

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

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

Note: See sections 5 and 6.

Permissible ingredients and requirements

Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
734	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">- limited to oral routes of administration; and- when the strain of Bacillus coagulans is confirmed to be Microbial Type Culture Collection (MTCC) accession number 5260. <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">- (CHILD2) ‘Not suitable for

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			children'. - (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'
735	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).
736	BACOPA MONNIERI	A, H	
737	BALLOTA NIGRA	A, H	
738	BALM OF GILEAD BUD DRY	A, H	
739	BALM OF GILEAD BUD POWDER	A, H	
740	BALSAM COPAIBA	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%.
741	BAMBUSA BREVIFLORA	A, E, H	
742	BAMBUSA TEXTILIS	A, H	
743	BANANA	E	
744	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%.
745	BAPTISIA CONFUSA	A, H	
746	BAPTISIA TINCTORIA	A, H	
747	BARBAREA VULGARIS	A, H	
748	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
749	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
750	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
751	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other

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			than topical and mucosal.
752	BARLEY BRAN	E	Gluten is a mandatory component of Barley bran when the route of administration is other than topical and mucosal.
753	BARLEY GERM	E	Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal.
754	BARLEY LEAF	E	
755	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
756	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
757	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%.
758	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

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			medicine must be no more than 0.1%.
759	BASIL OIL COMOROS	A, E, H	<p>Methyl chavicol is a mandatory component of Basil oil Comoros.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
760	BASIL OIL EUROPEAN	A, E, H	<p>Methyl chavicol is a mandatory component of Basil oil European.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL.</p> <p>When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a</p>

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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).
761	BASSIA SCOPARIA	A, H	
762	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
763	BAY LEAF	E	
764	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. 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. 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. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that

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			effect) - (NTAKEN) 'Not to be taken'
765	BEESWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
766	BEET RED	E	Permitted for use only as a colour for oral and topical use.
767	BEETROOT	E, H	
768	BEGONIA FIMBRISTIPULA	A, H	
769	BEHENETH-10	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are to be kept below the level of detection.
770	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.

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771	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
772	BEHENOYL STEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%.
773	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
774	BELLADONNA HERB DRY	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb dry. The concentration of alkaloids calculated as hyoscyamine in the medicine and must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
775	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb powder. The concentration of alkaloids

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			<p>calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p>
776	BELLADONNA HERB PREPARED	A, H	<p>Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application.</p> <p>The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p>
777	BELLIS PERENNIS	A, H	
778	BEMOTRIZINOL	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary</p>

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			<p>sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).
779	BENINCASA HISPIDA	A, E, H	
780	BENTONITE	E	
781	BENZALDEHYDE	E	
782	BENZALDEHYDE GLYCERYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
783	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%.
784	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.
785	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.
786	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%.
787	BENZOIN SIAM	A, E, H	

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788	BENZOIN SUMATRA	A, E, H	
789	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%.
790	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%.
791	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%.
792	BENZYL ALCOHOL	A, E	When used as an active ingredient: a) permitted for use only in medicated throat lozenges; and b) when the maximum

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			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).
793	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing benzoates require the warning statement: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.
794	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%.
795	BENZYL CINNAMATE	E	Only for use in topical

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			<p>medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.15%.</p>
796	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
797	BENZYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
798	BENZYL ISOAMYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
799	BENZYL ISOBUTYRATE	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>
800	BENZYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
801	BENZYL LAURATE	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>
802	BENZYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
803	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%.
804	BENZYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
805	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%.

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806	BENZYLIDENE ACETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
807	BENZYLIDENE CAMPHOR SULFONIC ACID	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6% (as acid).</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following</p>

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			statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
808	BERBERIS AQUIFOLIUM	A, H	
809	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).
810	BERBERIS VULGARIS	A, E, H	
811	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

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			effect)
812	BERGAMOT OIL BERGAPTEN-FREE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
813	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.
814	BERGAMOT OIL TERPENELESS	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%.
815	BERTHOLLETIA EXCELSA	A, E, H	
816	BETA RAPA	A, E, H	
817	BETA VULGARIS	A, E, H	
818	BETA,4-DIMETHYLCYCLOHEX-3-ENE-1-PROPAN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
819	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%.
820	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

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821	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%.
822	BETA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
823	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%.
824	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
825	BETA-IONONE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
826	BETA-IONONE EPOXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
827	BETA-ISO-METHYL IONONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
828	BETA-METHYL NAPHTHYL KETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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829	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%.
830	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 medicine must be no more 1%.
831	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%.

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832	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%.
833	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%.
834	BETA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
835	BETA-TOCOPHEROL	E	
836	BETACAROTENE	A, E	When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or

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			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.'
837	BETADEX	E	
838	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%.
839	BETAINE	E	Only for use in topical medicines for dermal application.
840	BETAINE HYDROCHLORIDE	E	
841	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 on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.

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			<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"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (METSAL) 'Contains methyl salicylate' (or words to that effect). <p>When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that

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			effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
842	BETULA NIGRA	A, H	Cresol, eugenol and methyl salicylate are mandatory components of Betula nigra. For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%. When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%. When the concentration of eugenol in the medicine is more than 25%: a) the nominal capacity of the container must be no more than 25 mL; b) the medicine must be fitted with a restricted flow insert; c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant

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			<p>closure; and</p> <p>d) the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>The following warning statement is required on the</p>

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

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			<p>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"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>In addition, when the ingredient is included in a medicine that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements

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Item	Ingredient name	Purpose	Specific requirements
			<p>under (a) & (b).</p> <p>a) The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (METSAL) 'Contains methyl salicylate' (or words to that effect). b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label: <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
844	BETULA PUBESCENS	A, E, H	
845	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
846	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%.
847	BIFIDOBACTERIUM ADOLESCENTIS	A	
848	BIFIDOBACTERIUM ANIMALIS	A	
849	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
850	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
851	BIFIDOBACTERIUM BIFIDUM	A	
852	BIFIDOBACTERIUM BREVE	A	
853	BIFIDOBACTERIUM INFANTIS	A	
854	BIFIDOBACTERIUM LACTIS	A	
855	BIFIDOBACTERIUM LONGUM	A	
856	BILBERRY	E	
857	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%.

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858	BIOTA ORIENTALIS	A, H	
859	BIOTIN	A, E	
860	BIRCH LEAF DRY	A, E, H	<p>Methyl salicylate is a mandatory component of birch leaf dry.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. <p>In addition, when the ingredient is included in a medicine that is listed in the</p>

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			<p>Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). <p>a) The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (METSAL) 'Contains methyl salicylate' (or words to that effect). <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (IRRIT) 'If irritation

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			develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
861	BIRCH TAR OIL RECTIFIED	A, E, H	Cresol is a mandatory component of birch tar oil rectified. For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%.
862	BIS-BUTYLDIMETICONE POLYGLYCERYL-3	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 in the medicine must be no more than 1.5%.
863	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
864	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.

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865	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%.
866	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%.
867	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%.
868	BISABOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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869	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
870	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.
871	BIXA ORELLANA	A, E, H	
872	BLACK BONED CHICKEN POWDER	A	
873	BLACK COHOSH DRY	A, H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
874	BLACK COHOSH POWDER	A, H	The medicine requires the following warning statement

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			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.'
875	BLACK CURRANT	E	
876	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%.
877	BLACK CURRANT FRESH	A, E, H	
878	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%.
879	BLACK OF CURACAO SPIDER	H	Only for use as an active homeopathic ingredient.

