

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

Volume 2

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
731	BACKHOUSIA CITRIODORA	A, E, H	<p>The herbal substance must be derived from leaf oil only.</p> <p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (IRRIT) 'If irritation develops - discontinue use' - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
732	BACOPA MONNIERI	A, H	
733	BALLOTA NIGRA	A, H	
734	BALM OF GILEAD BUD DRY	A, H	
735	BALM OF GILEAD BUD POWDER	A, H	
736	BALSAM COPAIBA	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
737	BAMBUSA BREVIFLORA	A, E, H	
738	BAMBUSA TEXTILIS	A, H	
739	BANANA	E	
740	BANANA DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
741	BAPTISIA CONFUSA	A, H	
742	BAPTISIA TINCTORIA	A, H	
743	BARBAREA VULGARIS	A, H	
744	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
745	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
746	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
747	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other

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			<p>than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
748	BARLEY BRAN	E	<p>Gluten is a mandatory component of Barley bran when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert name of ingredient]' or words to that effect.</p>
749	BARLEY GERM	E	<p>Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal.</p> <p>When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label:</p> <p>- (GLUTEN) 'Contains [insert</p>

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			name of ingredient]' or words to that effect.
750	BARLEY LEAF	E	
751	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
752	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
753	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%.
754	BASIC VIOLET 11:1	E	Only for use as a colour in topical medicines for dermal application and not intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
755	BASIL OIL COMOROS	A, E, H	Methyl chavicol is a mandatory component of Basil oil Comoros. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the

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

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757	BASSIA SCOPARIA	A, H	
758	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
759	BAY LEAF	E	
760	BAY OIL	A, E, H	<p>When the concentration of Bay oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is no more than 15 mL, there must be a restricted flow insert fitted on the container.</p> <p>When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
761	BEESWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
762	BEET RED	E	Permitted for use only as a colour for oral and topical use.
763	BEETROOT	E, H	
764	BEGONIA FIMBRISTIPULA	A, H	
765	BEHENETH-10	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are to be kept below the level of detection.
766	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
767	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.

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

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

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			<p>in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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).
775	BENINCASA HISPIDA	A, E, H	
776	BENTONITE	E	
777	BENZALDEHYDE	E	
778	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</p>

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			medicine must be no more than 5%.
779	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%.
780	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.
781	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.
782	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%.

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783	BENZOIN SIAM	A, E, H	
784	BENZOIN SUMATRA	A, E, H	
785	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%.
786	BENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
787	BENZYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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788	BENZYL ALCOHOL	E	
789	BENZYL BENZOATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing benzoates require the warning statement:</p> <p>- (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.</p>
790	BENZYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
791	BENZYL CINNAMATE	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 0.15%.</p>

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792	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
793	BENZYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
794	BENZYL ISOAMYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
795	BENZYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
796	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>
797	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>
798	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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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			medicine must be no more 1%.
799	BENZYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
800	BENZYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
801	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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802	BENZYLIDENE ACETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
803	BENZYLIDENE CAMPHOR SULFONIC ACID	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 6% (as acid).</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <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</p>

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			<p>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).
804	BERBERIS AQUIFOLIUM	A, H	
805	BERBERIS ARISTATA	A	<p>Only for use in oral medicines. The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
806	BERBERIS VULGARIS	A, E, H	
807	BERGAMOT OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour, the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%.</p> <p>The medicine requires the following warning statement</p>

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			on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
808	BERGAMOT OIL BERGAPTEN-FREE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
809	BERGAMOT OIL COLDPRESSED	A, E, H	When for internal use oxedrine is a mandatory component of bergamot oil coldpressed. The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.4 per cent or less of bergamot oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off

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

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816	BETA-CARYOPHYLLENE ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
817	BETA-DAMASCENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
818	BETA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
819	BETA-HOMO CYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
820	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
821	BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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-IONONE EPOXIDE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
823	BETA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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			1%.
824	BETA-METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
825	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%.
826	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%.

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

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			permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
831	BETA-TOCOPHEROL	E	
832	BETACAROTENE	A, E	When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or sublingual use in adults the medicine requires the following warning statement on the medicine label: - (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’
833	BETADEX	E	
834	BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.

