

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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
753	BACILLUS COAGULANS	A	<p>Only to be used in a medicine where Pathway International Pty Ltd (Client ID 23355), 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 2 September 2021.</p> <p>Only permitted for use in medicines:</p> <ul style="list-style-type: none"> <li>- limited to oral routes of administration; and</li> <li>- when the strain of Bacillus coagulans is confirmed to be Microbial Type Culture Collection (MTCC) accession number 5260.</li> </ul> <p>The strain of Bacillus coagulans must be declared on the label.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 6 billion CFU of Bacillus coagulans.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD2) 'Not suitable for children'.</li> <li>- (BACCOAG) 'Bacillus coagulans may affect the way</li> </ul>

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			some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'
754	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).
755	BACOPA MONNIERI	A, H	
756	BALLOTA NIGRA	A, H	
757	BALM OF GILEAD BUD DRY	A, H	
758	BALM OF GILEAD BUD POWDER	A, H	
759	BALSAM COPAIBA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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760	BAMBUSA BREVIFLORA	A, E, H	
761	BAMBUSA TEXTILIS	A, H	
762	BANANA	E	
763	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%.
764	BAPTISIA CONFUSA	A, H	
765	BAPTISIA TINCTORIA	A, H	
766	BARBAREA VULGARIS	A, H	
767	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
768	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
769	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
770	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other than topical and mucosal.
771	BARLEY BRAN	E	Gluten is a mandatory component of Barley bran when the route of administration is other than topical and mucosal.
772	BARLEY GERM	E	Gluten is a mandatory component of Barley germ when the route of administration is other than

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773	BARLEY LEAF	E	
774	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
775	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
776	BASIC RED 1	E	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.  The concentration in the medicine must be no more than 0.1%.
777	BASIC VIOLET 11:1	E	Only for use as a colour in topical medicines for dermal application and not intended for use in the eye or on damaged skin.  The concentration in the medicine must be no more than 0.1%.
778	BASIL OIL COMOROS	A, E, H	Methyl chavicol is a mandatory component of Basil oil Comoros.  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.  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

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			restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
779	BASIL OIL EUROPEAN	A, E, H	Methyl chavicol is a mandatory component of Basil oil European. 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. 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: - (CHILD) 'Keep out of reach of children' (or words to that effect).
780	BASSIA SCOPARIA	A, H	
781	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
782	BAY LEAF	E	
783	BAY OIL	A, E, H	When the concentration of Bay oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.

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			<p>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is no more than 15 mL, there must be a restricted flow insert fitted on the container.</p> <p>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or word to that effect)</li> <li>- (NTAKEN) 'Not to be taken'</li> </ul>
784	BEESWAX ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
785	BEET RED	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
786	BEETROOT	E, H	
787	BEGONIA FIMBRISTIPULA	A, H	
788	BEHENETH-10	E	Only for use in topical

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			<p>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 1.5%.</p> <p>Residual levels of ethylene oxide are to be kept below the level of detection.</p>
789	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
790	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
791	BEHENOYL STEARIC ACID	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 2.4%.</p>
792	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
793	BELLADONNA HERB DRY	A, H	<p>Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb dry.</p> <p>The concentration of alkaloids calculated as hyoscyamine in the medicine and must be no more than 300 micrograms/Kg or 300 micrograms/L or</p>

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			0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
794	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb powder. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 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%.
795	BELLADONNA HERB PREPARED	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
796	BELLIS PERENNIS	A, H	
797	BEMOTRIZINOL	A	Only for use as an active

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			ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the 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).
798	BENINCASA HISPIDA	A, E, H	
799	BENTONITE	E	
800	BENZALDEHYDE	E	
801	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%.
802	BENZALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and nasal sprays. The concentration in the medicine must be no more than 5%.
803	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.

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804	BENZOIC ACID	E, H	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this effect)' if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used] (or words to this effect)' if product contains one benzoate source.
805	BENZOIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
806	BENZOIN SIAM	A, E, H	
807	BENZOIN SUMATRA	A, E, H	
808	BENZOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
809	BENZOTHIAZOLE	E	Benzothiazole must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient

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			formulation. The total concentration of the fragrance proprietary excipient formulation containing benzothiazole must not be more than 1% of the total medicine.
810	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%.
811	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%.
812	BENZYL ALCOHOL	A, E	When used as an active ingredient: a) permitted for use only in medicated throat lozenges; and b) when the maximum recommended daily dose of the medicine provides more than 300mg, the following warning statement must be included on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).

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813	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application.
814	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%.
815	BENZYL CINNAMATE	E	Only for use in: (a) topical medicines for dermal application when the concentration of benzyl cinnamate in the medicine is not greater than 0.15%; or (b) medicines in combination with other permitted ingredients as a constituent of a flavour proprietary excipient formulation when the total flavour proprietary excipient formulation in the medicine is not more than 5%. Not to be included in medicines intended for use in the eye.
816	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%.

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817	BENZYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
818	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%.
819	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%.
820	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
821	BENZYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
822	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%.
823	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%.
824	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

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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%.
825	BENZYL TIGLATE	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%.
826	BENZYLIDENE ACETONE	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%.
827	BENZYLIDENE CAMPHOR SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 6% (as acid). When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged

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			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).
828	BERBERIS AQUIFOLIUM	A, H	
829	BERBERIS ARISTATA	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
830	BERBERIS VULGARIS	A, E, H	
831	BERGAMOT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour, the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The medicine requires the following warning statement on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
832	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

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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%.
833	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.
834	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%.
835	BERTHOLLETIA EXCELSA	A, E, H	
836	BETA RAPA	A, E, H	
837	BETA VULGARIS	A, E, H	
838	BETA,4-DIMETHYLCYCLOHEX-3-ENE-1-PROPAN-1-AL	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%.
839	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%.
840	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 medicine must be no more than 5%.
841	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%.
842	BETA-DAMASCONE	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%.
843	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%.
844	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
845	BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
846	BETA-IONONE EPOXIDE	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%.

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847	BETA-ISO-METHYL IONONE	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%.
848	BETA-METHYL NAPHTHYL KETONE	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%.
849	BETA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
850	BETA-NAPHTHOL ETHYLETHER	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%.
851	BETA-NAPHTHOL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
852	BETA-NAPHTHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.  The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
853	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%.
854	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
855	BETA-TOCOPHEROL	E	
856	BETACAROTENE	A, E	When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or sublingual use in adults the medicine requires the following warning statement on the medicine label: - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
857	BETADEX	E	
858	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%.
859	BETAINE	E	Only for use in topical medicines for dermal application.
860	BETAINE HYDROCHLORIDE	E	
861	BETULA LENTA	A, H	Methyl salicylate is a mandatory component of Betula lenta. Not to be included in medicines for use in the eye or

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) ‘Contains methyl salicylate’ (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</li> <li>ii) the following warning statements are required on the medicine label:</li> </ul>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</p> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
862	BETULA NIGRA	A, H	<p>Cresol, eugenol and methyl salicylate are mandatory components of Betula nigra.</p> <p>For external use only when the total concentration of cresols, xlenols and other phenol homologues in the medicine is greater than 3%.</p> <p>When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%.</p> <p>When the concentration of eugenol in the medicine is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 mL;</p> <p>b) the medicine must be fitted</p>

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			<p>with a restricted flow insert;</p> <p>c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and</p> <p>d) the medicine requires the following warning statements on the medicine label:</p> <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>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</li> <li>ii) the following warning statements are required on the medicine label: <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</li> <li>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</li> </ul> </li> <li>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> <li>- (IRRIT) 'If irritation develops, discontinue use'.</li> </ul> </li> </ul>
863	BETULA PENDULA	A, E, H	<p>Methyl salicylate is a mandatory component of Betula pendula.</p> <p>Not to be included in</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%</li> <li>ii) the following warning statements are required on the</li> </ul>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
864	BETULA PUBESCENS	A, E, H	
865	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%.
866	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%.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
867	BIFIDOBACTERIUM ADOLESCENTIS	A	
868	BIFIDOBACTERIUM ANIMALIS	A	
869	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
870	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
871	BIFIDOBACTERIUM BIFIDUM	A	
872	BIFIDOBACTERIUM BREVE	A	
873	BIFIDOBACTERIUM INFANTIS	A	
874	BIFIDOBACTERIUM LACTIS	A	
875	BIFIDOBACTERIUM LONGUM	A	
876	BILBERRY	E	
877	BIOSACCHARIDE GUM-1	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 5%.
878	BIOTA ORIENTALIS	A, H	
879	BIOTIN	A, E	
880	BIRCH LEAF DRY	A, E, H	Methyl salicylate is a mandatory component of birch leaf dry.  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

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> <li>- the delivery device is engaged into the container in such a way that prevents it from being readily removed;</li> <li>- direct suction through the delivery device results in delivery of no more than one dosage unit; and</li> <li>- actuation of the spray device is ergonomically difficult for young children to accomplish.</li> </ul> <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</li> </ul> <p>When for use in topical medicines for dermal application:</p> <ul style="list-style-type: none"> <li>i) the concentration of methyl salicylate in the medicine must not be more than 25%</li> <li>ii) the following warning statements are required on the medicine label: <ul style="list-style-type: none"> <li>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</li> <li>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</li> <li>- (SENS) 'Application to skin may increase sensitivity to</li> </ul> </li> </ul>

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			<p>sunlight.' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</p> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
881	BIRCH TAR OIL RECTIFIED	A, E, H	<p>Cresol is a mandatory component of birch tar oil rectified.</p> <p>For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%.</p>
882	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>
883	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	<p>Only for use in topical medicines for dermal application.</p>
884	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	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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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 4%.
885	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%.
886	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%.
887	BIS-STEARYL DIMETHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2.30%.
888	BIS-STEARYL ETHYLENEDIAMINE/NEOPENTYL 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%.
889	BISABOLENE	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%.
890	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
891	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.
892	BITTERN	A, E, H	Only to be used in a medicine where WA Salt Koolyanobbing Pty Ltd- Australia (Client ID 69736), 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 8 June 2022. Magnesium is a mandatory component of bittern. Only permitted for use in: - medicines limited to oral

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>routes of administration; and</p> <p>- topical medicines for dermal administration.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
893	BIXA ORELLANA	A, E, H	
894	BLACK BONED CHICKEN POWDER	A	
895	BLACK COHOSH DRY	A, H	The medicine requires the following warning statement

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			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.'
896	BLACK COHOSH POWDER	A, H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
897	BLACK CURRANT	E	
898	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%.