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880	BLACK PEPPER OIL	A, E, H	
881	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%.
882	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
883	BLACKBERRY	E	
884	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%.
885	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
886	BLACKCURRANT ESTERS	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%.
887	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%.
888	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap. When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or

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			words to that effect).
889	BLADDERWRACK DRY	A, H	<p>Iodine is a mandatory component of Bladderwrack dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
890	BLADDERWRACK POWDER	A, H	<p>Iodine is a mandatory component of Bladderwrack powder.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
891	BLAINVILLEA ACMELLA	A, E, H	<p>When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
892	BLETILLA STRIATA	A, H	
893	BLUE FLAG RHIZOME DRY	A, H	
894	BLUE FLAG RHIZOME POWDER	A, H	
895	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%.
896	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%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
897	BLUMEA LACERA	A, H	
898	BOEHMERIA NIVEA	A, H	
899	BOERHAVIA DIFFUSA	A, H	
900	BOERHAVIA REPENS	A, H	
901	BOGBEAN LEAF DRY	A, H	
902	BOGBEAN LEAF POWDER	A, H	
903	BOIS DE ROSE OIL	A, E, H	
904	BOMBAX CEIBA	A, H	

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905	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.
906	BORAX	A, E, H	<p>Boron is a mandatory component of Borax.</p> <p>The percentage of Boron from Borax should be calculated based on the molecular weight of Borax.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of Boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
907	BORAX PENTAHYDRATE	A, E	<p>Boron is a mandatory component of Borax Pentahydrate.</p> <p>The percentage of Boron from Borax pentahydrate should be calculated based on the molecular weight of Borax Pentahydrate.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron from Borax pentahydrate.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the</p>

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			medicine must be no more than 3500 mg/kg or 3500 g/L or 0.35%.
908	BORIC ACID	A, H	<p>Boron is a mandatory component of Boric acid.</p> <p>The percentage of Boron from Boric acid should be calculated based on the molecular weight of Boric acid.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
909	BORNEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
910	BORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
911	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%.
912	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%.
913	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%.
914	BOSWELLIA CARTERII	A, E, H	
915	BOSWELLIA SERRATA	A, E, H	
916	BOSWELLIA THURIFERA	A, H	

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917	BOVINE CALCIUM CHONDROITIN SULFATE	A	
918	BOVINE CHONDROITIN SULFATE	A	
919	BOVINE COLOSTRUM POWDER	A	The medicine requires the warning statement: - (BOVCOL) 'Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'
920	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk.'
921	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
922	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%.
923	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The medicine requires the following warning statements

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			on the medicine label: - (COWMK) 'Derived from cows milk' - (BABY3) 'Not suitable for use in children under the age of 12 months - except on the advice of a health professional)'
924	BRANDY	E	
925	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%.
926	BRASSICA CHINENSIS	A, H	Allyl isothiocyanate is a 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%.
927	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

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			be no more than 10 mg/kg or 10 mg/L or 0.001%.
928	BRASSICA NAPUS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
929	BRASSICA NIGRA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
930	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
931	BRASSICA OLERACEA VAR. CAPITATA	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata</p>

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			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%.
932	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%.
933	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%.
934	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%.
935	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%.
936	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%.
937	BRAZIL NUT	E	
938	BRILLIANT BLACK BN	E	Permitted for use only as a colour for oral and topical use.
939	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
940	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.

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941	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
942	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
943	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
944	BRIZA MEDIA	A, H	
945	BROCCOLI	E	
946	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (<i>Ananas comosus</i>). If used in a divided preparation, the allowed units are papain units and million papain units. If used in an undivided preparation, the allowed units are million papain units per gram.
947	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.
948	BROMOSTYROL	E	Not for use in infants Permitted for use only in

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			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
949	BROMUS CATHARTICUS	A, H	
950	BROMUS INERMIS	A, H	
951	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
952	BRONOPOL	E	Only for use in topical medicines for dermal application.
953	BROUSSONETIA PAPYRIFERA	A, H	
954	BROWN FK	E	Permitted for use only as a colour for topical use.
955	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
956	BRUSSEL SPROUT	E	
957	BRYONIA ALBA	A, H	
958	BRYONIA DIOICA	A, H	
959	BUCHU LEAF DRY	A, H	
960	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

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Item	Ingredient name	Purpose	Specific requirements
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
961	BUCHU LEAF POWDER	A, E, H	
962	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
963	BUDDLEJA OFFICINALIS	A, H	
964	BULNESIA SARMIENTI	A, E, H	
965	BUNIAS ORIENTALIS	A, H	
966	BUPLEURUM FALCATUM	A, H	
967	BURDOCK LEAF DRY	A, H	
968	BURDOCK LEAF POWDER	A, H	
969	BURDOCK ROOT DRY	A, H	
970	BURDOCK ROOT POWDER	A, H	
971	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
972	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%.
973	BUTANE	E	Only for use as an excipient propellant ingredient.
974	BUTOXYETHANOL	E	Only for use in topical medicines for dermal

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			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
975	BUTTER	E	
976	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%.
977	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%.
978	BUTTER STARTER DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
979	BUTYL 2-METHYLBUTYRATE	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%.
980	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%.
981	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%.
982	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
983	BUTYL CAPROATE	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>
984	BUTYL ESTER OF PVM/MA COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 15%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
985	BUTYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
986	BUTYL HYDROXYBENZOATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing hydroxybenzoates require the following warning statement</p>

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			on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
987	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%.
988	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%.
989	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%.

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990	BUTYL LEVULINATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
991	BUTYL METHOXYDIBENZOYLMETHAN E	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in preparation must be no more than 5%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words

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Item	Ingredient name	Purpose	Specific requirements
			to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
992	BUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
993	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
994	BUTYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
995	BUTYLATED HYDROXYANISOLE	E	
996	BUTYLATED HYDROXYTOLUENE	E	
997	BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
998	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%.
999	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%.
1000	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%.
1001	BUTYRALDEHYDE	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%.
1002	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%.
1003	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%.
1004	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%.
1005	C10-30 CHOLESTEROL/LANOSTEROL	E	Only for use in topical medicines for dermal

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Item	Ingredient name	Purpose	Specific requirements
	ESTERS		application.
1006	C11-13 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 not be more than 10%.
1007	C11-14-ISO-ALCOHOL C-13 RICH	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1008	C12-13 PARETH-23	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
1009	C12-13 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

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			<p>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>
1010	C12-15 ALKYL LACTATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1.2%.</p>
1011	C12-15 ALKYL OCTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
1012	C12-20 ACID PEG-8 ESTER	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1013	C12-20 ALKYL GLUCOSIDE	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 0.75%.</p>

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1014	C12-22 ALKYL ACRYLATE/HYDROXYETHYL ACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.
1015	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1016	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%.
1017	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%.
1018	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1019	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal

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Item	Ingredient name	Purpose	Specific requirements
			application.
1020	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%.
1021	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1022	C20-40 ALKYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1023	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%.
1024	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.

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			The concentration in the medicine must be no more than 2%.
1025	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%.
1026	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1027	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1028	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%
1029	CABBAGE	E	
1030	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

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Item	Ingredient name	Purpose	Specific requirements
			1%.
1031	CADE OIL	A, E, H	
1032	CAESALPINIA SAPPAN	A, H	
1033	CAFFEINE	A, E	<p>When used as an excipient, only for use in topical medicines for dermal application.</p> <p>Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine).</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg of caffeine from this ingredient.</p> <p>When for internal use or oral application, the following warning statement is required on the medicine label:</p> <p>- (ADULT) 'Adults only' (or words to that effect).</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,</p>

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			<p>the medicine must not contain a concentration of total caffeine greater than 33%.</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"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <p>may comply with the 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</p>

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			<p>required on the label:</p> <ul style="list-style-type: none"> - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' 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: <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1034	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</p>

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			<p>medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container.</p> <p>When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. <p>When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL.</p> <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine 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"> - (CHILD) 'Keep out of reach of children' (or word to that

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			<p>effect)</p> <p>- (NTAKEN) 'Not to be taken'.</p> <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> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect)</p> <p>- (NTAKEN) 'Not to be taken'.</p>
1035	CALAMINE	A, E	<p>Only for use as an active or excipient ingredient for dermal application.</p> <p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p>
1036	CALCIFEDIOL MONOHYDRATE	A	<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</p>

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			<p>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.</p> <p>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"> - (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); - (OTHVITD) 'The medicine should not be taken in combination with supplements containing Vitamin D without medical advice' (or words to that effect); - (CHILD9) 'Use in children under 9 years is not recommended' (or words to that effect).

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1037	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1038	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1039	CALCIUM ALGINATE	E	
1040	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.
1041	CALCIUM ASCORBATE	A, E, H	
1042	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1043	CALCIUM ASPARTATE	A	
1044	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1045	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.
1046	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1047	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	

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1048	CALCIUM CARBONATE	A, E, H	
1049	CALCIUM CASEINATE	E	
1050	CALCIUM CHLORIDE DIHYDRATE	E	
1051	CALCIUM CITRATE	A, E, H	
1052	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1053	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1054	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%.
1055	CALCIUM FOLINATE	A	Folinic acid is a mandatory component of calcium folinate. The maximum 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. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the

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Item	Ingredient name	Purpose	Specific requirements
			following warning statement is required on the medicine label: - (NEUR) 'Warning: Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect).'
1056	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1057	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1058	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1059	CALCIUM GLYCINATE DIHYDRATE	A	
1060	CALCIUM HEXAFLUROSILICATE	H	Only for use as an active homoeopathic ingredient.
1061	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1062	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1063	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1064	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			time.
1065	CALCIUM HYDROXYCITRATE	A, H	
1066	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1067	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1068	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%
1069	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1070	CALCIUM LACTATE	A, E, H	
1071	CALCIUM LACTATE GLUCONATE	A, E, H	
1072	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1073	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1074	CALCIUM LYSINATE	A	Only for use in oral medicines.
1075	CALCIUM METHIONINATE	A	Only for use in oral medicines.