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835	BETAINE	E	Only for use in topical medicines for dermal application.
836	BETAINE HYDROCHLORIDE	E	
837	BETULA LENTA	A, H	<p>Methyl salicylate is a mandatory component of <i>Betula lenta</i>.</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

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			<p>- actuation of the spray device is ergonomically difficult for young children to accomplish.</p> <p>The following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <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> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (IRRIT) 'If irritation develops, discontinue use.'; and</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</p>
838	BETULA NIGRA	A, H	Cresol, eugenol and methyl salicylate are mandatory components of Betula nigra.

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			<p>For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%.</p> <p>When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%.</p> <p>When the concentration of eugenol in the medicine is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 mL;</p> <p>b) the medicine must be fitted with a restricted flow insert;</p> <p>c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and</p> <p>d) the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid</p>

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			<p>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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			<p>effect);</p> <ul style="list-style-type: none"> - (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).
839	BETULA PENDULA	A, E, H	<p>Methyl salicylate is a mandatory component of Betula pendula.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p>

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			<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 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</p>

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			<p>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 develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
840	BETULA PUBESCENS	A, E, H	
841	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	E	<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>
842	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)-	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a</p>

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			medicine must be no more than 1%.
843	BIFIDOBACTERIUM ADOLESCENTIS	A	
844	BIFIDOBACTERIUM ANIMALIS	A	
845	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
846	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
847	BIFIDOBACTERIUM BIFIDUM	A	
848	BIFIDOBACTERIUM BREVE	A	
849	BIFIDOBACTERIUM INFANTIS	A	
850	BIFIDOBACTERIUM LACTIS	A	
851	BIFIDOBACTERIUM LONGUM	A	
852	BILBERRY	E	
853	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%.
854	BIOTA ORIENTALIS	A, H	
855	BIOTIN	A, E	
856	BIRCH LEAF DRY	A, E, H	Methyl salicylate is a mandatory component of birch leaf dry. Not to be included in medicines for use in the eye or

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			<p>on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:</p> <ul style="list-style-type: none"> - 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

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			<p>comply with all requirements 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 following warning statement is required on the medicine label:</p> <p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (IRRIT) 'If irritation develops, discontinue use.'; and</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).</p>

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Item	Ingredient name	Purpose	Specific requirements
857	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%.
858	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%.
859	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
860	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYL MALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
861	BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE	E	Only for use in topical medicines for dermal

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			<p>application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 2.5%.</p>
862	BIS-PEG-12 DIMETHICONE BEESWAX	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>
863	BIS-STEARYL ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE 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 7%.</p>
864	BISABOLENE	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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865	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
866	BITTER ALMOND OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The absence of amygdalin in the medicine must be declared.
867	BIXA ORELLANA	A, E, H	
868	BLACK BONED CHICKEN POWDER	A	
869	BLACK COHOSH DRY	A, H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'

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870	BLACK COHOSH POWDER	A, H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
871	BLACK CURRANT	E	
872	BLACK CURRANT ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
873	BLACK CURRANT FRESH	A, E, H	
874	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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Item	Ingredient name	Purpose	Specific requirements
			5%.
875	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
876	BLACK PEPPER OIL	A, E, H	
877	BLACK RASPBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
878	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
879	BLACKBERRY	E	
880	BLACKBERRY OILS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
881	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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Item	Ingredient name	Purpose	Specific requirements
			5%.
882	BLACKCURRANT ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
883	BLACKCURRANT JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
884	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

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			<p>'Contains sugars' (or words to that effect) if medicine contains two or more sugars.</p> <p>If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label:</p> <p>- (LACT) 'Contains lactose' (or words to that effect).</p>
885	BLADDERWRACK DRY	A, H	<p>Iodine is a mandatory component of Bladderwrack dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
886	BLADDERWRACK POWDER	A, H	<p>Iodine is a mandatory component of Bladderwrack powder.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily</p>

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			dose.
887	BLAINVILLEA ACMELLA	A, E, H	When used as an excipient, permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
888	BLETILLA STRIATA	A, H	
889	BLUE FLAG RHIZOME DRY	A, H	
890	BLUE FLAG RHIZOME POWDER	A, H	
891	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%.
892	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%.