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899	BLACK CURRANT FRESH	A, E, H	
900	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%.
901	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
902	BLACK PEPPER OIL	A, E, H	
903	BLACK RASPBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
904	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
905	BLACKBERRY	E	
906	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%.
907	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			flavour concentration in a medicine must be no more than 5%.
908	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%.
909	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 medicine must be no more than 5%.
910	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap.
911	BLADDERWRACK DRY	A, H	Iodine is a mandatory component of Bladderwrack dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
912	BLADDERWRACK POWDER	A, H	Iodine is a mandatory component of Bladderwrack

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			powder. 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.
913	BLAINVILLEA ACMELLA	A, E, H	When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
914	BLETILLA STRIATA	A, H	
915	BLUE FLAG RHIZOME DRY	A, H	
916	BLUE FLAG RHIZOME POWDER	A, H	
917	BLUEBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
918	BLUEBERRY JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
919	BLUMEA LACERA	A, H	
920	BOEHMERIA NIVEA	A, H	
921	BOERHAVIA DIFFUSA	A, H	
922	BOERHAVIA REPENS	A, H	
923	BOGBEAN LEAF DRY	A, H	
924	BOGBEAN LEAF POWDER	A, H	
925	BOIS DE ROSE OIL	A, E, H	
926	BOMBAX CEIBA	A, H	
927	BORAGO OFFICINALIS	A, E, H	Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of Borago officinalis.
928	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 not provide 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> <p>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that is:</p> <ul style="list-style-type: none"> <li>- listed in the Register on or after 2 March 2020; or</li> <li>- released for supply after 2</li> </ul>

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			<p>March 2021.</p> <p>(a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or</li> <li>- (ADULT) 'Adults only' (or words to that effect).</li> </ul> <p>(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or</li> <li>- (ADULT) 'Adults only' (or words to that effect).</li> </ul> <p>(c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>- (BORON) 'Contains boron' (or words to that effect).</li> </ul> <p>(d) When the medicine is for topical use for dermal application, the following</p>

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			warning statement is required on the label: - (BROKEN) 'Use on unbroken skin only' (or words to that effect).
929	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 not provide 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 not be more than 3500 mg/kg or 3500 g/L or 0.35%.</p> <p>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 March 2020; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>(a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that</li> </ul>

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			<p>effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <p>- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>(c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <p>- (BORON) 'Contains boron' (or words to that effect).</p> <p>(d) When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <p>- (BROKEN) 'Use on unbroken skin only' (or words to that effect).</p>
930	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>

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			<p>The maximum recommended daily dose must not provide 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 not be more than 3500 mg/kg or 3500 mg/L or 0.35%.</p> <p>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 March 2020; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>(a) When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or</li> <li>- (ADULT) 'Adults only' (or words to that effect).</li> </ul> <p>(b) When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none"> <li>- (NTAKEN2) 'Not to be taken by children under 2 years old'</li> </ul>

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			(or words to that effect); or - (ADULT) 'Adults only' (or words to that effect).  (c) When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: - (BORON) 'Contains boron' (or words to that effect).  (d) When the medicine is for topical use for dermal application, the following warning statement is required on the label: - (BROKEN) 'Use on unbroken skin only' (or words to that effect).
931	BORNEOL	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%.
932	BORNYL 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%.

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933	BORON NITRIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
934	BORONIA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
935	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%.
936	BOSWELLIA CARTERII	A, E, H	
937	BOSWELLIA SERRATA	A, E, H	
938	BOSWELLIA THURIFERA	A, H	
939	BOVINE CALCIUM CHONDROITIN SULFATE	A	
940	BOVINE CHONDROITIN SULFATE	A	
941	BOVINE COLOSTRUM POWDER	A	The following warning statement is required on the medicine label:

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			- (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).
942	BOVINE LACTOFERRIN	A	
943	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
944	BOVINE SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
945	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The following warning statement is required on the medicine label: - (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).
946	BRANDY	E	
947	BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye.  The concentration in the medicine must be no more than 1%.
948	BRASSICA CHINENSIS	A, H	Allyl isothiocyanate is a

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			mandatory component of Brassica chinensis 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%.
949	BRASSICA JUNCEA	A, H	Allyl isothiocyanate is a mandatory component of Brassica juncea 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%.
950	BRASSICA NAPUS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica napus 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%.
951	BRASSICA NIGRA	A, H	Allyl isothiocyanate is a mandatory component of Brassica nigra 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%.
952	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed.

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			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%.
953	BRASSICA OLERACEA VAR. CAPITATA	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata 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%.
954	BRASSICA OLERACEA VAR. GEMMIFERA	A, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var gemmifera 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%.
955	BRASSICA OLERACEA VAR. ITALICA	A, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica 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%.
956	BRASSICA OLERACEA VAR. VIRIDIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed. The concentration of allyl isothiocyanate from all

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			ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
957	BRASSICA PEKINENSIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica pekinensis 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%.
958	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%.
959	BRAZIL NUT	E	
960	BRILLIANT BLACK BN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
961	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
962	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
963	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
964	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical

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			and oral routes of administration.
965	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
966	BRIZA MEDIA	A, H	
967	BROCCOLI	E	
968	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple ( <i>Ananas comosus</i> ).
969	BROMINE	H	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.
970	BROMOSTYROL	E	Not for use in infants 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%.
971	BROMUS CATHARTICUS	A, H	
972	BROMUS INERMIS	A, H	
973	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
974	BRONOPOL	E	Only for use in topical medicines for dermal application.
975	BROUSSONETIA PAPYRIFERA	A, H	

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976	BROWN FK	E	Permitted for use only as a colour for topical use.
977	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
978	BRUSSEL SPROUT	E	
979	BRYONIA ALBA	A, H	
980	BRYONIA DIOICA	A, H	
981	BUCHU LEAF DRY	A, H	
982	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%.
983	BUCHU LEAF POWDER	A, E, H	
984	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
985	BUDDLEJA OFFICINALIS	A, H	
986	BULNESIA SARMIENTI	A, E, H	
987	BUNIAS ORIENTALIS	A, H	
988	BUPLEURUM FALCATUM	A, H	
989	BURDOCK LEAF DRY	A, H	
990	BURDOCK LEAF POWDER	A, H	
991	BURDOCK ROOT DRY	A, H	
992	BURDOCK ROOT POWDER	A, H	
993	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.

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994	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%.
995	BUTANE	E	Only for use as an excipient propellant ingredient.
996	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%.
997	BUTTER	E	
998	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%.
999	BUTTER ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1000	BUTTER STARTER DISTILLATE	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%.
1001	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%.
1002	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%.
1003	BUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1004	BUTYL BUTYRYL LACTATE	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%.
1005	BUTYL CAPROATE	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%.
1006	BUTYL ESTER OF PVM/MA 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 15%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1007	BUTYL 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%.
1008	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.

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1009	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%.
1010	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%.
1011	BUTYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1012	BUTYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1013	BUTYL METHOXYDIBENZOYLMETHAN E	A E	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.

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			<p>The concentration in preparation must not be more than 5%.</p> <p>When used in primary sunscreen products, the following warning statements are required 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>
1014	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>
1015	BUTYL STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
1016	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>
1017	BUTYLATED HYDROXYANISOLE	E	

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1018	BUTYLATED HYDROXYTOLUENE	E	
1019	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%.
1020	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%.
1021	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%.
1022	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%.
1023	BUTYRALDEHYDE	E	Permitted for use only in

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			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%.
1024	BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1025	C1-8 ALKYL TETRAHYDROXYCYCLOHEXAN OATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.012%.
1026	C10-12 ALKANE/CYCLOALKANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1027	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.

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1028	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>
1029	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>
1030	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>
1031	C12-13 PARETH-3	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>

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1032	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%.
1033	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1034	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%.
1035	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%.
1036	C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.

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1037	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1038	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%.
1039	C15-16 ISOPARAFFIN	E	C15-16 isoparaffin must only be included in topical medicines: (a) for dermal application; and (b) where the dosage form of the medicine is not spray. The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%. When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%.
1040	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%.

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1041	C17-18 ISOPARAFFIN	E	C17-18 isoparaffin must only be included in topical medicines: (a) for dermal application; and (b) where the dosage form of the medicine is not spray. The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%. When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C17-18 isoparaffin) in the medicine must not be more than 25%.
1042	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1043	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1044	C2-OCTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1045	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1046	C20-40 ALKYL STEARATE	E	Only for use in topical

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			medicines for dermal 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%.
1047	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%.
1048	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%.
1049	C30-45 ALKYL CETEARYL DIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1050	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1051	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.