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1076	CALCIUM OROTATE	A, E, H	
1077	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1078	CALCIUM PANTOTHENATE	A, E, H	
1079	CALCIUM PHOSPHATE	A, E, H	
1080	CALCIUM PYRUVATE	A	
1081	CALCIUM SACCHARATE	E	
1082	CALCIUM SILICATE	E	
1083	CALCIUM SODIUM CASEINATE	A, H	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk'.
1084	CALCIUM SODIUM LACTATE	A, E, H	
1085	CALCIUM STEARATE	E	
1086	CALCIUM SUCCINATE	A, E, H	
1087	CALCIUM SULFATE	A, E, H	
1088	CALCIUM SULFATE DIHYDRATE	A, E, H	
1089	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1090	CALCIUM THREONINATE	A	
1091	CALENDULA FLOWER DRY	A, E, H	
1092	CALENDULA FLOWER POWDER	A, H	
1093	CALENDULA OFFICINALIS	A, E, H	
1094	CALLERYA RETICULATA	A, H	

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Item	Ingredient name	Purpose	Specific requirements
1095	CALLICARPA PEDUNCULATA	A, H	
1096	CALLISTEMON CITRINUS	A, H	
1097	CALLISTEPHUS CHINENSIS	A, H	
1098	CALLITRIS INTRATROPICA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1099	CALLITRIS RHOMBOIDEA	A, H	
1100	CALLUNA VULGARIS	A, E, H	
1101	CALOCHORTUS TOLMIEI	A, H	
1102	CALTHA PALUSTRIS	A, H	
1103	CALUMBA ROOT DRY	A, H	
1104	CALUMBA ROOT POWDER	A, H	
1105	CALVATIA GIGANTEA	A, E, H	
1106	CALYCANTHUS FLORIDUS	A, H	
1107	CALYCANTHUS PRAECOX	A, H	
1108	CAMELLIA JAPONICA	A, H	
1109	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.
1110	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

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Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <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"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee)

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			when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1111	CAMPHENE	E	Permitted for use only in combination with other 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%.
1112	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%.
1113	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%.

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1114	CAMPBOR BENZALKONIUM METHOSULFATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the preparation must be no more than 6%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none">- (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none">- (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).
1115	CAMPBOR OIL BROWN	A, H	camphor, cineole and safrole are mandatory components of

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Item	Ingredient name	Purpose	Specific requirements
			<p>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> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>In essential oil preparations, if</p>

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			<p>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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <p>When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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>
1116	CAMPHOR OIL WHITE	A, E, H	<p>Camphor and safrole are mandatory components of camphor oil white.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less</p>

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			<p>than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and

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Item	Ingredient name	Purpose	Specific requirements
			- (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. 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.
1117	CAMPSIS GRANDIFLORA	A, H	
1118	CANADA BALSAM	A, H	
1119	CANANGA ODORATA	A, E, H	
1120	CANANGA OIL	A, E, H	
1121	CANARIUM INDICUM	A, H	The plant part must be seed and the plant preparation is oil. The medicine requires the following warning statement on the medicine label: - (DERIVED) 'This product contains material derived from nuts' (or words to that effect).
1122	CANARIUM LUZONICUM	A, H	
1123	CANDELILLA WAX	A, E, H	
1124	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1125	CANDIDA UTILIS	A, E, H	When used as an excipient, only for use in medicines in combination with other permitted ingredients as a

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Item	Ingredient name	Purpose	Specific requirements
			flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
1126	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1127	CANOLA OIL	A, E, H	Allyl isothiocyanate is a mandatory component of canola oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1128	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1129	CANTHAXANTHIN	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1130	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%.

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1131	CAPROIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1132	CAPRYLIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1133	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>

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1134	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1135	CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3%
1136	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1137	CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER	E	Only to be used in a medicine where A S Harrison & Co Pty Ltd (Client ID 50284), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020. Only for use in 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 10%.
1138	CAPRYLOYL GLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Item	Ingredient name	Purpose	Specific requirements
			for use in the eye. The concentration in the medicine must not be more than 2%
1139	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%.
1140	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%
1141	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%.
1142	CAPSELLA BURSA-PASTORIS	A, H	
1143	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.

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1144	CAPSICUM ANNUUM	A, E, H	
1145	CAPSICUM DRY	A, E, H	
1146	CAPSICUM FRUIT OLEORESIN	A, E	
1147	CAPSICUM FRUTESCENS	A, E, H	
1148	CAPSICUM POWDER	A, E, H	
1149	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1150	CARAMEL	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1151	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must be no more than 0.2%. Except when used in a medicine containing only homeopathic preparations, a child resistant closure must be fitted onto the container.
1152	CARAWAY DRY	A, H	
1153	CARAWAY OIL	A, E, H	
1154	CARAWAY POWDER	A, H	
1155	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1156	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines for dermal application and not

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Item	Ingredient name	Purpose	Specific requirements
			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.
1157	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1158	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1159	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1160	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1161	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1162	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1163	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
1164	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1165	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1166	CARBOMER U-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1167	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1168	CARBON BLACK	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1169	CARBON DIOXIDE	E	
1170	CARDAMOM FRUIT DRY	A, H	
1171	CARDAMOM FRUIT POWDER	A, E, H	
1172	CARDAMOM OIL	A, E, H	
1173	CARDIOSPERMUM HALICACABUM	A, H	
1174	CARICA PAPAYA	A, E, H	
1175	CARLINA ACAULIS	A, H	
1176	CARMELLOSE	E	
1177	CARMELLOSE CALCIUM	E	

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1178	CARMELLOSE SODIUM	E	
1179	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1180	CARMOISINE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1181	CARMOISINE ALUMINIUM LAKE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1182	CARNAUBA WAX	A, E, H	
1183	CARNOSINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1184	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%.
1185	CAROB GUM	E	
1186	CAROB POD	E	
1187	CAROTENES	E	Permitted as an excipient ingredient as a colour for oral and topical use.

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1188	CARPINUS BETULUS	A, H	
1189	CARPINUS CORDATA	A, H	
1190	CARRAGEENAN	E	
1191	CARROT	E	
1192	CARROT SEED OIL	A, E, H	
1193	CARTHAMUS TINCTORIUS	A, E, H	<p>Carthamus tinctorius (sunflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only.</p> <p>If for oral use, the medicine requires the following warning statement on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).</p>
1194	CARUM CARVI	A, H	
1195	CARVACROL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1196	CARVACRYL METHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
1197	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%.
1198	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%.
1199	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1200	CARYA ILLINOINENSIS	A, H	
1201	CARYA OVATA	A, H	
1202	CARYOPHYLLENE OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1203	CASCARA DRY	A, H	<p>Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’; and - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>product' [or words to that effect].</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' [or words to that effect]. <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"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <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"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' [or words to that effect]; and - (LAX2) 'Prolonged use may cause serious bowel problems'.
1204	CASCARA POWDER	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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> <ul style="list-style-type: none"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <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"> - (LAX5) 'This product contains [name of the herb(s)]

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>or the chemical component(s)']; and</p> <ul style="list-style-type: none"> - (LAX4) 'This product may have laxative effect'. <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"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
1205	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1206	CASEIN	E	
1207	CASHEW NUT	E	
1208	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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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 0.0275%.
1209	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%.
1210	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.
1211	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"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’; and - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (LAX1) 'Drink plenty of water' (or words to that effect). <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"> - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. <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"> - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.
1212	CASSIA OIL	A, E, H	The concentration of Cassia oil in the product must be no more

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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%.
1213	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%.
1214	CASTANEA MOLLISSIMA	A, H	
1215	CASTANEA SATIVA	A, H	
1216	CASTOR OIL	A, E	
1217	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1218	CASUARINA EQUISITIFOLIA	A, H	
1219	CATALPA BIGNONIOIDES	A, H	
1220	CATALPA OVATA	A, H	
1221	CATECHU	A, H	
1222	CATHARANTHUS ROSEUS	A, H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus. The concentration of

