparation, the pH of the preparation must not exceed 11.5.
1750	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 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>
1751	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</p>

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			<p>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>
1752	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>

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			- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1753	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>
1754	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</p>

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			<p>monohydrate.</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>
1755	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>
1756	DIBUTYL ADIPATE	E	<p>Only for use in topical medicines for dermal application.</p>
1757	DIBUTYL PHTHALATE	E	<p>Only for use in topical medicines for dermal</p>

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			application.
1758	DIBUTYL SEBACATE	E	
1759	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%.
1760	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1761	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1762	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 must be no more than 10%.
1763	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%.

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1764	DICHLOROBENZYL ALCOHOL	E	
1765	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.
1766	DICTAMNUS ALBUS	A, H	
1767	DICTAMNUS DESYCARPUS	A, H	
1768	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%.
1769	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1770	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 5%.
1771	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%.

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1772	DIETHYL MALONATE	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>
1773	DIETHYL PHTHALATE	E	
1774	DIETHYLAMINE	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>
1775	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</li> </ul>



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			<p>clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <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>
1776	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>
1777	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>
1778	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</p>

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			1%.
1779	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1780	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%.
1781	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1782	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%.
1783	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%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).

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1784	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>
1785	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>
1786	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>
1787	DIGITALIS PURPUREA	A, H	<p>The concentration of equivalent dry Digitalis purpurea in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.</p>
1788	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p>
1789	DIHEXYL FUMARATE	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1790	DIHYDRO JASMONE	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>
1791	DIHYDRO TERPINYLACETATE	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>
1792	DIHYDRO-ALPHA-TERPINEOL	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>
1793	DIHYDRO-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</p>

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			fragrance concentration in a medicine must be no more 1%.
1794	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%.
1795	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%.
1796	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%.
1797	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%.
1798	DIHYDROCOUMARIN	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1799	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%.
1800	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%.
1801	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%.
1802	DIHYDROINDENYL-2,4- DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1803	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%.
1804	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 1%.
1805	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%.
1806	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1807	DIISOPROPYL ADIPATE	E	Only for use in topical medicines for dermal

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			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%.
1808	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%.
1809	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1810	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1811	DILL HERB OIL	A, E, H	
1812	DILL SEED OIL	A, E, H	
1813	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%.
1814	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



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			medicine must be no more than 4%.
1815	DIMETHICONE 12500	E	
1816	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%.
1817	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%.
1818	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%.
1819	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%.

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1820	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%.
1821	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%.
1822	DIMETHYL ANTHRANILATE	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%.
1823	DIMETHYL BENZYL 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%.
1824	DIMETHYL BENZYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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			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%.
1825	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 1%.
1826	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%.
1827	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%.
1828	DIMETHYL PHTHALATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1829	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%.
1830	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%.
1831	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%.
1832	DIMETHYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1833	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1834	DIMETHYL SULFOXIDE	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%.
1835	DIMETHYLACETAL	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%.
1836	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	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%.
1837	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1838	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.

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1839	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%.
1840	DIMETICONE 10	E	
1841	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1842	DIMETICONE 1000	E	
1843	DIMETICONE 1510	E	Permitted for use only in combination with other permitted ingredients as a printing ink. If used in a printing ink the total printing ink concentration in a medicine must be no more than 0.1%
1844	DIMETICONE 2	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 9.602%.
1845	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1846	DIMETICONE 200	E	Only for use in topical

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				medicines for dermal application.
1847	DIMETICONE 30	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%.
1848	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.
1849	DIMETICONE 360	E		Only for use in topical medicines for dermal application.
1850	DIMETICONE 450	E		Only for use in topical medicines for dermal application.
1851	DIMETICONE 5	E		Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1852	DIMETICONE 50	E		Only for use in topical medicines for dermal application.
1853	DIMETICONE 5000	E		Only for use in topical medicines for dermal

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			application.
1854	DIMETICONE 6	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%.
1855	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1856	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1857	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%.
1858	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%.
1859	DIMETICONOL	E	Only for use in topical medicines for dermal application.



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1860	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%.
1861	DIMETICONOL/PROPYLSILSESQ UIOXANE/SILICATE 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 damaged skin. The concentration in the medicine must not be more than 10%.
1862	DIMOCARPUS LONGAN	A, H	
1863	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1864	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1865	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1866	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

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			5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1867	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%
1868	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.
1869	DIOSCOREA COLLETTII	A, H	
1870	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1871	DIOSCOREA JAPONICA	A, H	
1872	DIOSCOREA OPPOSITIFOLIA	A, H	
1873	DIOSCOREA POLYSTACHYA	A, H	
1874	DIOSCOREA SEPTEMLOBA	A, H	
1875	DIOSCOREA VILLOSA	A, E, H	
1876	DIOSPYROS KAKI	A, E, H	
1877	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application.  The concentration in the medicine must be no more than 3%.  When used in primary sunscreen products, the medicine requires the following warning statements

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			<p>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>
1878	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>
1879	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSOSTEARATE	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>
1880	DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p>
1881	DIPHENYL DIMETHICONE	E	<p>Only for use in topical medicines for dermal application.</p>

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1882	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%.
1883	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%.
1884	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%.
1885	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%.
1886	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.