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1052	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%
1053	CABBAGE	E	
1054	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%.
1055	CADE OIL	A, E, H	
1056	CAESALPINIA SAPPAN	A, H	
1057	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: (a) oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and (b) topical medicines for dermal application that are directed for use in adults only. When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg of caffeine

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			<p>from this ingredient.</p> <p>When for internal use or oral application, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> </ul> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for topical application:</p> <ul style="list-style-type: none"> <li>(a) the concentration of total caffeine in the medicine must not be more than 1%; and</li> <li>(b) the medicine must not be intended for use on broken skin.</li> </ul> <p>The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the</p>

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			<p>requirements in paragraphs (a) to (d) below.</p> <p>(a) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>(b) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>(c) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>(d) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of</li> </ul>

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			<p>caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
1058	CAJUPUT OIL	A, E, H	<p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container.</p> <p>When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect)</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL.</p>

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			<p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or word to that effect)</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the medicine must have the restricted flow insert fitted on the container and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or word to that effect)</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul>
1059	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 un compounded medicine substance packed for retail sale and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in</p>

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1060	CALCIFEDIOL MONOHYDRATE	A	<p>force or existing from time to time.</p> <p>Only to be used in a medicine where DSM Nutritional Products Pty Ltd (Client ID 31685), 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 30 June 2021.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 10 micrograms of calcifediol.</p> <p>Only for use in oral medicines. Calcifediol must not be used in medicines with other Vitamin D analogues; such as ergocalciferol or colecalciferol.</p> <p>The medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> <li>- (CFEDIOL) 'Calcifediol may have similar effects to Vitamin D. Consult your health care professional before taking in combination with other medicines.' (or words to that effect);</li> <li>- (OTHVITD) 'The medicine should not be taken in combination with supplements containing Vitamin D without medical advice' (or words to that effect);</li> <li>- (CHILD9) 'Use in children under 9 years is not</li> </ul>

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1061	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1062	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1063	CALCIUM ALGINATE	E	
1064	CALCIUM AMINO ACID CHELATE	A, H	Calcium is a mandatory component of calcium amino acid chelate. The concentration of calcium in the calcium amino acid chelate must be no more than 25% w/w.
1065	CALCIUM ASCORBATE	A, E, H	
1066	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1067	CALCIUM ASPARTATE	A	
1068	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1069	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.
1070	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1071	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1072	CALCIUM CARBONATE	A, E, H	
1073	CALCIUM CASEINATE	E	
1074	CALCIUM CHLORIDE DIHYDRATE	E	
1075	CALCIUM CITRATE	A, E, H	

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1076	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1077	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1078	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular weight of Calcium fluoride.  The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.
1079	CALCIUM FOLINATE	A	Folinic acid is a mandatory component of calcium folinate.  The maximum recommended daily dose must not provide more than 500 micrograms of folinic acid.  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.
1080	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1081	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1082	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1083	CALCIUM GLYCINATE DIHYDRATE	A	
1084	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.

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1085	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1086	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1087	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1088	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.
1089	CALCIUM HYDROXYCITRATE	A, H	
1090	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1091	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1092	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%
1093	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1094	CALCIUM LACTATE	A, E, H	
1095	CALCIUM LACTATE GLUCONATE	A, E, H	
1096	CALCIUM LACTATE PENTAHYDRATE	A, E, H	

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1097	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1098	CALCIUM LYSINATE	A	Only for use in oral medicines.
1099	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1100	CALCIUM OROTATE	A, E, H	
1101	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1102	CALCIUM PANTOTHENATE	A, E, H	
1103	CALCIUM PHOSPHATE	A, E, H	
1104	CALCIUM PYRUVATE	A	
1105	CALCIUM SACCHARATE	E	
1106	CALCIUM SILICATE	E	
1107	CALCIUM SODIUM CASEINATE	A, H	
1108	CALCIUM SODIUM LACTATE	A, E, H	
1109	CALCIUM STEARATE	E	
1110	CALCIUM SUCCINATE	A, E, H	
1111	CALCIUM SULFATE	A, E, H	
1112	CALCIUM SULFATE DIHYDRATE	A, E, H	
1113	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1114	CALCIUM THREONINATE	A	
1115	CALENDULA FLOWER DRY	A, E, H	
1116	CALENDULA FLOWER POWDER	A, H	
1117	CALENDULA OFFICINALIS	A, E, H	
1118	CALLERYA RETICULATA	A, H	
1119	CALLICARPA PEDUNCULATA	A, H	
1120	CALLISTEPHUS CHINENSIS	A, H	
1121	CALLITRIS COLUMELLARIS	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%.
1122	CALLITRIS COLUMELLARIS SUBSP. 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%.
1123	CALLITRIS RHOMBOIDEA	A, H	
1124	CALLUNA VULGARIS	A, E, H	
1125	CALOCHORTUS TOLMIEI	A, H	
1126	CALTHA PALUSTRIS	A, H	
1127	CALUMBA ROOT DRY	A, H	
1128	CALUMBA ROOT POWDER	A, H	
1129	CALVATIA GIGANTEA	A, E, H	
1130	CALYCANTHUS FLORIDUS	A, H	
1131	CALYCANTHUS PRAECOX	A, H	
1132	CAMELLIA JAPONICA	A, H	
1133	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only.
1134	CAMELLIA SINENSIS	A, E, H	Caffeine is a mandatory component of Camellia sinensis.  When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.

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			<p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour</p>

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			<p>period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> <li>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</li> </ul>
1135	CAMPHENE	E	Permitted for use only in combination with other

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			permitted ingredients as a coating solution, 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%.
1136	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%.
1137	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%.
1138	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 not be more than 6%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words

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1139	CAMPHOR OIL BROWN	A, H	<p>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>camphor, cineole and saffrole 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 of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach</p>

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			<p>of children' (or words to that effect); and</p> <ul style="list-style-type: none"> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.</p> <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>When the concentration of cineole in the preparation is</p>

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			<p>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>
1140	CAMPBOR OIL WHITE	A, E, H	<p>Camphor and safrole are mandatory components of camphor oil white.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted</p>

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			<p>flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:</p> <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 saffrole in a medicine must be no more than 0.1%.</p>

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			When for topical use then the concentration of safrole in a medicine must be no more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.
1141	CAMPSIS GRANDIFLORA	A, H	
1142	CANADA BALSAM	A, H	
1143	CANANGA ODORATA	A, E, H	
1144	CANANGA OIL	A, E, H	
1145	CANARIUM INDICUM	A, H	Only for use when the plant part is seed and the plant preparation is oil.
1146	CANARIUM LUZONICUM	A, H	
1147	CANDELILLA WAX	A, E, H	
1148	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1149	CANDIDA UTILIS	A, E, H	When used as an excipient, only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
1150	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1151	CANOLA OIL	A, E, H	Allyl isothiocyanate is a mandatory component of canola oil when the plant part is seed. The concentration of allyl

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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%.
1152	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1153	CANTHAXANTHIN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1154	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%.
1155	CAPROIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1156	CAPRYLIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, 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>
1157	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>
1158	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1159	CAPRYLIC/CAPRIC/MYRISTIC/STEARIC 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 medicine is not to exceed 3%</p>
1160	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	<p>Only for use in topical medicines for dermal application.</p>
1161	CAPRYLOYL GLYCERIN/SEBACIC ACID 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 not be more than 10%.</p>

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1162	CAPRYLOYL GLYCINE	E	Only for use in 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 2%
1163	CAPRYLOYL SALICYLIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must not be more than 0.3%.
1164	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%
1165	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%.
1166	CAPSELLA BURSA-PASTORIS	A, H	
1167	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.

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1168	CAPSICUM ANNUUM	A, E, H	
1169	CAPSICUM DRY	A, E, H	
1170	CAPSICUM FRUIT OLEORESIN	A, E	
1171	CAPSICUM FRUTESCENS	A, E, H	
1172	CAPSICUM POWDER	A, E, H	
1173	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1174	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1175	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must not be more than 0.2%.
1176	CARAWAY DRY	A, H	
1177	CARAWAY OIL	A, E, H	
1178	CARAWAY POWDER	A, H	
1179	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1180	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.

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1181	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1182	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1183	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1184	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1185	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1186	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1187	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1188	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1189	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1190	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.

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			The concentration in the medicine must be no more than 5%.
1191	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1192	CARBON BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1193	CARBON DIOXIDE	E	
1194	CARDAMOM FRUIT DRY	A, H	
1195	CARDAMOM FRUIT POWDER	A, E, H	
1196	CARDAMOM OIL	A, E, H	
1197	CARDIOSPERMUM HALICACABUM	A, H	
1198	CARICA PAPAYA	A, E, H	
1199	CARLINA ACAULIS	A, H	
1200	CARMELLOSE	E	
1201	CARMELLOSE CALCIUM	E	
1202	CARMELLOSE SODIUM	E	
1203	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1204	CARMOISINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1205	CARMOISINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1206	CARNAUBA WAX	A, E, H	
1207	CARNOSINE	E	Only for use in topical

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			medicines for dermal 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%.
1208	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%.
1209	CAROB GUM	E	
1210	CAROB POD	E	
1211	CAROTENES	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1212	CARPINUS BETULUS	A, H	
1213	CARPINUS CORDATA	A, H	
1214	CARRAGEENAN	E	
1215	CARROT	E	
1216	CARROT SEED OIL	A, E, H	
1217	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

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1218	CARUM CARVI	A, H	
1219	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%.
1220	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%.
1221	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%.
1222	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

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			fragrance concentration in a medicine must be no more 1%.
1223	CARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1224	CARYA ILLINOINENSIS	A, H	
1225	CARYA OVATA	A, H	
1226	CARYOPHYLLENE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1227	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara dry when the route of administration is oral. 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: - (CHILD3) 'Use in children

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

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			<p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
1228	CASCARA POWDER	A, H	<p>Hydroxyanthracene derivatives calculated as cascaroside 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>
1229	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1230	CASEIN	E	
1231	CASHEW NUT	E	
1232	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> <p>The concentration in the</p>

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			medicine must be no more than 0.0275%.
1233	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%.
1234	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.
1235	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';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).</li> </ul> <p>When promoted or marketed as</p>

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			<p>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>
1236	CASSIA OIL	A, E, H	<p>The concentration of Cassia oil in the product must be no more than 2% unless the preparation is for dermal use as a rubefacient, in which case the concentration of cassia oil must be no more than 5%.</p>

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1237	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%.
1238	CASTANEA MOLLISSIMA	A, H	
1239	CASTANEA SATIVA	A, H	
1240	CASTOR OIL	A, E	
1241	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1242	CASUARINA EQUISETIFOLIA	A, H	
1243	CATALPA BIGNONIOIDES	A, H	
1244	CATALPA OVATA	A, H	
1245	CATECHU	A, H	
1246	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%.
1247	CAULIFLOWER	E	
1248	CAULOPHYLLUM THALICTROIDES	A, E, H	
1249	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.