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1223	CAULIFLOWER	E	
1224	CAULOPHYLLUM THALICTROIDES	A, E, H	
1225	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1226	CEANOTHUS AMERICANUS	A, H	
1227	CEDAR LEAF OIL	A, E, H	
1228	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%.
1229	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1230	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%.
1231	CEDARWOOD OIL VIRGINIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1232	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%.
1233	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1234	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%.
1235	CEDRUS ATLANTICA	A, E, H	
1236	CEDRUS DEODARA	A, H	
1237	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1238	CEDRYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1239	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%.
1240	CELERY LEAF	E, H	
1241	CELERY SEED DRY	A, E, H	
1242	CELERY SEED OIL	A, E, H	
1243	CELERY SEED POWDER	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1244	CELLACEFATE	E	
1245	CELLULOSE	A	<p>Must be derived from <i>Trichoderma longibrachiatum</i> only.</p> <p>If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram.</p> <p>If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.</p>
1246	CELLULOSE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1247	CELOSIA ARGENTEA	A, H	
1248	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1249	CENTAUREA CYANUS	A, E, H	
1250	CENTAURIUM ERYTHRAEA	A, H	
1251	CENTELLA ASIATICA	A, E, H	
1252	CENTELLA ASIATICA MERISTEM CELL CULTURE	E	<p>Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			0.05%.
1253	CENTIPEDA CUNNINGHAMII	A, E, H	
1254	CENTIPEDA MINIMA	A, H	
1255	CEPHALANOPSIS SEGETUM	A, H	
1256	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1257	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%.
1258	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1259	CERATONIA SILIQUA	A, E, H	
1260	CERATOSTIGMA WILLMOTTIANUM	A, H	
1261	CERESIN	E	Only for use in topical medicines for dermal application.
1262	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			must be a water extract. The concentration must be no more than 0.5%.
1263	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1264	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1265	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1266	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1267	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1268	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.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1269	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1270	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1271	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%.
1272	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1273	CETETH-10	E	Only for use in topical medicines for dermal application.
1274	CETETH-2	E	Only for use in topical medicines for dermal application.
1275	CETETH-24	E	Only for use in topical medicines for dermal application.
1276	CETETH-5	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1277	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1278	CETOMACROGOL 1000 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1279	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%.
1280	CETOSTEARYL ALCOHOL	E	
1281	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 %
1282	CETRARIA ISLANDICA	A, H	
1283	CETRIMONIUM BROMIDE	E	Only for use in topical

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
1284	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1285	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1286	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1287	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1288	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1289	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%.
1290	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1291	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%.
1292	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1293	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1294	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1295	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1296	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%.
1297	CETILPYRIDINIUM CHLORIDE	A, E	When used as an excipient ingredient, only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			When used as as an active ingredient: a) permitted for use only in medicated throat lozenges; b) the medicine must not contain more than 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).
1298	CHAENOMELES LAGENARIA	A, H	
1299	CHAENOMELES SPECIOSA	A, H	
1300	CHALK	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
1301	CHAMAECYPARIS LAWSONIANA	A, H	
1302	CHAMAELIRIUM LUTEUM	A, H	
1303	CHAMAEMELUM NOBILE	A, E, H	
1304	CHAMOMILE FLOWER DRY	A, E, H	
1305	CHAMOMILE OIL ENGLISH	A, E, H	

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Item	Ingredient name	Purpose	Specific requirements
1306	CHAMOMILE OIL GERMAN	A, E, H	
1307	CHANGIUM SMYRNIOIDES	A, H	
1308	CHEIRANTHUS CHEIRI	A, H	
1309	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'.
1310	CHELONE GLABRA	A, H	
1311	CHENOPODIUM ALBUM	A, H	
1312	CHENOPODIUM VULVARIA	A, H	
1313	CHERRY	E	
1314	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%.
1315	CHESTNUT SWEET	E, H	
1316	CHICKEN COMB EXTRACT	A	
1317	CHILLI	E, H	
1318	CHIMAPHILA UMBELLATA	A, H	Arbutin is a mandatory component of Chimaphila umbellata. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
1319	CHIONANTHUS VIRGINICA	A, H	
1320	CHLORELLA	E	Iodine is a mandatory component of Chlorella. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1321	CHLORELLA PYRENOIDOSA	E	
1322	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.
1323	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal

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Item	Ingredient name	Purpose	Specific requirements
			application.
1324	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1325	CHLOROACETAMIDE	E	Only for use in topical medicines for dermal application.
1326	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1327	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1328	CHLOROFORM	E	The residual solvent limit must be no more than 0.6 mg per recommended daily dose and the concentration in the medicine must be no more than 0.006%.
1329	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.

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Item	Ingredient name	Purpose	Specific requirements
1330	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1331	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1332	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1333	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1334	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1335	CHOCOLATE BROWN HT	E	Permitted for use only as a colour for oral and topical use.
1336	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1337	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1338	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.

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Item	Ingredient name	Purpose	Specific requirements
1339	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%.
1340	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1341	CHOLINE BITARTRATE	A, E	
1342	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1343	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%.
1344	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.
1345	CHONDRUS DRY	A, E, H	Iodine is a mandatory

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			<p>component of Chondrus dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
1346	CHONDRUS EXTRACT	A, E, H	<p>Iodine is a mandatory component of Chondrus extract.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
1347	CHROMIC CHLORIDE HEXAHYDRATE	A, H	<p>When used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic chloride hexahydrate.</p> <p>The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate.</p>

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			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).
1348	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.
1349	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.
1350	CHRYSANTHEMUM BALSAMITA	A, H	
1351	CHRYSANTHEMUM INDICUM	A, H	
1352	CHRYSANTHEMUM LEUCANTHEMUM	A, H	

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1353	CHRYSANTHEMUM MARSHALLII	A, H	
1354	CHRYSANTHEMUM SINENSE	A, H	
1355	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1356	CHRYSOSPORIUM PRUINOSUM	A, H	
1357	CIBOTIUM BAROMETZ	A, H	
1358	CICHORIUM INTYBUS	A, E, H	
1359	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1 mg of the dry herbal material.
1360	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.
1361	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.
1362	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

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			micrograms concentration of quinidine per g or mL.
1363	CINCHONA PUBESCENS	A, H	<p>Quinidine and quinine are mandatory components of <i>Cinchona pubescens</i>.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1364	CINEOLE	E	<p>In liquid preparations when the concentration of cineole in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
1365	CINNAMALDEHYDE	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>
1366	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>
1367	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</p>

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			<p>25 millilitres and the following warning statements must be included on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist'. <p>In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container.</p> <p>In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert 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</p>

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

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			<p>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>
1368	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>
1369	CINNAMOMUM VERUM	A, E, H	<p>When used as an active ingredient coumarin is a mandatory component of Cinnamomum verum and the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is essential oil, distillate, fixed oil or infused oil.</p> <p>The concentration of cinnamon bark oil in the medicine must be no more than 2%.</p> <p>Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the</p>

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			<p>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>
1370	CINNAMON BARK OIL	A, E, H	<p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active</p>

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			ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1371	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>
1372	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"> - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. <p>When the concentration of cinnamon leaf oil in the preparation is more than 25%</p>

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			<p>and the nominal capacity of the container is no more than 15 mL, the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1373	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>
1374	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>

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Item	Ingredient name	Purpose	Specific requirements
1375	CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1376	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%.
1377	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%.
1378	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%.

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1379	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%.
1380	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%.
1381	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%.
1382	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 be no more than 6%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine

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			<p>must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).
1383	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1384	CIS-3-HEXEN-1-OL	E	<p>Permitted for use only in combination with other</p>

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			permitted ingredients as a flavour or a fragrance. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1385	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%.
1386	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%.
1387	CIS-3-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1388	CIS-3-HEXENYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1389	CIS-3-HEXENYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1390	CIS-3-HEXENYL 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%.
1391	CIS-3-HEXENYL HEXANOATE	E	Permitted for use only in combination with 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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1392	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%.
1393	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%.
1394	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%.
1395	CIS-3-HEXENYL METHYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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			1%.
1396	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%.
1397	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%.
1398	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%.
1399	CIS-6-NONEN-1-AL	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%.
1400	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%.
1401	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%.
1402	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%.

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1403	CIS-JASMONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1404	CISTANCHE DESERTICOLA	A, H	
1405	CISTANCHE SALSA	A, H	
1406	CISTUS LADANIFERUS	A, E, H	
1407	CITRAL	E	
1408	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%.
1409	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%.
1410	CITRIC ACID	A, E	Where intended for topical use, sponsors should consider the

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			<p>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"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under 12 years is not recommended'
1411	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</p>

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			<p>statements on the medicine label:</p> <ul style="list-style-type: none"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under 12 years is not recommended'
1412	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"> - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or

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			words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children under 12 years is not recommended.'
1413	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1414	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%.
1415	CITRON	E	
1416	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'.