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893	BLUMEA LACERA	A, H	
894	BOEHMERIA NIVEA	A, H	
895	BOERHAVIA DIFFUSA	A, H	
896	BOERHAVIA REPENS	A, H	
897	BOGBEAN LEAF DRY	A, H	
898	BOGBEAN LEAF POWDER	A, H	
899	BOIS DE ROSE OIL	A, E, H	
900	BOMBAX CEIBA	A, H	
901	BORAGO OFFICINALIS	A, E, H	Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of <i>Borago officinalis</i> .
902	BORAX	A, E, H	<p>Boron is a mandatory component of Borax.</p> <p>The percentage of Boron from Borax should be calculated based on the molecular weight of Borax.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of Boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
903	BORAX PENTAHYDRATE	A, E	Boron is a mandatory component of Borax

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			<p>Pentahydrate.</p> <p>The percentage of Boron from Borax pentahydrate should be calculated based on the molecular weight of Borax Pentahydrate.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron from Borax pentahydrate.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 g/L or 0.35%.</p>
904	BORIC ACID	A, H	<p>Boron is a mandatory component of Boric acid.</p> <p>The percentage of Boron from Boric acid should be calculated based on the molecular weight of Boric acid.</p> <p>The maximum recommended daily dose must provide no more than 6mg of Boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
905	BORNEOL	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
906	BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
907	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%.
908	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

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			fragrance concentration in a medicine must be no more 1%.
909	BORONIA MEGASTIGMA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
910	BOSWELLIA CARTERII	A, E, H	
911	BOSWELLIA SERRATA	A, E, H	
912	BOSWELLIA THURIFERA	A, H	
913	BOVINE CALCIUM CHONDROITIN SULFATE	A	
914	BOVINE CHONDROITIN SULFATE	A	
915	BOVINE COLOSTRUM POWDER	A	The medicine requires the warning statement: - (BOVCOL) 'Products containing bovine colostrum powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'
916	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from

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			cow's milk.'
917	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
918	BOVINE SODIUM CHONDROITIN SULFATE	A	
919	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The medicine requires the following warning statements 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)'
920	BRANDY	E	
921	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%.
922	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

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			be no more than 10 mg/kg or 10 mg/L or 0.001%.
923	BRASSICA JUNCEA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica juncea when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
924	BRASSICA NAPUS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
925	BRASSICA NIGRA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>

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Item	Ingredient name	Purpose	Specific requirements
926	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
927	BRASSICA OLERACEA VAR. CAPITATA	A, E, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. capitata when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
928	BRASSICA OLERACEA VAR. GEMMIFERA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var gemmifera when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
929	BRASSICA OLERACEA VAR. ITALICA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica</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%.
930	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 ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
931	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%.
932	BRASSICA RAPA	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica rapa when the plant part is seed.
			The concentration of allyl isothiocyanate from all

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			ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
933	BRAZIL NUT	E	
934	BRILLIANT BLACK BN	E	Permitted for use only as a colour for oral and topical use.
935	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
936	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
937	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
938	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour for oral and topical use.
939	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
940	BRIZA MEDIA	A, H	
941	BROCCOLI	E	
942	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.

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			If used in an undivided preparation, the allowed units are million papain units per gram.
943	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.
944	BROMOSTYROL	E	Not for use in infants Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
945	BROMUS CATHARTICUS	A, H	
946	BROMUS INERMIS	A, H	
947	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
948	BRONOPOL	E	Only for use in topical medicines for dermal application.
949	BROUSSONETIA PAPYRIFERA	A, H	
950	BROWN FK	E	Permitted for use only as a colour for topical use.

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951	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
952	BRUSSEL SPROUT	E	
953	BRYONIA ALBA	A, H	
954	BRYONIA DIOICA	A, H	
955	BUCHU LEAF DRY	A, H	
956	BUCHU LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
957	BUCHU LEAF POWDER	A, E, H	
958	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
959	BUDDLEJA OFFICINALIS	A, H	
960	BULNESIA SARMIENTI	A, E, H	
961	BUNIAS ORIENTALIS	A, H	
962	BUPLEURUM FALCATUM	A, H	
963	BURDOCK LEAF DRY	A, H	
964	BURDOCK LEAF POWDER	A, H	

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965	BURDOCK ROOT DRY	A, H	
966	BURDOCK ROOT POWDER	A, H	
967	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
968	BUTAN-1-OL	E	The residual solvent limit for Butan-1-ol is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
969	BUTANE	E	Only for use as an excipient propellant ingredient.
970	BUTOXYETHANOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
971	BUTTER	E	
972	BUTTER ACIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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973	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%.
974	BUTTER STARTER DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
975	BUTYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
976	BUTYL ACETATE	E	The residual solvent limit for Butyl acetate is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
977	BUTYL BUTYRATE	E	Permitted for use only in combination with other

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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%.
978	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%.
979	BUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
980	BUTYL ESTER OF PVM/MA COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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Item	Ingredient name	Purpose	Specific requirements
			<p>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).
981	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>
982	BUTYL HYDROXYBENZOATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (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.