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1250	CEANOTHUS AMERICANUS	A, H	
1251	CEDAR LEAF OIL	A, E, H	
1252	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%.
1253	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%.
1254	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 medicine must be no more 1%.
1255	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

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			medicine must be no more than 1%.
1256	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%.
1257	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%.
1258	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%.
1259	CEDRUS ATLANTICA	A, E, H	
1260	CEDRUS DEODARA	A, H	
1261	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1262	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

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			1%.
1263	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%.
1264	CELERY LEAF	E, H	
1265	CELERY SEED DRY	A, E, H	
1266	CELERY SEED OIL	A, E, H	
1267	CELERY SEED POWDER	A, H	
1268	CELLACEFATE	E	
1269	CELLULASE	A	Must be derived from <i>Trichoderma longibrachiatum</i> only.
1270	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%.
1271	CELOSIA ARGENTEA	A, H	
1272	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1273	CENTAUREA CYANUS	A, E, H	
1274	CENTAURIUM ERYTHRAEA	A, H	
1275	CENTELLA ASIATICA	A, E, H	
1276	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

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			on damaged skin. The concentration in the medicine must be no more than 0.05%.
1277	CENTIPEDA CUNNINGHAMII	A, E, H	
1278	CENTIPEDA MINIMA	A, H	
1279	CEPHALANOPSIS SEGETUM	A, H	
1280	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1281	CERAMIDE 2	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
1282	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1283	CERATONIA SILIQUA	A, E, H	
1284	CERATOSTIGMA WILLMOTTIANUM	A, H	
1285	CERESIN	E	Only for use in topical medicines for dermal application.
1286	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

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			more than 0.5%.
1287	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1288	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1289	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1290	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1291	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1292	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.
1293	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1294	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal

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1295	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%.
1296	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1297	CETETH-10	E	Only for use in topical medicines for dermal application.
1298	CETETH-2	E	Only for use in topical medicines for dermal application.
1299	CETETH-24	E	Only for use in topical medicines for dermal application.
1300	CETETH-5	E	Only for use in topical medicines for dermal application.
1301	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1302	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.

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			The concentration in the medicine must be no more than 2%.
1303	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%.
1304	CETOSTEARYL ALCOHOL	E	
1305	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 %
1306	CETRARIA ISLANDICA	A, H	
1307	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1308	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1309	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1310	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.

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1311	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1312	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1313	CETYL DIMETICONE/BIS- VINYLDIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
1314	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1315	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%.
1316	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1317	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1318	CETYL PALMITATE	E	Only for use in topical

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			medicines for dermal application.
1319	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1320	CETYL-PG HYDROXYETHYL PALMITAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 8%.
1321	CETYLPIRIDINIUM CHLORIDE	A, E	When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient: a) permitted for use only in medicated throat lozenges; b) the medicine must not contain more than 2 mg of cetylpyridinium chloride per lozenge; c) the maximum recommended daily dose of the medicine must not provide more than 24 mg of cetylpyridinium chloride; and d) the medicine label must specify that the medicine is only to be used for 7 days (or less).
1322	CHAENOMELES LAGENARIA	A, H	
1323	CHAENOMELES SPECIOSA	A, H	
1324	CHALK	A, E	When used as an active ingredient, can only be

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			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.
1325	CHAMAECYPARIS LAWSONIANA	A, H	
1326	CHAMAELIRIUM LUTEUM	A, H	
1327	CHAMAEMELUM NOBILE	A, E, H	
1328	CHAMOMILE FLOWER DRY	A, E, H	
1329	CHAMOMILE OIL ENGLISH	A, E, H	
1330	CHAMOMILE OIL GERMAN	A, E, H	
1331	CHANGIUM SMYRNIODES	A, H	
1332	CHEIRANTHUS CHEIRI	A, H	
1333	CHELIDONIUM MAJUS	A, E, H	When for oral or sublingual use, the medicine requires the following warning statement on the medicine label: - (CELAND) 'WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a healthcare professional'.
1334	CHELONE GLABRA	A, H	
1335	CHENOPODIUM ALBUM	A, H	
1336	CHENOPODIUM VULVARIA	A, H	
1337	CHERRY	E	
1338	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%.

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1339	CHESTNUT SWEET	E, H	
1340	CHICKEN COMB EXTRACT	A	
1341	CHILLI	E, H	
1342	CHIMAPHILA UMBELLATA	A, H	<p>Beta-arbutin is a mandatory component of Chimaphila umbellata.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
1343	CHIONANTHUS VIRGINICA	A, H	
1344	CHLORELLA	E	<p>Iodine is a mandatory component of Chlorella.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>

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1345	CHLORELLA PYRENOIDOSA	E	
1346	CHLORELLA VULGARIS	A, E	Iodine is a mandatory component of Chlorella vulgaris. 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.
1347	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1348	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1349	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1350	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1351	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

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			0.006%.
1352	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1353	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1354	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1355	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1356	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1357	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1358	CHOCOLATE BROWN HT	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1359	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1360	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1361	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.

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1362	CHOLESTERYL/BEHENYL/OCTYL LDODECYL 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%.
1363	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1364	CHOLINE BITARTRATE	A, E	
1365	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1366	CHONDRODENDRON TOMENTOSUM	A, H	The concentration of equivalent dry Chondrodendron tomentosum in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1367	CHONDRUS CRISPUS	A, E, H	Iodine is a mandatory component of Chondrus crispus.  Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.  Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1368	CHONDRUS DRY	A, E, H	Iodine is a mandatory component of Chondrus dry.  Only for external use when the concentration of iodine in the

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1369	CHONDRUS EXTRACT	A, E, H	<p>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>
1370	CHROMIC CHLORIDE HEXAHYDRATE	A, 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 dose.</p>
			<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>

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1371	CHROMIUM NICOTINATE	A	Chromium is a mandatory component of chromium nicotinate.  The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.  Chromium nicotinate is considered to be an organic form of chromium.
1372	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate.  The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.  Chromium picolinate is considered to be an organic form of chromium.
1373	CHRYSANTHEMUM BALSAMITA	A, H	
1374	CHRYSANTHEMUM INDICUM	A, H	
1375	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1376	CHRYSANTHEMUM MARSHALLII	A, H	
1377	CHRYSANTHEMUM SINENSE	A, H	
1378	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1379	CHRYSOSPORIUM PRUINOSUM	A, H	
1380	CIBOTIUM BAROMETZ	A, H	
1381	CICHORIUM INTYBUS	A, E, H	
1382	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
1383	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.
1384	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 quinidine per g or mL.
1385	CINCHONA OFFICINALIS	A, H	Quinidine and quinine are mandatory components of Cinchona officinalis. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1386	CINCHONA PUBESCENS	A, H	Quinidine and quinine are mandatory components of Cinchona pubescens. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1387	CINEOLE	E	In liquid preparations when the concentration of cineole in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres;

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			<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 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
1388	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>
1389	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>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
1390	CINNAMOMUM CAMPHORA	A, E, H	<p>Camphor, cineole and safrrole 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 and the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect);</li> <li>- (NTAKEN) 'Not to be taken';</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>- Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist'.</li> </ul> <p>In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container.</p> <p>In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>have a restricted flow insert fitted on the container.</p> <p>In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> <li>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1391	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>
1392	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>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>The concentration of cinnamon bark oil in the medicine must be no more than 2%.</p> <p>Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the plant part is leaf.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25%:</p> <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>
1393	CINNAMON BARK OIL	A, E, H	The concentration of cinnamon

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			<p>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>
1394	CINNAMON DRY	A, H	<p>Cinnamon bark oil is a mandatory component of cinnamon dry.</p> <p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1395	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</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>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 effect).</li> <li>- (NTAKEN) 'Not to be taken'.</li> </ul> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1396	CINNAMON POWDER	A, E, H	<p>Cinnamon bark oil is a mandatory component of cinnamon powder.</p> <p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1397	CINNAMYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1398	CINNAMYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1399	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%.
1400	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%.
1401	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%.
1402	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%.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
1403	CINNAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
1404	CINNAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1405	CINOXATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must not be more than 6%.  When used in primary sunscreen products, the following warning statements are required on the 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).
1406	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	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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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1407	CIS-3-HEXEN-1-OL	E	cis-3-Hexen-1-ol must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 5% of the total medicine. The total concentration of fragrance proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 1% of the total medicine.
1408	CIS-3-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1409	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%.
1410	CIS-3-HEXENYL ACETATE	E	Permitted for use only in

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1411	CIS-3-HEXENYL BENZOATE	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>
1412	CIS-3-HEXENYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1413	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>
1414	CIS-3-HEXENYL HEXANOATE	E	<p>Permitted for use only in combination with other</p>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1415	CIS-3-HEXENYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1416	CIS-3-HEXENYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1417	CIS-3-HEXENYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1418	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

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 1%.
1419	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%.
1420	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%.
1421	CIS-4-HEPTENAL	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%.
1422	CIS-6-NONEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1423	CIS-6-NONENOL	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%.
1424	CIS-BETA-OCIMENE	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%.
1425	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%.
1426	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

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1427	CISTANCHE DESERTICOLA	A, H	
1428	CISTANCHE SALSA	A, H	
1429	CISTUS LADANIFERUS	A, E, H	
1430	CITRAL	E	
1431	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%.
1432	CITRAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1433	CITRIC ACID	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label: - (SENS) 'Application to skin