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1417	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%.
1418	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%.
1419	CITRONELLIC 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%.
1420	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

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Item	Ingredient name	Purpose	Specific requirements
			<p>a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
1421	CITRONELLYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1422	CITRONELLYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1423	CITRONELLYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more 1%.
1424	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%.
1425	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%.
1426	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%.
1427	CITRONELLYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1428	CITRONELLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1429	CITRULLUS COLOCYNTHIS	H	Only for use as an active homoeopathic ingredient. When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).
1430	CITRULLUS VULGARIS	A, H	
1431	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.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1432	CITRUS AURANTIUM	A, E, H	<p>Oxedrine is a mandatory component of Citrus aurantium when intended for internal use.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.</p> <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1433	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1434	CITRUS CHACHIENSIS	A, H	
1435	CITRUS EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1436	CITRUS FIBRE	E	
1437	CITRUS LIMETTA	A, H	When the plant preparation is

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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.
1438	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 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.
1439	CITRUS MAXIMA	A, H	

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Item	Ingredient name	Purpose	Specific requirements
1440	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.
1441	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%.
1442	CITRUS RETICULATA	A, E, H	Oxedrine is a mandatory component of Citrus reticulata when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1443	CITRUS SINENSIS	A, E, H	Oxedrine is a mandatory component of Citrus sinensis when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.

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Item	Ingredient name	Purpose	Specific requirements
1444	CITRUS SINENSIS PEEL MOLASSES EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1445	CITRUS UNSHIU	A, E, H	Oxedrine is a mandatory component of Citrus unshiu when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1446	CITRUS X PARADISI	A, E, H	
1447	CITRUS X WILSONII	A, H	
1448	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%.
1449	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%.
1450	CIVET SYNTHETIC	E	Permitted for use only in

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1451	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%.
1452	CLARY OIL	A, E, H	
1453	CLEMATIS ARMANDII	A, H	
1454	CLEMATIS CHINENSIS	A, E, H	
1455	CLEMATIS RECTA	A, H	
1456	CLEMATIS VITALBA	A, H	
1457	CLERODENDRUM TRICHOTOMUM	A, H	
1458	CLINOPODION POLYCEPHALUM	A, H	
1459	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1460	CLIVER HERB DRY	A, H	
1461	CLIVER HERB POWDER	A, H	
1462	CLOVE BUD OIL	A, E, H	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.

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Item	Ingredient name	Purpose	Specific requirements
			<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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
1463	CLOVE DRY	A, E, H	
1464	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%</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <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> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
1465	CLOVE OIL TERPENES	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>
1466	CLOVE POWDER	A, E, H	
1467	CLOVE STEM OIL	A, E, H	When the concentration of Clove Stem Oil in the preparation is more than 25%,

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
1468	CLUPEA HARENGUS LIPID EXTRACT	A	<p>Only for use in oral medicines.</p> <p>The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty</p>

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Item	Ingredient name	Purpose	Specific requirements
			acids.
1469	CNICUS BENEDICTUS	A, H	
1470	CNICUS JAPONICUS	A, H	
1471	CNIDIUM MONNIERI	A, H	
1472	CNIDIUM OFFICINALE	A, H	
1473	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1474	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1475	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1476	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%.
1477	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 b) no more than 15% in wash

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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.
1478	COCCOLOBIA UVIFERA	A, H	
1479	COCCULUS ORBICULATUS	A, H	
1480	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1481	COCHLEARIA OFFICINALIS	A, H	
1482	COCILLANA DRY	A, H	
1483	COCILLANA POWDER	A, H	
1484	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1485	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.
1486	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%
1487	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.
1488	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%.
1489	COCOA POWDER	A, E, H	
1490	COCOLYCERIDES	E	
1491	COCONUT	E	
1492	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1493	COCONUT OIL	A, E, H	
1494	COCOS NUCIFERA	A, E, H	
1495	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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. - (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. - (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>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1496	CODONOPSIS LANCEOLATA	A, H	
1497	CODONOPSIS PILOSULA	A, H	
1498	CODONOPSIS TANGSHEN	A, H	
1499	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 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"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <p>may comply with the requirements in paragraphs (a) to (e) below.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<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"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1500	COFFEA CANEPHORA	A, E, H	<p>Caffeine is a mandatory 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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <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</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <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"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1501	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</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <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</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <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"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee)

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1502	COFFEE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1503	COFFEE SOLID EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1504	COGNAC OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1505	COGNAC OIL GREEN	A, E, H	
1506	COGNAC OIL WHITE	E	Permitted for use only in combination with other

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Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1507	COIX LACHRYMA-JOBI	A, H	
1508	COLA ACUMINATA	A, E, H	Caffeine is a mandatory component of Cola acuminata. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the

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			<p>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"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine

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			<p>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> <ul style="list-style-type: none"> - (CAFFLMT) ‘Limit the use of caffeine-containing products (including tea and coffee) when taking this product.’ - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).
1509	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</p>

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			<p>that contains the ingredient that:</p> <ul style="list-style-type: none"> - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. <p>A medicine that contains the ingredient and that:</p> <ul style="list-style-type: none"> - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; <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</p>

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			<p>oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (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.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' 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: <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1510	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.

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1511	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1512	COLLAGEN	E	
1513	COLLINSONIA CANADENSIS	A, H	
1514	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1515	COLOPHONY	A, E, H	
1516	COMMIPHORA HABESSINICA	A, H	
1517	COMMIPHORA KATAF	A, H	
1518	COMMIPHORA MYRRHA	A, E, H	
1519	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1520	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1521	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

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			seafood ¹ .
1522	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).
1523	CONIFER PHYTOSTEROL COMPLEX	A	
1524	CONIOSELIMUM UNIVITTATUM	A, H	
1525	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.
1526	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry <i>Convallaria majalis</i> in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1527	CONYZA CANADENSIS	A, H	
1528	COPAIBA OIL	A, E, H	
1529	COPAIFERA LANGSDORFFII	A, E, H	
1530	COPERNICIA CERIFERA	A, E, H	
1531	COPOVIDONE	E	
1532	COPPER	H	Only for use as an active homoeopathic ingredient. When for internal use the maximum daily dose must not contain more than 5 mg of

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			copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1533	COPPER (II) ASPARTATE	A, H	Copper is a mandatory component of copper (II) aspartate. The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate. 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.
1534	COPPER (II) GLYCINATE	A, H	Copper is a mandatory component of copper (II) glycinate. The percentage of copper from copper (II) glycinate should be 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.

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1535	COPPER (II) LYSINATE	A, H	<p>Copper is a mandatory component of copper (II) lysinate.</p> <p>The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1536	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1537	COPPER CHLOROPHYLL	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>
1538	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1539	COPPER GLUCONATE	A, E	<p>Copper is a mandatory component of copper gluconate.</p> <p>The percentage of copper from copper gluconate should be</p>

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			<p>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>
1540	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>
1541	COPTIS CHINENSIS	A, H	
1542	COPTIS JAPONICA	A, H	
1543	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>
1544	CORDYCEPS SINENSIS	A, E, H	<p>Must not contain material of animal origin such as insect larvae.</p>
1545	CORIANDER DRY	A, H	
1546	CORIANDER OIL	A, E, H	

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1547	CORIANDER POWDER	A, H	
1548	CORIANDRUM SATIVUM	A, E, H	
1549	CORN GLYCERIDES	E	
1550	CORN SILK DRY	A, H	
1551	CORN SILK POWDER	A, H	
1552	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%.
1553	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%.
1554	CORNUS FLORIDA	A, H	
1555	CORNUS OFFICINALIS	A, H	
1556	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1557	CORYDALIS AMBIGUA	A, E, H	
1558	CORYDALIS BUNGEANA	A, H	
1559	CORYDALIS CAVA	A, H	
1560	CORYDALIS FABACEA	A, H	
1561	CORYDALIS FORMOSA	A, H	
1562	CORYDALIS TURTSCHANINOVII	A, H	

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1563	CORYLUS AMERICANA	A, H	
1564	CORYLUS AVELLANA	A, H	
1565	CORYMBIA CITRIODORA	A, E, H	<p>Cineole is a mandatory component of Corymbia citriodora.</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>
1566	CORYMBIA FICIFOLIA	A, H	<p>Cineole is a mandatory component of Corymbia ficifolia.</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>
1567	COSMOS BIPINNATUS	A, H	
1568	COSTUS ROOT OIL	A, H	
1569	COSTUS SPICATUS	A, H	
1570	COTTONSEED OIL	A, E, H	
1571	COUCH GRASS RHIZOME DRY	A, H	
1572	COUCH GRASS RHIZOME POWDER	A, H	
1573	COUMARIN	H	Only for use as an active homoeopathic ingredient.