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1887	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%.
1888	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1889	DIPSACUS ASPER	A, H	
1890	DIPSACUS JAPONICUS	A, H	
1891	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%.
1892	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1893	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1894	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%.

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1895	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.  The concentration in the medicine must be no more than 14%.
1896	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).’
1897	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%.
1898	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%.

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1899	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%.
1900	DISODIUM LAURIL SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must not be more than 0.35%.
1901	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%.
1902	DISODIUM NADH	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.02%.
1903	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

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			medicine must be no more than 1%.
1904	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	<p>Only for use as an active ingredient in sunscreens for dermal 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>
1905	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>
1906	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>
1907	DISODIUM STEAROYL GLUTAMATE	E	<p>Only for use in topical medicines for dermal</p>



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			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%.
1908	DISPERSIBLE CELLULOSE	E	
1909	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%.
1910	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%.
1911	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1912	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%.
1913	DISTEARYLDIMONIUM	E	Only for use in topical

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	CHLORIDE		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%.
1914	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%.
1915	DL-ALPHA-TOCOPHEROL	A, E	
1916	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1917	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1918	DL-BORNEOL	E	
1919	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1920	DL-THREONINE	A, E	
1921	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.
1922	DOCUSATE SODIUM	E	
1923	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

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			medicine must be no more than 1%.
1924	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%.
1925	DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1926	DODECENE	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%.
1927	DODECYL 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%.

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1928	DODECYL 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%.
1929	DOLICHOS LABLAB	A, H	
1930	DOLOMITE	A, E, H	
1931	DRACAENA DRACO	A, H	
1932	DRIED BUTTERMILK	E	
1933	DRIED CALCIUM SULFATE	A, E, H	
1934	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
1935	DRIMIA INDICA	A, H	
1936	DRIMIA MARITIMA	A, H	
1937	DROMETRIZOLE TRISILOXANE	A	Only for use as an active ingredient in sunscreens for dermal application.  The concentration in a medicine must be no more than 10%.  When used in primary sunscreen products, the medicine requires the following warning statements on the label:  - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and  - (SUNPRO) 'Wear protective clothing - hats and eyewear'

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			when exposed to the sun' (or words to this effect).
1938	DROSERANGLICA	A, H	
1939	DROSERABURMANNI	A, H	
1940	DROSERAINTERMEDIA	A, H	
1941	DROSERARAMENTACIA	A, H	
1942	DROSERAROTUNDIFOLIA	A, E, H	
1943	DROSERAROTUNDIFOLIAMIS	A, H	
1944	DRYNARIAFORTUNEI	A, H	
1945	DRYOBALANOPSAROMATICA	A, H	
1946	DRYOPTERISFILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1947	DULACIAINOPIFLORA	A, H	
1948	DUNALIELLALSALINA	A, E, H	
1949	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%.
1950	DURVILLAEANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1951	DWARFPINE-NEEDLE OIL	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1952	DYSPHANIA AMBROSIOIDES	A, H	<p>Volatile oil components (of <i>Dysphania ambrosioides</i>) are mandatory components of <i>Dysphania ambrosioides</i>.</p>
1953	ECAMSULE	A	<p>Only for use as an active ingredient in sunscreens for dermal 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>
1954	ECHINACEA ANGUSTIFOLIA	A, E, H	
1955	ECHINACEA PALLIDA	A, E, H	
1956	ECHINACEA PURPUREA	A, E, H	
1957	ECHINOPA SPINOSISSIMUS	A, H	

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1958	ECLIPTA PROSTRATA	A, H	
1959	ECTOIN	E	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. The concentration in the medicine must be no more than 3%.
1960	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%.
1961	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1962	EGG LECITHIN	A, E	
1963	EGGSHELL MEMBRANE HYDROLYSATE	A	
1964	EGGSHELL MEMBRANE POWDER	A	
1965	EICHHORNIA CRASSIPES	A, H	
1966	ELAEAGNUS ANGUSTIFOLIA	A, H	
1967	ELAEIS GUINEENSIS	A, E, H	
1968	ELASTIN	E	Only for use in topical medicines for dermal application.
1969	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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				If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1970	ELDER FLOWER BLACK DRY	A, E, H		
1971	ELDER FLOWER BLACK POWDER	A, H		
1972	ELECAMPANE RHIZOME DRY	A, H		
1973	ELECAMPANE RHIZOME POWDER	A, H		
1974	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%.
1975	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%.
1976	ELEMOL	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%.
1977	ELEOCHARIS DULCIS	A, H		
1978	ELETTARIA CARDAMOMUM	A, E, H		