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			<p>may increase sensitivity to sunlight.' (or words to that effect)</p> <ul style="list-style-type: none"> <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>
1434	CITRIC ACID DIHYDRATE	A, E	<p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <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> </ul>

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			- (CHILD3) 'Use in children under 12 years is not recommended'
1435	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 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>
1436	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>

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1437	CITROL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1438	CITRON	E	
1439	CITRONELLA OIL	A, E, H	Medicines for topical use containing citronella oil require the following warning statement on the medicine label:  - (CITRON) 'Contains citronella oil'.
1440	CITRONELLA TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1441	CITRONELLAL	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%.
1442	CITRONELLIC ACID	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%.
1443	CITRONELLOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
1444	CITRONELLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1445	CITRONELLYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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1446	CITRONELLYL FORMATE	E	5%. 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%.
1447	CITRONELLYL 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%.
1448	CITRONELLYL 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%.
1449	CITRONELLYL OXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1450	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>
1451	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 medicine must be no more than 1%.</p>
1452	CITRULLINE	A	<p>Only to be used in a medicine where Kyowa Hakko Bio Co Ltd (Client ID 11072), 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 2 March 2022.</p> <p>Only permitted for use in medicines:</p> <ul style="list-style-type: none"> <li>- limited to oral routes of administration; and</li> <li>- when the maximum recommended daily dose does not provide more than 6g of citrulline.</li> </ul>

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1453	CITRULLUS COLOCYNTHIS	H	Citrullus colocynthis can only be included in medicines for oral use when the dilution of the mother tincture is 10,000 fold (4X) or more.
1454	CITRULLUS VULGARIS	A, H	
1455	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.
1456	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 medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or

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			c) for use in soaps or bath or shower gels that are washed off the skin.
1457	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1458	CITRUS CHACHIENSIS	A, H	
1459	CITRUS 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%.
1460	CITRUS FIBRE	E	
1461	CITRUS LIMETTA	A, 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 limetta oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1462	CITRUS LIMON	A, E, H	Oxedrine is a mandatory component of Citrus limon when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. When the plant preparation is oil or distillate, the warning

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			statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus limon oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1463	CITRUS MAXIMA	A, H	
1464	CITRUS MEDICA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus medica oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1465	CITRUS OIL DISTILLED	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1466	CITRUS OIL TERPENES AND TERPENOIDS	E	Citrus oil terpenes and terpenoids must only be included in medicines when in

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			<p>combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing citrus oil terpenes and terpenoids must not be more than 1% of the total medicine.</p>
1467	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>
1468	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>
1469	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>
1470	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>
1471	CITRUS X PARADISI	A, E, H	

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1472	CITRUS X WILSONII	A, H	
1473	CIVET	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1474	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%.
1475	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%.
1476	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%.
1477	CLARY OIL	A, E, H	
1478	CLEMATIS ARMANDII	A, H	
1479	CLEMATIS CHINENSIS	A, E, H	
1480	CLEMATIS RECTA	A, H	

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1481	CLEMATIS VITALBA	A, H	
1482	CLERODENDRUM TRICHOTOMUM	A, H	
1483	CLINOPODION POLYCEPHALUM	A, H	
1484	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1485	CLIVER HERB DRY	A, H	
1486	CLIVER HERB POWDER	A, H	
1487	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'
1488	CLOVE DRY	A, E, H	
1489	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>
1490	CLOVE OIL TERPENES	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%.
1491	CLOVE POWDER	A, E, H	
1492	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>
1493	CLUPEA HARENGUS LIPID	A	Only for use in oral medicines.

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	EXTRACT		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.
1494	CNICUS BENEDICTUS	A, H	
1495	CNICUS JAPONICUS	A, H	
1496	CNIDIUM MONNIERI	A, H	
1497	CNIDIUM OFFICINALE	A, H	
1498	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1499	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1500	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1501	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.
1502	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 medicine must be: a) no more than 1% in leave on medicines

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			b) no more than 15% in wash on /wash off medicines c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection.
1503	COCCOLOBIA UVIFERA	A, H	
1504	COCCULUS ORBICULATUS	A, H	
1505	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1506	COCHLEARIA OFFICINALIS	A, H	
1507	COCILLANA DRY	A, H	
1508	COCILLANA POWDER	A, H	
1509	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1510	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.
1511	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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			0.025%
1512	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.
1513	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%.
1514	COCOA POWDER	A, E, H	
1515	COCOLYCIDES	E	
1516	COCONUT	E	
1517	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1518	COCONUT OIL	A, E, H	
1519	COCOS NUCIFERA	A, E, H	
1520	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 no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per

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			<p>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>
1521	CODONOPSIS LANCEOLATA	A, H	
1522	CODONOPSIS PILOSULA	A, H	
1523	CODONOPSIS TANGSHEN	A, H	
1524	COFFEA ARABICA	A, E, H	<p>Caffeine is a mandatory component of Coffea arabica.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of</p>

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			<p>total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of</p>

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			<p>total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> <li>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</li> </ul>
1525	COFFEA CANEPHORA	A, E, H	Caffeine is a mandatory

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			<p>component of Coffea canephora.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral</p>

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			<p>application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> <li>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</li> </ul> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> </ul>

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			- (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).
1526	COFFEE	E, H	<p>Caffeine is a mandatory component of coffee.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum</p>

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

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			<p>oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> <li>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</li> </ul>
1527	COFFEE OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1528	COFFEE SOLID 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>
1529	COGNAC OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1530	COGNAC OIL GREEN	A, E, H	
1531	COGNAC OIL WHITE	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>
1532	COIX LACHRYMA-JOBI	A, H	
1533	COLA ACUMINATA	A, E, H	<p>Caffeine is a mandatory component of Cola acuminata.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register before 2 September 2019; and</li> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p>

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

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			<p>80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</li> <li>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</li> </ul>
1534	COLA NITIDA	A, E, H	<p>Caffeine is a mandatory component of Cola nitida.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that:</p> <ul style="list-style-type: none"> <li>- is listed in the Register on or after 2 September 2019; or</li> <li>- is released for supply after 2 March 2021.</li> </ul> <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> <li>- was listed in the Register</li> </ul>

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			<p>before 2 September 2019; and</p> <ul style="list-style-type: none"> <li>- is released for supply before 2 March 2021;</li> </ul> <p>may comply with the requirements in paragraphs (a) to (e) below.</p> <p>a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine.</p> <p>b) When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>c) When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>d) When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>- (ADULT) 'Adults only' (or words to that effect).</li> <li>- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'</li> </ul>

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			<p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
1535	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.
1536	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1537	COLLAGEN	E	
1538	COLLINSONIA CANADENSIS	A, H	
1539	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1540	COLOPHONY	A, E, H	
1541	COMMIPHORA HABESSINICA	A, H	
1542	COMMIPHORA KATAF	A, H	
1543	COMMIPHORA MYRRHA	A, E, H	

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1544	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1545	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1546	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'.
1547	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).
1548	CONIFER PHYTOSTEROL COMPLEX	A	
1549	CONIOSELIVM UNIVITTATUM	A, H	
1550	CONIVM MACVLATVM	H	Only for use as an active homoeopathic ingredient. The homoeopathic potency of <i>Conium maculatum</i> in the final medicine must be 12X or greater.
1551	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry <i>Convallaria</i>

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			majalis in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1552	CONYZA CANADENSIS	A, H	
1553	COPAIBA OIL	A, E, H	
1554	COPAIFERA LANGSDORFFII	A, E, H	
1555	COPERNICIA CERIFERA	A, E, H	
1556	COPOVIDONE	E	
1557	COPPER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>
1558	COPPER (II) ASPARTATE	A, H	<p>Copper is a mandatory component of copper (II) aspartate.</p> <p>The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1559	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</p>

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			calculated based on the molecular weight of Copper (II) glycinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1560	COPPER (II) LYSINATE	A, H	Copper is a mandatory component of copper (II) lysinate. The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1561	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1562	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%.
1563	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1564	COPPER GLUCONATE	A, E	Copper is a mandatory

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			<p>component of copper gluconate.</p> <p>The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate.</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>
1565	COPPER TRIPEPTIDE-1	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1566	COPTIS CHINENSIS	A, H	
1567	COPTIS JAPONICA	A, H	
1568	CORALLINA OFFICINALIS	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 is to be no more than 1%.</p>
1569	CORDYCEPS SINENSIS	A, E, H	<p>Must not contain material of animal origin such as insect larvae.</p>
1570	CORIANDER DRY	A, H	
1571	CORIANDER OIL	A, E, H	
1572	CORIANDER POWDER	A, H	

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1573	CORIANDRUM SATIVUM	A, E, H	
1574	CORMUS DOMESTICA	A, H	
1575	CORN GLYCERIDES	E	
1576	CORN SILK DRY	A, H	
1577	CORN SILK POWDER	A, H	
1578	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%.
1579	CORN SYRUP SOLIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1580	CORNUS FLORIDA	A, H	
1581	CORNUS OFFICINALIS	A, H	
1582	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1583	CORYDALIS AMBIGUA	A, E, H	
1584	CORYDALIS BUNGEANA	A, H	
1585	CORYDALIS CAVA	A, H	
1586	CORYDALIS FABACEA	A, H	
1587	CORYDALIS FORMOSA	A, H	
1588	CORYDALIS TURTSCHANINOVII	A, H	
1589	CORYLUS AMERICANA	A, H	
1590	CORYLUS AVELLANA	A, H	
1591	CORYMBIA CITRIODORA	A, E, H	Cineole is a mandatory component of <i>Corymbia citriodora</i> .