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			The concentration in the medicine must be no more than 0.001%.
1574	CRANBERRY	E	
1575	CRATAEGUS CUNEATA	A, E, H	
1576	CRATAEGUS LAEVIGATA	A, E, H	
1577	CRATAEGUS MONOGYNA	A, E, H	
1578	CRATAEGUS PINNATIFIDA	A, E, H	
1579	CRATEVA MAGNA	A, E, H	
1580	CREATINE	A, E	
1581	CREATINE MONOHYDRATE	A, E	
1582	CREATINE PHOSPHATE	A, E	
1583	CREATININE	E	Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1584	CREOSOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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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1585	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1586	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%.
1587	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%.
1588	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%.
1589	CROCUS SATIVUS	A, H	
1590	CROSCARMELLOSE SODIUM	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine

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			label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
1591	CROSPROVIDONE	E	
1592	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1593	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1594	CRYPTOMERIA JAPONICA	A, H	
1595	CUBEB OIL	A, H	
1596	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%.
1597	CUCUMBER	E	
1598	CUCUMIS MELO	A, H	
1599	CUCUMIS SATIVUS	A, E, H	
1600	CUCURBITA MAXIMA	A, E, H	
1601	CUCURBITA MOSCHATA	A, H	
1602	CUCURBITA PEPO	A, E, H	

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1603	CULLEN CORYLIFOLIUM	A, H	
1604	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%.
1605	CUMIN OIL	A, E, H	
1606	CUMINALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1607	CUMINUM CYMINUM	A, H	
1608	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%.
1609	CUPRESSUS ARIZONICA	A, H	
1610	CUPRESSUS FUNEBRIS	A, E, H	
1611	CUPRESSUS MACROCARPA	A, H	

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1612	CUPRESSUS SEMPERVIRENS	A, E, H	
1613	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1614	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1615	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.
1616	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate. The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate. 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

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			more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.
1617	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>
1618	CUPRIC SULFATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate.</p> <p>The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>

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1619	CUPRIC SULFATE MONOHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate.</p> <p>The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.</p>
1620	CUPRIC SULFATE PENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no</p>

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			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.
1621	CURCULIGO ORCHIOIDES	A, H	
1622	CURCUMA AROMATICA	A, H	
1623	CURCUMA LONGA	A, E, H	
1624	CURCUMA XANTHORRHIZA	A, H	
1625	CURCUMA ZEDOARIA	A, H	
1626	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1627	CUSCUTA EPITHYMUM	A, H	
1628	CUSCUTA EUROPAEA	A, H	
1629	CUSCUTA HYGROPHILAE	A, H	
1630	CUSCUTA RACEMOSA	A, H	
1631	CUSPARIA FEBRIFUGA	A, H	
1632	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1633	CYANOCOBALAMIN	A, E, H	
1634	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. 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 the medicine must be no more than 5%.
1635	CYATHULA OFFICINALIS	A, H	
1636	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1637	CYCLAMEN PURPURASCENS	A, H	
1638	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%.
1639	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%.
1640	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%.

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1641	CYCLOHEXANEETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1642	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%.
1643	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%.
1644	CYCLOHEXYL PHENETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1645	CYCLOHEXYL SALICYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1646	CYCLOHEXYLETHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1647	CYCLOMETHICONE	E	<p>Only for use as an excipient ingredient in topical medicines.</p>
1648	CYCLOPENTADECANONE	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1649	CYDONIA OBLONGA	A, H	
1650	CYMBOPOGON FLEXUOSUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1651	CYMBOPOGON MARTINI	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1652	CYMBOPOGON NARDUS	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1653	CYMBOPOGON SCHOENANTHUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1654	CYNANCHUM ATRATUM	A, H	
1655	CYNANCHUM STAUNTONII	A, E, H	
1656	CYNARA SCOLYMUS	A, E, H	
1657	CYNODON DACTYLON	A, E, H	
1658	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1659	CYPERUS LONGUS	A, H	
1660	CYPERUS ROTUNDUS	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1661	CYPRESS OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1662	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1663	CYSTEINE	A	When the ingredient is included in a medicine for internal use that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The maximum recommended daily dose must contain no more than 450 mg of cysteine. b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1664	CYSTEINE HYDROCHLORIDE	A	<p>When the ingredient is included in a medicine for internal use that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). <p>a) The maximum recommended daily dose must contain no more than 585 mg of cysteine hydrochloride.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1665	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	<p>When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient and the total flavour proprietary excipient formulation concentration in a medicine must not be more than 5%.</p> <p>In addition, when the</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>ingredient is included in a medicine for internal use that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). <p>a) The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1666	CYSTINE	A	<p>When the ingredient is included in a medicine for internal use that is listed in the Register:</p> <ul style="list-style-type: none"> - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>under (a) & (b); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b).</p> <p>a) The maximum recommended daily dose must contain no more than 450 mg of cystine.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1667	CYTISUS SCOPARIUS	A, H	<p>Sparteine is a mandatory component of Cytisus scoparius.</p> <p>The concentration of Sparteine in the medicine must be no more than 0.001%.</p>
1668	D-ALPHA-TOCOPHEROL	A, E	
1669	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1670	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1671	D-ALPHA-TOCOPHERYL PHOSPHATES	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 3%.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1672	D-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1673	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%.
1674	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%.
1675	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1676	D-PULEGONE	E	Permitted for use only in combination with 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 concentration of d-pulegone in the medicine must not be more than 4%.
1677	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.
1678	DACTYLIS GLOMERATA	A, H	
1679	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1680	DAEMONOROPS DRACO	A, E, H	
1681	DAHLIA PINNATA	A, H	
1682	DALBERGIA ODORIFERA	A, H	
1683	DAMIANA LEAF POWDER	A	
1684	DANDELION LEAF DRY	A, H	
1685	DANDELION LEAF POWDER	A, H	

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Item	Ingredient name	Purpose	Specific requirements
1686	DANDELION ROOT DRY	A, H	
1687	DANDELION ROOT POWDER	A, H	
1688	DAPHNE GENKWA	A, H	
1689	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1690	DATE	E	
1691	DATURA STRAMONIUM	A, H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1692	DAUCUS CAROTA	A, E, H	
1693	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%.
1694	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>application and not be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1695	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>
1696	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>
1697	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			1%.
1698	DECAHYDROSPIRO(FURAN-2(3H),5'-(4,7)METHANO(5H)INDENE)	E	Permitted for use only in combination with other permitted ingredients as a fragrance. The total fragrance concentration in a medicine must be no more than 1%.
1699	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%.
1700	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%.
1701	DECANAL DIMETHYL ACETAL	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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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
1702	DECARBOXY CARNOISINE DIHYDROCHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05.
1703	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%.
1704	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%.
1705	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
1706	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1707	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1708	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%.
1709	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1710	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>),

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
1711	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
1712	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>
1713	DEHYDROACETIC ACID	E	<p>Only for use in topical medicines for dermal application.</p>
1714	DEHYDROMENTHOFUROLACT ONE	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>
1715	DEHYDROXANTHAN GUM	E	<p>Only for use in topical medicines for dermal application and not to be</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1716	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1717	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%.
1718	DELTA-DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1719	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1720	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%.
1721	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%.
1722	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%.