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1979	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1980	ELEUTHEROCOCCUS ROOT DRY	A, H	
1981	ELEUTHEROCOCCUS ROOT POWDER	A, H	
1982	ELEUTHEROCOCCUS SENTICOSUS	A, H	
1983	ELSHOLTZIA SPLENDENS	A, H	
1984	ELYMUS REPENS	A, E, H	
1985	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 material was extracted were healthy and fit for human consumption.</p>
1986	EMULSIFYING WAX	E	
1987	ENOXOLONE	E	Only for use in topical medicines for dermal application.
1988	ENZYME MODIFIED CREAM	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%.
1989	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%.
1990	EPHEDRA SINICA	A, H	Ephedrine and Pseudoephedrine (of Ephedra sinica) are mandatory components of Ephedra sinica. 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%.
1991	EPIGAEA REPENS	A, H	
1992	EPILOBIUM ANGUSTIFOLIUM	E	Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye. The extract must be processed from the flower, leaf and stem (herb top flowering) of the plant. The extracts used must be: 1:20 in 100% water or 1:2 in 100% water. The concentrations of Epilobium angustifolium must be no more than 0.75% for a

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			1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.
1993	EPILOBIUM PALUSTRE	A, H	
1994	EPILOBIUM PARVIFLORUM	A, H	
1995	EPIMEDIUM BREVICORNU	A, H	
1996	EPIMEDIUM GRANDIFLORUM	A, H	
1997	EPIMEDIUM SAGITTATUM	A, H	
1998	EPOXY CEDRENE	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%.
1999	EQUISETUM ARVENSE	A, E, H	
2000	EQUISETUM HIEMALE	A, H	
2001	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2002	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%.
2003	ERIGERON BREVISCAPUS	A, H	
2004	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components.

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			<p>The concentration of amygdalin in the medicine must be 0%.</p> <p>The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
2005	ERIOCAULON BUERGERIANUM	A, H	
2006	ERIODICTYON CRASSIFOLIUM	A, H	
2007	ERIODICTYON GLUTINOSUM	A, H	
2008	ERODIUM CICUTARIUM	A, H	
2009	ERUCA SATIVA	A, H	
2010	ERYTHORBIC ACID	E	
2011	ERYTHRITOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
2012	ERYTHROSINE	E	Only for use as a colour for oral and topical use.
2013	ERYTHROSINE ALUMINIUM LAKE	E	Only for use as a colour for oral and topical use.
2014	ERYTHRULOSE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2%.</p> <p>The medicine requires the</p>

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			following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
2015	ESCHSCHOLZIA CALIFORNICA	A, H	
2016	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2017	ETHANOL	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.  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: - (ETHAN) 'Contains ethanol or contains alcohol'.
2018	ETHANOL ABSOLUTE	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.  When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the

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			following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'
2019	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2020	ETHOHEXADIOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (EHEXAD) 'Contains ethohexadiol' (or words to that effect).
2021	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2022	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%.
2023	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 1%.

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2024	ETHYL (2,4-DIMETHYL-[1,3]DIOXOLAN-2-YL) 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>
2025	ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE	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>
2026	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	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>
2027	ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-CARBOXYLATE	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>
2028	ETHYL 2-BUTENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p>

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2029	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 fragrance concentration in a medicine must be no more than 1%.
2030	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%.
2031	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%.
2032	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



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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2033	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%.
2034	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%.
2035	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%.
2036	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 concentration in a medicine must be no more than 5%.

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2037	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%.
2038	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%.
2039	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%.
2040	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 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 ACRYLATE	E	
2042	ETHYL AMYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a

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			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%.
2043	ETHYL ANTHRANILATE	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 BENZOATE	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%.
2045	ETHYL BENZOYL 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%.
2046	ETHYL BUTYLACETYLAMINOPROPION	E	Only for use in topical medicines for dermal

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	ATE		<p>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>
2047	ETHYL 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 1%.</p>
2048	ETHYL CAPRATE	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>
2049	ETHYL CAPROATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
2050	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%.
2051	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%.
2052	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%.
2053	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 no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more than

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			1%.
2054	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%.
2055	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.
2056	ETHYL 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%.
2057	ETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<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>
2058	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>
2059	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 1%.</p>
2060	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>

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2061	ETHYL 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%.
2062	ETHYL LINALOOL	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%.
2063	ETHYL LINALYL 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%.
2064	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2065	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2066	ETHYL MACADAMIATE	E	Only for use in topical medicines for dermal application and not to be



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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
2067	ETHYL MALTOL	E	
2068	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%.
2069	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2070	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%.
2071	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%.