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			<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>
1592	CORYMBIA FICIFOLIA	A, H	<p>Cineole is a mandatory component of Corymbia ficifolia.</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>

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			<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>
1593	COSMOS BIPINNATUS	A, H	
1594	COSTUS ROOT OIL	A, H	
1595	COSTUS SPICATUS	A, H	
1596	COTTONSEED OIL	A, E, H	
1597	COUCH GRASS RHIZOME DRY	A, H	
1598	COUCH GRASS RHIZOME POWDER	A, H	
1599	COUMARIN	E, H	<p>Only for use as an active homoeopathic ingredient or excipient ingredient.</p> <p>When used as an active homoeopathic ingredient, the concentration in the medicine must be no more than 0.001%.</p> <p>When used as an excipient, must only be used in topical medicines for dermal application.</p> <p>The requirements specified in paragraph (a) below apply to medicines that contain the ingredient that are:</p>

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			<ul style="list-style-type: none"> <li>- listed in the Register on or after 2 March 2020; or</li> <li>- released for supply after 2 March 2021.</li> </ul> <p>a) When used as an excipient:</p> <ul style="list-style-type: none"> <li>- the concentration of coumarin in the medicine must not be more than 0.001%; and</li> <li>- the label of the medicine must specify that the product should only be used by adults.</li> </ul>
1600	CRANBERRY	E	
1601	CRATAEGUS CUNEATA	A, E, H	
1602	CRATAEGUS GERMANICA	A, H	
1603	CRATAEGUS LAEVIGATA	A, E, H	
1604	CRATAEGUS MONOGYNA	A, E, H	
1605	CRATAEGUS PINNATIFIDA	A, E, H	
1606	CRATEVA MAGNA	A, E, H	
1607	CREATINE	A, E	
1608	CREATINE MONOHYDRATE	A, E	
1609	CREATINE PHOSPHATE	A, E	
1610	CREATININE	E	<p>Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1611	CREOSOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
1612	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1613	CRESOL	E	Only for use as a preservative in topical medicines. 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%.
1614	CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1615	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00341%.
1616	CROCUS SATIVUS	A, H	
1617	CROSCARMELLOSE SODIUM	E	
1618	CROSPVIDONE	E	
1619	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.

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1620	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1621	CRYPTOMERIA JAPONICA	A, H	
1622	CUBEB OIL	A, H	
1623	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%.
1624	CUCUMBER	E	
1625	CUCUMIS MELO	A, H	
1626	CUCUMIS SATIVUS	A, E, H	
1627	CUCURBITA MAXIMA	A, E, H	
1628	CUCURBITA MOSCHATA	A, H	
1629	CUCURBITA PEPO	A, E, H	
1630	CULLEN CORYLIFOLIUM	A, H	
1631	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%.
1632	CUMIN OIL	A, E, H	
1633	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1634	CUMINUM CYMINUM	A, H	
1635	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%.
1636	CUPRESSUS ARIZONICA	A, H	
1637	CUPRESSUS FUNEBRIS	A, E, H	
1638	CUPRESSUS SEMPERVIRENS	A, E, H	
1639	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1640	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1641	CUPRIC CITRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate. The percentage of copper from cupric citrate should be calculated based on the molecular weight of cupric citrate. The medicine must not contain more than 750 micrograms of copper from cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily dose.

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1642	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate.</p> <p>The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate.</p> <p>The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.</p>
1643	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>
1644	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</p>

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			sulfate. 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%.
1645	CUPRIC SULFATE MONOHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate. The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate. 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%. When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.
1646	CUPRIC SULFATE PENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate. The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate. When for internal use the maximum daily dose must not

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			contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate. The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.
1647	CURCULIGO ORCHIOIDES	A, H	
1648	CURCUMA AROMATICA	A, H	
1649	CURCUMA LONGA	A, E, H	
1650	CURCUMA XANTHORRHIZA	A, H	
1651	CURCUMA ZEDOARIA	A, H	
1652	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1653	CUSCUTA EPITHYMUM	A, H	
1654	CUSCUTA EUROPAEA	A, H	
1655	CUSCUTA HYGROPHILAE	A, H	
1656	CUSCUTA RACEMOSA	A, H	
1657	CUSPARIA FEBRIFUGA	A, H	
1658	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1659	CYANOCOBALAMIN	A, E, H	
1660	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. 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 the medicine must be no more than 5%.
1661	CYATHULA OFFICINALIS	A, H	
1662	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1663	CYCLAMEN PURPURASCENS	A, H	
1664	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%.
1665	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%.
1666	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%.
1667	CYCLOHEXANEETHANOL	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%.
1668	CYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1669	CYCLOHEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1670	CYCLOHEXYL PHENETHYL 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%.
1671	CYCLOHEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1672	CYCLOHEXYLETHYL ACETATE	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%.
1673	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1674	CYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1675	CYDONIA OBLONGA	A, H	
1676	CYMBOPOGON FLEXUOSUS	A, E, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon flexuosus and the concentration of aldehydes calculated as citral in the medicine must not be more than 5%.

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1677	CYMBOPOGON MARTINI	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon martini and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1678	CYMBOPOGON NARDUS	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon nardus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1679	CYMBOPOGON SCHOENANTHUS	A, E, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon schoenanthus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1680	CYNANCHUM ATRATUM	A, H	
1681	CYNANCHUM STAUNTONII	A, E, H	
1682	CYNARA SCOLYMUS	A, E, H	
1683	CYNODON DACTYLON	A, E, H	
1684	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1685	CYPERUS LONGUS	A, H	
1686	CYPERUS ROTUNDUS	A, H	
1687	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

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			medicine must be no more than 1%.
1688	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1689	CYSTEINE	A	The maximum recommended daily dose must not contain more than 450 mg of cysteine. 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.
1690	CYSTEINE HYDROCHLORIDE	A	The maximum recommended daily dose must contain no more than 585 mg of cysteine hydrochloride. 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.
1691	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	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%. The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate. When cysteine, cystine and/or

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			their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.
1692	CYSTINE	A	The maximum recommended daily dose must contain no more than 450 mg of cystine. 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.
1693	CYTISUS SCOPARIUS	A, H	Sparteine is a mandatory component of <i>Cytisus scoparius</i> . The concentration of Sparteine in the medicine must be no more than 0.001%.
1694	D-ALPHA-TOCOPHEROL	A, E	
1695	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1696	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1697	D-ALPHA-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 or on damaged skin. The concentration in the medicine must be no more than 3%.
1698	D-BORNEOL	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%.
1699	D-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1700	D-FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1701	D-LIMONENE	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%.
1702	D-PULEGONE	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%. The concentration of d-pulegone in the medicine must not be more than 4%.
1703	D-RIBOSE-L-CYSTEINE	A	Only for use in oral medicines. Cysteine is a mandatory component of D-Ribose-L-Cysteine. The medicine must provide no more than 450 mg of cysteine per maximum recommended daily dose.
1704	DACTYLIS GLOMERATA	A, H	
1705	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1706	DAEMONOROPS DRACO	A, E, H	
1707	DAHLIA PINNATA	A, H	
1708	DALBERGIA ODORIFERA	A, H	
1709	DAMIANA LEAF POWDER	A	
1710	DANDELION LEAF DRY	A, H	
1711	DANDELION LEAF POWDER	A, H	
1712	DANDELION ROOT DRY	A, H	
1713	DANDELION ROOT POWDER	A, H	
1714	DAPHNE GENKWA	A, H	
1715	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1716	DATE	E	
1717	DATURA STRAMONIUM	A, H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory

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			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%.
1718	DAUCUS CAROTA	A, E, H	
1719	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%.
1720	DEA-OLETH-3 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 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1721	DECAHYDRO-1,1,7-TRIMETHYL-3A,7-METHANO-3AH-CYCLOPENTACYCLOOCT-3-YL FORMATE	E	Decahydro-1,1,7-trimethyl-3a,7-methano-3ah-cyclopentacyclooct-3-yl formate must only be included in medicines when in

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			<p>combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing decahydro-1,1,7-trimethyl-3a,7-methano-3ah-cyclopentacyclooct-3-yl formate must not be more than 1% of the total medicine.</p>
1722	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>
1723	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>
1724	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>
1725	DECAHYDROSPIRO(FURAN-2(3H),5'-(4,7)METHANO(5H)INDENE)	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			fragrance. The total fragrance concentration in a medicine must be no more than 1%.
1726	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%.
1727	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%.
1728	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%.
1729	DECARBOXY CARNOISINE DIHYDROCHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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			medicine must be no more than 0.05.
1730	DECENAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1731	DECYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1732	DECYL 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%.
1733	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1734	DECYL OLEATE	E	Only for use in topical medicines for dermal

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1735	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%.
1736	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1737	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 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

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			regulations made under that Act, as in force or existing from time to time.
1738	DEER VELVET ANTLER SLICE	A	<p>Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions:</p> <p>a) the medicines are for oral use only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p>
1739	DEERTONGUE ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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1740	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1741	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%.
1742	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%.
1743	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1744	DELTA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1745	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

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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%.
1746	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%.
1747	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%.
1748	DELTA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1749	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%.
1750	DELTA-TOCOPHEROL	E	
1751	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%.
1752	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1753	DENATONIUM BENZOATE	E	
1754	DENDROBIUM NOBILE	A, H	
1755	DESCURAINIA SOPHIA	A, H	
1756	DESMODIUM STYRACIFOLIUM	A, H	
1757	DESMODIUM TRIQUETUM	A, H	
1758	DEVIL'S CLAW TUBER DRY	A, H	
1759	DEVIL'S CLAW TUBER POWDER	A, H	
1760	DEXPANTHENOL	A, E	
1761	DEXTRAN 20	E	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.  The concentration in the medicine must be no more than

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			0.3%.
1762	DEXTRAN 40	A, E	
1763	DEXTRATES	E	
1764	DEXTRIN	E	
1765	DEXTRIN PALMITATE	E	Only for use in topical medicines for dermal 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%.
1766	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A	Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil. Only for use in oral medicines when in combination with other active or excipient ingredients. The ratio of DHA to EPA must be 2:1.
1767	DI-C12-13 ALKYL MALATE	E	Only for use in topical medicines for dermal 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%.
1768	DI-C12-15 ALKYL FUMARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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			5%.
1769	DI-N-PROPYL ISOCINCHOMERONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
1770	DI-PPG-3 MYRISTYL ETHER ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1771	DIACETIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1772	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%.