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Item	Ingredient name	Purpose	Specific requirements
1723	DELTA-TOCOPHEROL	E	
1724	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%.
1725	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1726	DENATONIUM BENZOATE	E	
1727	DENDROBIUM NOBILE	A, H	
1728	DESCURAINIA SOPHIA	A, H	
1729	DESMODIUM STYRACIFOLIUM	A, H	
1730	DESMODIUM TRIQUETUM	A, H	
1731	DEVIL'S CLAW TUBER DRY	A, H	
1732	DEVIL'S CLAW TUBER POWDER	A, H	
1733	DEXPANTHENOL	A, E	
1734	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 0.3%.
1735	DEXTRAN 40	A, E	

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Item	Ingredient name	Purpose	Specific requirements
1736	DEXTRATES	E	
1737	DEXTRIN	E	
1738	DEXTRIN PALMITATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1739	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A	<p>Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil.</p> <p>Only for use in oral medicines when in combination with other active or excipient ingredients.</p> <p>The ratio of DHA to EPA must be 2:1.</p>
1740	DI-C12-13 ALKYL MALATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
1741	DI-C12-15 ALKYL FUMARATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%.
1742	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%.
1743	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%.
1744	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%.
1745	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1746	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%.
1747	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1748	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1749	DIANTHUS SUPERBUS	A, H	
1750	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1751	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1752	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

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Item	Ingredient name	Purpose	Specific requirements
			calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.
1753	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1754	DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate trihydrate. 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.
1755	DIBASIC SODIUM PHOSPHATE	A, E, H	When used as an active ingredient and the preparation

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1756	DIBASIC SODIUM PHOSPHATE DIHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1757	DIBASIC SODIUM PHOSPHATE DODECAHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dodecahydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of</p>

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			this medicine contains [state quantity and units] of sodium (or words to that effect).'
1758	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1759	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

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>dibasic sodium phosphate monohydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1760	DIBENZYL KETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1761	DIBUTYL ADIPATE	E	<p>Only for use in topical medicines for dermal application.</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1762	DIBUTYL PHTHALATE	E	Only for use in topical medicines for dermal application.
1763	DIBUTYL SEBACATE	E	
1764	DIBUTYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1765	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1766	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1767	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%.
1768	DICETYL PHOSPHATE	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
1769	DICHLOROBENZYL ALCOHOL	E	
1770	DICHLOROMETHANE	E	The concentration in the medicine must be no more than 0.06%. The residual solvent limit for Dichloromethane is 6 mg per recommended daily dose.
1771	DICTAMNUS ALBUS	A, H	
1772	DICTAMNUS DESYCARPUS	A, H	
1773	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%.
1774	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1775	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1776	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%.
1777	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%.
1778	DIETHYL PHTHALATE	E	
1779	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%.
1780	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicine must be no more than 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).
1781	DIETHYLAMINOMETHYLCOUMARIN	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
1782	DIETHYLDIMETHYL-2-	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	CYCLOHEXENONE		combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1783	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%.
1784	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1785	DIETHYLHEXYL CARBONATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1786	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1787	DIETHYLHEXYL SYRINGYLIDENEMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			for use in the eye. The concentration in the medicine must be no more than 1%.
1788	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).
1789	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 bedding or on large areas of the body, especially if you keep using it for a long time.'
1790	DIGITALIS LEAF DRY	A, H	The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			10mg/L or 0.001%.
1791	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%.
1792	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%.
1793	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1794	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%.
1795	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%.
1796	DIHYDRO TERPINYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1797	DIHYDRO-ALPHA-TERPINEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1798	DIHYDRO-BETA-IONONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1799	DIHYDRO-ISOJASMONE	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>
1800	DIHYDROACTINIDIOLIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1801	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%.
1802	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%.
1803	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%.
1804	DIHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1805	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%.
1806	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%.
1807	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%.
1808	DIHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1809	DIHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1810	DIHYDROMYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1811	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1812	DIISOPROPYL ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1813	DIISOPROPYL SEBACATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1814	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1815	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1816	DILL HERB OIL	A, E, H	
1817	DILL SEED OIL	A, E, H	
1818	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%.
1819	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1820	DIMETHICONE 12500	E	
1821	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%.
1822	DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1823	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%.
1824	DIMETHICONE/METHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1825	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%.
1826	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%.
1827	DIMETHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1828	DIMETHYL BENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1829	DIMETHYL BENZYL CARBINYL 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%.
1830	DIMETHYL BENZYL CARBINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1831	DIMETHYL BENZYL CARBINYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1832	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
1833	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%.
1834	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%.
1835	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%.
1836	DIMETHYL SULFATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1837	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%.
1838	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1839	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%.
1840	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%.
1841	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	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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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more than 1%.
1842	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1843	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1844	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%.
1845	DIMETICONE 10	E	
1846	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1847	DIMETICONE 1000	E	
1848	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%
1849	DIMETICONE 2	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			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%.
1850	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1851	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1852	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%.
1853	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.
1854	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1855	DIMETICONE 450	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			application.
1856	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1857	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1858	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1859	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%.
1860	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1861	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1862	DIMETICONE CROSSPOLYMER-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1863	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%.
1864	DIMETICONOL	E	Only for use in topical medicines for dermal application.
1865	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%.
1866	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1867	DIMOCARPUS LONGAN	A, H	
1868	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1869	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1870	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1871	DIOCTYL TEREPHTHALATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1872	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%
1873	DIOLAMINE CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			for use in the eye.
1874	DIOSCOREA COLLETTII	A, H	
1875	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1876	DIOSCOREA JAPONICA	A, H	
1877	DIOSCOREA OPPOSITIFOLIA	A, H	
1878	DIOSCOREA POLYSTACHYA	A, H	
1879	DIOSCOREA SEPTEMLOBA	A, H	
1880	DIOSCOREA VILLOSA	A, E, H	
1881	DIOSPYROS KAKI	A, E, H	
1882	DIOXYBENZONE	A	<p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in the medicine must be no more than 3%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (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).
1883	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin.</p> <p>The concentration in the</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 0.5%.
1884	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSOSTEARATE	E	Only for use in topical medicines for dermal 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%.
1885	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%.
1886	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1887	DIPHENYL METHANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1888	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
1889	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%.
1890	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%.
1891	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1892	DIPROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.2%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1893	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1894	DIPSACUS ASPER	A, H	
1895	DIPSACUS JAPONICUS	A, H	
1896	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%.
1897	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1898	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1899	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%.
1900	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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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			14%.
1901	DISODIUM EDETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
1902	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%.
1903	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%.
1904	DISODIUM INOSINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1905	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%.
1906	DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1907	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1908	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1909	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (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).
1910	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1911	DISODIUM RUTINYL DISULFATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.05%.</p>
1912	DISODIUM STEAROYL	E	<p>Only for use in topical medicines for dermal</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
	GLUTAMATE		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%.
1913	DISPERSIBLE CELLULOSE	E	
1914	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%.
1915	DISTEARDIMONIUM HECTORITE	E	Only for use in topical medicines for dermal application and not to be included for medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1916	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1917	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1918	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%.
1919	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%.
1920	DL-ALPHA-TOCOPHEROL	A, E	
1921	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1922	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1923	DL-BORNEOL	E	
1924	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1925	DL-THREONINE	A, E	
1926	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.
1927	DOCUSATE SODIUM	E	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1928	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%.
1929	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%.
1930	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%.
1931	DODECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1932	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%.
1933	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%.
1934	DOLICHOS LABLAB	A, H	
1935	DOLOMITE	A, E, H	
1936	DRACAENA DRACO	A, H	
1937	DRIED BUTTERMILK	E	
1938	DRIED CALCIUM SULFATE	A, E, H	
1939	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
1940	DRIMIA INDICA	A, H	
1941	DRIMIA MARITIMA	A, H	
1942	DROMETRIZOLE TRISILOXANE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (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).
1943	DROSERANGLICA	A, H	
1944	DROSERABURMANNI	A, H	
1945	DROSERAINTERMEDIA	A, H	
1946	DROSERARAMENTACIA	A, H	
1947	DROSERAROTUNDIFOLIA	A, E, H	
1948	DROSERAROTUNDIFOLIAMIS	A, H	
1949	DRYNARIAFORTUNEI	A, H	
1950	DRYOBALANOPSAROMATICA	A, H	
1951	DRYOPTERISFILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1952	DULACIAINOPIFLORA	A, H	
1953	DUNALIELLASALINA	A, E, H	
1954	DUPICAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
1955	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%.
1956	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%.
1957	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1958	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>following warning statements on the label:</p> <ul style="list-style-type: none"> - (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).
1959	ECHINACEA ANGUSTIFOLIA	A, E, H	
1960	ECHINACEA PALLIDA	A, E, H	
1961	ECHINACEA PURPUREA	A, E, H	
1962	ECHINOPA SPINOSISSIMUS	A, H	
1963	ECLIPTA PROSTRATA	A, H	
1964	ECTOIN	E	<p>Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1965	EDETATE SODIUM	E	<p>Only for use in topical medicines for dermal application and nasal medicines.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1966	EDETIC ACID	E	<p>The concentration in the medicine must be no more than 0.25%.</p>