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2072	ETHYL MYRISTATE	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%.
2073	ETHYL OLEATE	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%.
2074	ETHYL ORTHO-METHOXYBENZYL 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%.
2075	ETHYL OXYHYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2076	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 1%.</p>
2077	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>
2078	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 1%.</p>
2079	ETHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<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>
2080	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 no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2081	ETHYL RICINOLEATE	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>
2082	ETHYL 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>
2083	ETHYL SEBACATE	E	Permitted for use only in

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			<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>
2084	ETHYL STEARATE	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>
2085	ETHYL SUCCINATE	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>
2086	ETHYL TARTRATE	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>
2087	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			medicine must be no more than 5%.
2088	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%.
2089	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%.
2090	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%.
2091	ETHYL VANILLIN	E	
2092	ETHYL-2-METHYL-1,3-DIOXOLANE-2-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%.
2093	ETHYL-2-METHYL-4-	E	Permitted for use only in

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	PENTENOATE		<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2094	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>
2095	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>
2096	ETHYLCELLULOSE	E	
2097	ETHYLENE BRASSYLATE	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>
2098	ETHYLENE GLYCOL	E	<p>The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose.</p> <p>The concentration in the</p>

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			medicine must be no more than 0.062%.
2099	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2100	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%.
2101	ETHYLENE/VINYL ACETATE 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 16%.
2102	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2103	ETHYLENEDIAMINE/HYDROGE NATED 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%.
2104	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal



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	COPOLYMER		<p>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 6%.</p>
2105	ETHYLHEXYL BENZOATE	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 3.5%.</p>
2106	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>
2107	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>

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			<p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
2108	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>
2109	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>
2110	EUCALYPTUS DIVES	A, E, H	<p>Cineole is a mandatory component of Eucalyptus dives.</p> <p>In liquid preparations when the</p>

	<p>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> <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>
<p>2111 EUCALYPTUS FRUTICETORUM A, E, H</p>	<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 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</p>

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			<p>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>
2112	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> <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> <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</p>

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			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.
2113	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> <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>

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2114	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 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>
2115	EUCALYPTUS RADIATA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus radiata.</p> <p>In liquid preparations when the</p>

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			<p>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> <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>
2116	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> <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</p>

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			<p>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>
2117	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> <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</p>

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			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.
2118	EUCOMMIA ULMOIDES	A, H	
2119	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 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</p>

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			<p>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>
2120	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 fragrance concentration in a medicine must be no more 1%.</p>
2121	EUONYMUS ATROPURPUREUS	A, H	
2122	EUONYMUS EUROPAEUS	A, H	<p>The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.</p>
2123	EUPATORIUM FORTUNEI	A, H	
2124	EUPATORIUM JAPONICUM	A, H	
2125	EUPATORIUM PERFOLIATUM	A, H	
2126	EUPATORIUM PURPUREUM	A, H	
2127	EUPHAUSIA SUPERBA OIL	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> <li>- (SFOOD) 'Derived from seafood'</li> </ul>

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			or - (SHELL) 'Contains crustacean shellfish'.
2128	EUPHORBIA CYPARISSIAS	A, H	
2129	EUPHORBIA DRY	A, H	
2130	EUPHORBIA HETERODOXA	A, H	
2131	EUPHORBIA HIRTA	A, H	
2132	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%.
2133	EUPHORBIA PEKINENSIS	A, H	
2134	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2135	EUPHORBIA POWDER	A, H	
2136	EUPHORBIA RESINIFERA	A, H	
2137	EUPHORBIA SIEBOLDIANA	A, H	
2138	EUPHRASIA OFFICINALIS	A, H	
2139	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2140	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2141	EURYALE FEROX	A, H	
2142	EUTERPE OLERACEA	A, E	The plant part must be derived from the fruit.  When used as an excipient:

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			<ul style="list-style-type: none"> <li>- permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation;</li> <li>- the total flavour proprietary excipient formulation in a medicine must not be more than 5%; and</li> <li>- the following warning statement is required on the medicine label:</li> <li>- (ACAI) ‘Contains acai’.</li> </ul>
2143	EVENING PRIMROSE OIL	A, E, H	
2144	EVERNIA PRUNASTRA EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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