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1773	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%.
1774	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1775	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1776	DIANTHUS SUPERBUS	A, H	
1777	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1778	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1779	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.  The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.  The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is:

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			<p>- listed in the Register on or after 1 March 2021; or</p> <p>- released for supply after 1 March 2022.</p> <p>(a) When used in a medicine:</p> <p>(i) with an oral route of administration;</p> <p>(ii) not indicated for laxative (or related) use; and</p> <p>(iii) where the maximum recommended daily dose for:</p> <p>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>(b) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
1780	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is

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			<p>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>
1781	DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate trihydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
1782	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>
1783	DIBASIC SODIUM PHOSPHATE	A, E, H	When used as an active

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	DIHYDRATE		ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1784	DIBASIC SODIUM PHOSPHATE DODECAHYDRATE	A, E, H	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. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1785	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	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. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH

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			of the preparation must not exceed 11.5.
1786	DIBASIC SODIUM PHOSPHATE MONOHYDRATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1787	DIBENZYL KETONE	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%.
1788	DIBUTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1789	DIBUTYL PHTHALATE	E	Only for use in topical medicines for dermal application.
1790	DIBUTYL SEBACATE	E	
1791	DIBUTYLAMINE	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 the medicine must be no more than 5%.
1792	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1793	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1794	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%.
1795	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%.
1796	DICHLOROBENZYL ALCOHOL	E	
1797	DICHLOROMETHANE	E	The concentration in the medicine must be no more than 0.06%. The residual solvent limit for

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			Dichloromethane is 6 mg per recommended daily dose.
1798	DICTAMNUS ALBUS	A, H	
1799	DICTAMNUS DESYCARPUS	A, H	
1800	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%.
1801	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1802	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1803	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%.
1804	DIETHYL HYDROGEN 2-HYDROXYPROPANE-1,2,3-TRICARBOXYLATE	E	Diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the

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			fragrance proprietary excipient formulation containing diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must not be more than 1% of the total medicine.
1805	DIETHYL MALONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1806	DIETHYL PHTHALATE	E	
1807	DIETHYLAMINE	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%.
1808	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words

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			to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1809	DIETHYLAMINOMETHYLCOUMARIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1810	DIETHYLDIMETHYL-2-CYCLOHEXENONE	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%.
1811	DIETHYLENE GLYCOL	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%.
1812	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1813	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

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			3%.
1814	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1815	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%.
1816	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).
1817	DIETHYLTOLUAMIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 20%. The medicine requires the following warning statement on the medicine label: - (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or

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			bedding or on large areas of the body, especially if you keep using it for a long time.'
1818	DIGITALIS LEAF DRY	A, H	The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1819	DIGITALIS LEAF POWDER	A, H	The concentration of Digitalis leaf powder in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1820	DIGITALIS PURPUREA	A, H	The concentration of equivalent dry Digitalis purpurea in the medicine must be no more than 10mg/Kg or 10mg/L or 0.001%.
1821	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1822	DIHEXYL FUMARATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1823	DIHYDRO JASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1824	DIHYDRO TERPINYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1825	DIHYDRO-ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1826	DIHYDRO-BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1827	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%.
1828	DIHYDROACTINIDIOLIDE	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%.
1829	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%.
1830	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%.
1831	DIHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1832	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

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			1%.
1833	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%.
1834	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%.
1835	DIHYDROINDENYL-2,4-DIOXANE	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%.
1836	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%.
1837	DIHYDROMYRCENOL	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 than 1%.</p>
1838	DIHYDROMYRCENYL 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>
1839	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1840	DIISOPROPYL 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>
1841	DIISOPROPYL SEBACATE	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>
1842	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.

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1843	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1844	DILL HERB OIL	A, E, H	
1845	DILL SEED OIL	A, E, H	
1846	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%.
1847	DIMER DISTEARYLTRICARBONATE	E	Only for use in topical medicines for dermal application and not to be used in medicines intended for use in the eye.  The concentration in the medicine must be no more than 4%.
1848	DIMETHICONE 12500	E	
1849	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%.
1850	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

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			medicine must be no more than 15%.
1851	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%.
1852	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%.
1853	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%.
1854	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%.
1855	DIMETHYL ANTHRANILATE	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>
1856	DIMETHYL BENZYL CARBINOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1857	DIMETHYL BENZYL CARBINYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1858	DIMETHYL BENZYL CARBINYL 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>
1859	DIMETHYL BENZYL CARBINYL	E	Permitted for use only in

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	ISOBUTYRATE		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%.
1860	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%.
1861	DIMETHYL PHTHALATE	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%.
1862	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%.
1863	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%.

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1864	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1865	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1866	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%.
1867	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%.
1868	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%.

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1869	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1870	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1871	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%.
1872	DIMETICONE 10	E	
1873	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1874	DIMETICONE 1000	E	
1875	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%
1876	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%.
1877	DIMETICONE 20	E	Only for use in topical

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			medicines for dermal application.
1878	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1879	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%.
1880	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.
1881	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1882	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1883	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1884	DIMETICONE 50	E	Only for use in topical medicines for dermal application.

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1885	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1886	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%.
1887	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1888	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1889	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%.
1890	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%.
1891	DIMETICONOL	E	Only for use in topical medicines for dermal

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1892	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%.
1893	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%.
1894	DIMOCARPUS LONGAN	A, H	
1895	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1896	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1897	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1898	DIOCTYL TEREPHTHALATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1899	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%
1900	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.
1901	DIOSCOREA COLLETTII	A, H	
1902	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1903	DIOSCOREA JAPONICA	A, H	
1904	DIOSCOREA OPPOSITIFOLIA	A, H	
1905	DIOSCOREA POLYSTACHYA	A, H	
1906	DIOSCOREA SEPTEMLOBA	A, H	
1907	DIOSCOREA VILLOSA	A, E, H	
1908	DIOSPYROS KAKI	A, E, H	
1909	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 on the label:  - (AVOID) 'Avoid prolonged exposure in the sun' (or words

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			to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1910	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin. The concentration in the medicine must be no more than 0.5%.
1911	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSTEARATE	E	Only for use in topical medicines for dermal 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%.
1912	DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1913	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1914	DIPHENYL METHANE	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%.
1915	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%.
1916	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%.
1917	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%.
1918	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1919	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.

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			The concentration in the medicine must be no more than 4.2%.
1920	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1921	DIPSACUS ASPER	A, H	
1922	DIPSACUS JAPONICUS	A, H	
1923	DIPTERYX ODORATA	A, E, H	When used as an active ingredient coumarin is a mandatory component of <i>Dipteryx odorata</i> and the concentration of coumarin in the medicine must be no more than 0.001%.
1924	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1925	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1926	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%.
1927	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

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			14%.
1928	DISODIUM EDETATE	E	
1929	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%.
1930	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%.
1931	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%.
1932	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%.
1933	DISODIUM LAURIMINODIPROPIONATE	E	Only for use in topical medicines for dermal

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	TOCOPHERYL PHOSPHATES		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%.
1934	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1935	DISODIUM OLEAMIDO PEG-2 SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye. The concentration in the medicine must be no more than 1%.
1936	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the 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 when exposed to the sun' (or words to this effect).

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1937	DISODIUM RICINOLEAMIDO MEA-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 3%.
1938	DISODIUM RUTINYL DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 0.05%.
1939	DISODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.  The concentration in the medicine must be no more than 1%.
1940	DISPERSIBLE CELLULOSE	E	
1941	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%.
1942	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.

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			The concentration in the medicine must be no more than 2%.
1943	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1944	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%.
1945	DISTEARYLDIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1946	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%.
1947	DL-ALPHA-TOCOPHEROL	A, E	
1948	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1949	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1950	DL-BORNEOL	E	

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1951	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1952	DL-THREONINE	A, E	
1953	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.
1954	DOCUSATE SODIUM	E	
1955	DODECAHYDRO-3A,6,6,9A-TETRAMETHYLNAPHTHO(2,1-B)FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1956	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%.
1957	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%.
1958	DODECENE	E	Only for use in topical

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			medicines for dermal 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%.
1959	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%.
1960	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%.
1961	DOLICHOS LABLAB	A, H	
1962	DOLOMITE	A, E, H	
1963	DRACAENA DRACO	A, H	
1964	DRIED BUTTERMILK	E	
1965	DRIED CALCIUM SULFATE	A, E, H	
1966	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2021; or - released for supply after 1

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			<p>March 2022.</p> <p>(a) Magnesium is a mandatory component of dried magnesium sulfate.</p> <p>(b) When used in a medicine:</p> <p>(i) with an oral route of administration;</p> <p>(ii) not indicated for laxative (or related) use; and</p> <p>(iii) where the maximum recommended daily dose for:</p> <p>(A) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(B) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(C) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>(c) When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
1967	DRIMIA INDICA	A, H	
1968	DRIMIA MARITIMA	A, H	
1969	DROMETRIZOLE TRISILOXANE	A	Only for use as an active

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			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 when exposed to the sun' (or words to this effect).
1970	DROSERANGLICA	A, H	
1971	DROSERABURMANNI	A, H	
1972	DROSERAINTERMEDIA	A, H	
1973	DROSERARAMENTACIA	A, H	
1974	DROSERAROTUNDIFOLIA	A, E, H	
1975	DROSERAROTUNDIFOLIAMIS	A, H	
1976	DRYNARIAFORTUNEI	A, H	
1977	DRYOBALANOPSAROMATICA	A, H	
1978	DRYOPTERISFILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1979	DULACIAINOPIFLORA	A, H	
1980	DUNALIELLASALINA	A, E, H	
1981	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%.