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Item	Ingredient name	Purpose	Specific requirements
1967	EGG LECITHIN	A, E	
1968	EGGSHELL MEMBRANE HYDROLYSATE	A	
1969	EGGSHELL MEMBRANE POWDER	A	
1970	EICHHORNIA CRASSIPES	A, H	
1971	ELAEAGNUS ANGUSTIFOLIA	A, H	
1972	ELAEIS GUINEENSIS	A, E, H	
1973	ELASTIN	E	Only for use in topical medicines for dermal application.
1974	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%.
1975	ELDER FLOWER BLACK DRY	A, E, H	
1976	ELDER FLOWER BLACK POWDER	A, H	
1977	ELECAMPANE RHIZOME DRY	A, H	
1978	ELECAMPANE RHIZOME POWDER	A, H	
1979	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1980	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%.
1981	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%.
1982	ELEOCHARIS DULCIS	A, H	
1983	ELETTARIA CARDAMOMUM	A, E, H	
1984	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1985	ELEUTHEROCOCCUS ROOT DRY	A, H	
1986	ELEUTHEROCOCCUS ROOT POWDER	A, H	
1987	ELEUTHEROCOCCUS SENTICOSUS	A, H	
1988	ELSHOLTZIA SPLENDENS	A, H	
1989	ELYMUS REPENS	A, E, H	
1990	EMU OIL	A, E	Emu oil ingredients must meet the following two requirements: 1) the manufacturing process is to include steps such as

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Item	Ingredient name	Purpose	Specific requirements
			<p>cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and</p> <p>2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption.</p>
1991	EMULSIFYING WAX	E	
1992	ENOXOLONE	E	Only for use in topical medicines for dermal application.
1993	ENZYME MODIFIED CREAM	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1994	EPHEDRA DISTACHYA	A, H	<p>Ephedrine and Pseudoephedrine (of Ephedra distachya) are mandatory components of Ephedra distachya and must be declared in the application.</p> <p>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%.</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1995	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%.
1996	EPIGAEA REPENS	A, H	
1997	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 5% for a 1:20 extract in 100% water.
1998	EPILOBIUM PALUSTRE	A, H	
1999	EPILOBIUM PARVIFLORUM	A, H	
2000	EPIEDIUM BREVICORNU	A, H	
2001	EPIEDIUM GRANDIFLORUM	A, H	
2002	EPIEDIUM SAGITTATUM	A, H	
2003	EPOXY CEDRENE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2004	EQUISETUM ARVENSE	A, E, H	
2005	EQUISETUM HIEMALE	A, H	
2006	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2007	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%.
2008	ERIGERON BREVISCAPUS	A, H	
2009	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components. The concentration of amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2010	ERIOCAULON BUERGERIANUM	A, H	
2011	ERIODICTYON CRASSIFOLIUM	A, H	
2012	ERIODICTYON GLUTINOSUM	A, H	
2013	ERODIUM CICUTARIUM	A, H	
2014	ERUCA SATIVA	A, H	
2015	ERYTHORBIC ACID	E	
2016	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%.
2017	ERYTHROSINE	E	Only for use as a colour for oral and topical use.
2018	ERYTHROSINE ALUMINIUM LAKE	E	Only for use as a colour for oral and topical use.
2019	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: - (EYE) 'Avoid contact with eyes'.
2020	ESCHSCHOLZIA CALIFORNICA	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2021	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2022	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>
2023	ETHANOL ABSOLUTE	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>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2024	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2025	ETHOHEXADIOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (EHEXAD) 'Contains ethohexadiol' (or words to that effect).
2026	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2027	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%.
2028	ETHOXYMETHOXY CYCLODODECANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Item	Ingredient name	Purpose	Specific requirements
2029	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%.
2030	ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2031	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%.
2032	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%.
2033	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2034	ETHYL 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%.
2035	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%.
2036	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%.
2037	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
2038	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%.
2039	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%.
2040	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%.
2041	ETHYL 3-	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	MERCAPTOPROPIONATE		combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2042	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%.
2043	ETHYL 4,7-OCTADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2044	ETHYL ACETATE	E	The residual solvent limit for ethyl acetate is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
2045	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2046	ETHYL ACRYLATE	E	
2047	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%.
2048	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%.
2049	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more 1%.
2050	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%.
2051	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)'.
2052	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 fragrance concentration in a medicine must be no more 1%.
2053	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in 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%.
2054	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%.
2055	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%.
2056	ETHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2057	ETHYL CROTONATE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2058	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%.
2059	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%.
2060	ETHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.
2061	ETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2062	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%.
2063	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more 1%.
2064	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%.
2065	ETHYL LEVULATE	E	Permitted for use only in combination with 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 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%.
2067	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2068	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%.
2069	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2070	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2071	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%.
2072	ETHYL MALTOL	E	
2073	ETHYL MENTHANE CARBOXAMIDE	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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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
2074	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2075	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%.
2076	ETHYL METICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2077	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more 1%.
2078	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%.
2079	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%.
2080	ETHYL OXYHYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2081	ETHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
2082	ETHYL PARA-ANISATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2083	ETHYL PELARGONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
2084	ETHYL 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

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Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more 1%.
2085	ETHYL 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%.
2086	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%.
2087	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%.
2088	ETHYL SEBACATE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2089	ETHYL 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%.
2090	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%.
2091	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%.
2092	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

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Item	Ingredient name	Purpose	Specific requirements
			flavour concentration in a medicine must be no more than 5%.
2093	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%.
2094	ETHYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2095	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%.
2096	ETHYL VANILLIN	E	
2097	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

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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 1%.
2098	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%.
2099	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%.
2100	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%.
2101	ETHYLCELLULOSE	E	
2102	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

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Item	Ingredient name	Purpose	Specific requirements
			1%.
2103	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%.
2104	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2105	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%.
2106	ETHYLENE/VINYL ACETATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 16%.
2107	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2108	ETHYLENEDIAMINE/HYDROGE	E	Only for use in topical

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Item	Ingredient name	Purpose	Specific requirements
	NATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE		medicines for dermal 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%.
2109	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%.
2110	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%.
2111	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. The concentration in the medicine must be no more than 10%.
2112	ETHYLHEXYL TRIAZONE	A	Only for use as an active ingredient in sunscreens for

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Item	Ingredient name	Purpose	Specific requirements
			<p>dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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). <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).
2113	ETHYLHEXYLGLYCERIN	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 5%.
2114	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2115	EUCALYPTUS DIVES	A, E, H	Cineole is a mandatory component of Eucalyptus dives. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, 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

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Item	Ingredient name	Purpose	Specific requirements
			millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2116	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 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>
2117	EUCALYPTUS GLOBULUS	A, E, H	Cineole is a mandatory

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Item	Ingredient name	Purpose	Specific requirements
			<p>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 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>
2118	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>

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Item	Ingredient name	Purpose	Specific requirements
			<p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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>
2119	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
2120	EUCALYPTUS RADIATA	A, E, H	<p>Cineole is a mandatory component of <i>Eucalyptus radiata</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning

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Item	Ingredient name	Purpose	Specific requirements
			<p>statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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>
2121	EUCALYPTUS ROSTRATA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus rostrata.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ul style="list-style-type: none"> a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			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.
2122	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> <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</p>

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Item	Ingredient name	Purpose	Specific requirements
			to 25 millilitres the medicine must also have a child resistant closure.
2123	EUCOMMIA ULMOIDES	A, H	
2124	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"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ <p>c) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15mL, a restricted flow insert</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>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"> - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2125	EUGENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2126	EUONYMUS ATROPURPUREUS	A, H	
2127	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2128	EUPATORIUM FORTUNEI	A, H	
2129	EUPATORIUM JAPONICUM	A, H	
2130	EUPATORIUM PERFOLIATUM	A, H	
2131	EUPATORIUM PURPUREUM	A, H	
2132	EUPHAUSIA SUPERBA OIL	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (SFOOD) 'Derived from

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			seafood' or - (SHELL) 'Contains crustacean shellfish'.
2133	EUPHORBIA CYPARISSIAS	A, H	
2134	EUPHORBIA DRY	A, H	
2135	EUPHORBIA HETERODOXA	A, H	
2136	EUPHORBIA HIRTA	A, H	
2137	EUPHORBIA LATHYRIS	A, H	Levodopa (of Euphorbia lathyris) is a mandatory component of Euphorbia lathyris. The concentration of Levodopa (of Euphorbia lathyris) in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%.
2138	EUPHORBIA PEKINENSIS	A, H	
2139	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2140	EUPHORBIA POWDER	A, H	
2141	EUPHORBIA RESINIFERA	A, H	
2142	EUPHORBIA SIEBOLDIANA	A, H	
2143	EUPHRASIA OFFICINALIS	A, H	
2144	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2145	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.

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

Volume 2

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2146	EURYALE FERROX	A, H	
2147	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'.
2148	EVENING PRIMROSE OIL	A, E, H	
2149	EVERNIA PRUNASTRA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