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1982	DURVILLAEA ANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1983	DWARF PINE-NEEDLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1984	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1985	ECAMSULE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the 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).
1986	ECHINACEA ANGUSTIFOLIA	A, E, H	
1987	ECHINACEA PALLIDA	A, E, H	
1988	ECHINACEA PURPUREA	A, E, H	
1989	ECHINOPA SPINOSISSIMUS	A, H	
1990	ECLIPTA PROSTRATA	A, H	
1991	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%.
1992	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%.
1993	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1994	EGG LECITHIN	A, E	
1995	EGGSHELL MEMBRANE HYDROLYSATE	A	
1996	EGGSHELL MEMBRANE POWDER	A	
1997	ELAEAGNUS ANGUSTIFOLIA	A, H	
1998	ELAEIS GUINEENSIS	A, E, H	
1999	ELASTIN	E	Only for use in topical medicines for dermal application.

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2000	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2001	ELDER FLOWER BLACK DRY	A, E, H	
2002	ELDER FLOWER BLACK POWDER	A, H	
2003	ELECAMPANE RHIZOME DRY	A, H	
2004	ELECAMPANE RHIZOME POWDER	A, H	
2005	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%.
2006	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%.
2007	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%.

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2008	ELEOCHARIS DULCIS	A, H	
2009	ELETTARIA CARDAMOMUM	A, E, H	
2010	ELEUTHEROCOCCUS NODIFLORUS	A, H	
2011	ELEUTHEROCOCCUS ROOT DRY	A, H	
2012	ELEUTHEROCOCCUS ROOT POWDER	A, H	
2013	ELEUTHEROCOCCUS SENTICOSUS	A, H	
2014	ELSHOLTZIA SPLENDENS	A, H	
2015	ELYMUS REPENS	A, E, H	
2016	EMU OIL	A, E	Emu oil ingredients must meet the following two requirements: 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 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.
2017	EMULSIFYING WAX	E	
2018	ENOXOLONE	E	Only for use in topical medicines for dermal application.
2019	ENZYME MODIFIED CREAM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
2020	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%.
2021	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%.
2022	EPIGAEA REPENS	A, H	
2023	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 1:2 extract in 100% water, and

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			5% for a 1:20 extract in 100% water.
2024	EPILOBIUM PALUSTRE	A, H	
2025	EPILOBIUM PARVIFLORUM	A, H	
2026	EPIMEDIUM BREVICORNU	A, H	
2027	EPIMEDIUM GRANDIFLORUM	A, H	
2028	EPIMEDIUM SAGITTATUM	A, H	
2029	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%.
2030	EQUISETUM ARVENSE	A, E, H	
2031	EQUISETUM HIEMALE	A, H	
2032	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2033	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%.
2034	ERIGERON BREVISCAPUS	A, H	
2035	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components.  The concentration of amygdalin in the medicine must be 0%.  The concentration of

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			hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
2036	ERIOCAULON BUERGERIANUM	A, H	
2037	ERIODICTYON CRASSIFOLIUM	A, H	
2038	ERIODICTYON GLUTINOSUM	A, H	
2039	ERODIUM CICUTARIUM	A, H	
2040	ERUCA SATIVA	A, H	
2041	ERYTHORBIC ACID	E	
2042	ERYTHRITOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2043	ERYTHROSINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2044	ERYTHROSINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2045	ERYTHRULOSE	E	Only for use in topical medicines for dermal 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%. The medicine requires the following warning statement on the medicine label:

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			- (EYE) 'Avoid contact with eyes'.
2046	ESCHSCHOLZIA CALIFORNICA	A, H	
2047	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2048	ETHANOL	A, E	<p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p> <p>When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label:</p> <p>- (ETHAN) 'Contains ethanol or contains alcohol'.</p>
2049	ETHANOL ABSOLUTE	A, E	When ethanol absolute is 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.
2050	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2051	ETHOHEXADIOL	E	Only for use in topical medicines for dermal

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			application. The medicine requires the following warning statement on the medicine label: - (EHEXAD) 'Contains ethohexadiol' (or words to that effect).
2052	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2053	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%.
2054	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%.
2055	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2056	ETHYL (3AR,4S,7R,7AR)-REL- OCTAHYDRO-4,7-	E	Permitted for use only in combination with other

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	METHANO[3AH]INDENE-3A-CARBOXYLATE		permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2057	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2058	ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-CARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2059	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2060	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%.

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2061	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%.
2062	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%.
2063	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.  If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2064	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%.

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2065	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%.
2066	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%.
2067	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%.
2068	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%.
2069	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

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2070	ETHYL ACETATE	E	5%. 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%.
2071	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%.
2072	ETHYL ACRYLATE	E	
2073	ETHYL AMYL KETONE	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 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%.

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2075	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%.
2076	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%.
2077	ETHYL BUTYLACETYLAMINOPROPIONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes (or words to that effect)'.
2078	ETHYL 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%.
2079	ETHYL CAPRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2080	ETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2081	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%.
2082	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

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2083	ETHYL CROTONATE	E	5%. 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%.
2084	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 1%.
2085	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%.
2086	ETHYL HYDROXYBENZOATE	E	
2087	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2088	ETHYL 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%.
2089	ETHYL LACTATE	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%.
2090	ETHYL LAURATE	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%.
2091	ETHYL LEVULATE	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%.
2092	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%.
2093	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%.
2094	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%.
2095	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2096	ETHYL LINOLENATE	E	Only for use in topical

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<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			medicines for dermal application.
2097	ETHYL MACADAMIATE	E	Only for use in topical medicines for dermal 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%.
2098	ETHYL MALTOL	E	
2099	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%.
2100	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2101	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%.
2102	ETHYL METICONE	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 3%.
2103	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%.
2104	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%.
2105	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%.
2106	ETHYL OXYHYDRATE	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>
2107	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>
2108	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>
2109	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>
2110	ETHYL PHENYLACETATE	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>
2111	ETHYL PHENYLGLYCIDATE	E	<p>Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).</p>
2112	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>
2113	ETHYL PYRUVATE	E	<p>Ethyl pyruvate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient</p>

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			formulation containing ethyl pyruvate must not be more than 5% of the total medicine.
2114	ETHYL RICINOLEATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2115	ETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2116	ETHYL SEBACATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2117	ETHYL STEARATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2118	ETHYL SUCCINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2119	ETHYL TARTRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2120	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.  If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2121	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%.
2122	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

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			1%.
2123	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%.
2124	ETHYL VANILLIN	E	
2125	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%.
2126	ETHYL-2-METHYL-4-PENTENOATE	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%.
2127	ETHYL-2-METHYLPENTENOATE	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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2128	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	Only for use in topical medicines for dermal application.  The concentration in the medicine must be no more than 0.002%.
2129	ETHYLCELLULOSE	E	
2130	ETHYLENE BRASSYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.  If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2131	ETHYLENE GLYCOL	E	The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose.  The concentration in the medicine must be no more than 0.062%.
2132	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2133	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%.
2134	ETHYLENE/VINYL ACETATE COPOLYMER	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 16%.
2135	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2136	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
2137	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 6%.
2138	ETHYLHEXYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
2139	ETHYLHEXYL METHOXYCRYLENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 10%.
2140	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 not be more than 5%.</p> <p>When used in primary sunscreen products, the following warning statements are required 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>
2141	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>
2142	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>
2143	EUCALYPTUS DIVES	A, E, H	Cineole is a mandatory component of Eucalyptus

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			<p>dives.</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>
2144	EUCALYPTUS FRUTICETORUM	A, E, H	<p>Cineole is a mandatory component of Eucalyptus fruticetorum.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must</p>

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			<p>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>
2145	EUCALYPTUS GLOBULUS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus globulus.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <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</p>

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			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.
2146	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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2147	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>
2148	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> <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>
2149	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>
2150	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: <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>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.
2151	EUCOMMIA ULMOIDES	A, H	
2152	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 container is no more than</p>

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			15mL, a 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 words to that effect) - (NTAKEN) ‘Not to be taken’
2153	EUGENYL 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%.
2154	EUONYMUS ATROPURPUREUS	A, H	
2155	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2156	EUPATORIUM FORTUNEI	A, H	
2157	EUPATORIUM JAPONICUM	A, H	
2158	EUPATORIUM PERFOLIATUM	A, H	
2159	EUPATORIUM PURPUREUM	A, H	
2160	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.
2161	EUPHORBIA CYPARISSIAS	A, H	
2162	EUPHORBIA DRY	A, H	
2163	EUPHORBIA HETERODOXA	A, H	
2164	EUPHORBIA HIRTA	A, H	
2165	EUPHORBIA LATHYRIS	A	Levodopa is a mandatory component of Euphorbia

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			lathyrus. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
2166	EUPHORBIA PEKINENSIS	A, H	
2167	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2168	EUPHORBIA POWDER	A, H	
2169	EUPHORBIA RESINIFERA	A, H	
2170	EUPHORBIA SIEBOLDIANA	A, H	
2171	EUPHRASIA OFFICINALIS	A, H	
2172	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2173	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2174	EURYALE FEROX	A, H	
2175	EUTERPE OLERACEA	A, E	The plant part must be derived from the fruit. When used as an excipient: - permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation; - the total flavour proprietary excipient formulation in a medicine must not be more than 5%; and - the following warning statement is required on the medicine label: - (ACAI) 'Contains acai'.
2176	EVENING PRIMROSE OIL	A, E, H	
2177	EVERNIA PRUNASTRI EXTRACT	E	Permitted for use only in

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<b>Permissible ingredients and requirements</b>			
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>
<b>Item</b>	<b>Ingredient name</b>	<b>Purpose</b>	<b>Specific requirements</b>
			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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