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Item	Ingredient name	Purpose	Specific requirements
983	BUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
984	BUTYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
985	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%.
986	BUTYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Item	Ingredient name	Purpose	Specific requirements
987	BUTYL METHOXYDIBENZOYLMETHAN E	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in preparation must be no more than 5%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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).

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988	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%.
989	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
990	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%.
991	BUTYLATED HYDROXYANISOLE	E	
992	BUTYLATED HYDROXYTOLUENE	E	
993	BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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Item	Ingredient name	Purpose	Specific requirements
			10%.
994	BUTYLIDENE PHTHALIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
995	BUTYLOCTYL SALICYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
996	BUTYLPHENYL METHYLPROPIONAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
997	BUTYRALDEHYDE	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%.
998	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%.
999	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%.
1000	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%.
1001	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.

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1002	C11-13 ALKANE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p>
1003	C11-14-ISO-ALCOHOL C-13 RICH	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1004	C12-13 PARETH-23	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
1005	C12-13 PARETH-3	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
1006	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>
1007	C12-15 ALKYL OCTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
1008	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>
1009	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</p>

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Item	Ingredient name	Purpose	Specific requirements
			0.75%.
1010	C12-22 ALKYL ACRYLATE/HYDROXYETHYL ACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.
1011	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1012	C14-22 ALCOHOLS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.55%.
1013	C15-19 ALKANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.

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Item	Ingredient name	Purpose	Specific requirements
1014	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1015	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1016	C2-OCTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1017	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1018	C20-40 ALKYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1019	C20-40 PARETH-24	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

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Item	Ingredient name	Purpose	Specific requirements
			0.25%.
1020	C20-40 PARETH-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1021	C30-45 ALKYL CETEARYL DIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1022	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1023	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1024	C9-15 ALKYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.12%

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Item	Ingredient name	Purpose	Specific requirements
1025	CABBAGE	E	
1026	CABREUVA OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1027	CADE OIL	A, E, H	
1028	CAESALPINIA SAPPAN	A, H	
1029	CAFFEINE	A, E	When used as an excipient, only for use in topical medicines for dermal application. Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and contains no more than 100 mg of caffeine per maximum daily dose. Medicines for oral use containing caffeine as an active ingredient require the following warning statement on the medicine label: - (ADULT) 'Adults only' (or words to that effect). When the route of administration is oral or sublingual and the medicine

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			<p>provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1030	CAJUPUT OIL	A, E, H	<p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be</p>

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			<p>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 effect) - (NTAKEN) 'Not to be taken'. <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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>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 effect) - (NTAKEN) 'Not to be taken'.
1031	CALAMINE	A, E	<p>Only for use as an active or excipient ingredient for dermal application.</p> <p>When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.</p>
1032	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 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>

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			<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).
1033	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1034	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.

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1035	CALCIUM ALGINATE	E	
1036	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.
1037	CALCIUM ASCORBATE	A, E, H	
1038	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1039	CALCIUM ASPARTATE	A	
1040	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1041	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.
1042	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1043	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1044	CALCIUM CARBONATE	A, E, H	
1045	CALCIUM CASEINATE	E	
1046	CALCIUM CHLORIDE	E	

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	DIHYDRATE		
1047	CALCIUM CITRATE	A, E, H	
1048	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1049	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1050	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%.
1051	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 following warning statement is required on the medicine label:

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			- (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).'
1052	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1053	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1054	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1055	CALCIUM GLYCINATE DIHYDRATE	A	
1056	CALCIUM HEXAFLUROSILICATE	H	Only for use as an active homoeopathic ingredient.
1057	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1058	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1059	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1060	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.
1061	CALCIUM HYDROXYCITRATE	A, H	
1062	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1063	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1064	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%
1065	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1066	CALCIUM LACTATE	A, E, H	
1067	CALCIUM LACTATE GLUCONATE	A, E, H	
1068	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1069	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1070	CALCIUM LYSINATE	A	Only for use in oral medicines.

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1071	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1072	CALCIUM OROTATE	A, E, H	
1073	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1074	CALCIUM PANTOTHENATE	A, E, H	
1075	CALCIUM PHOSPHATE	A, E, H	
1076	CALCIUM PYRUVATE	A	
1077	CALCIUM SACCHARATE	E	
1078	CALCIUM SILICATE	E	
1079	CALCIUM SODIUM CASEINATE	A, H	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk'.
1080	CALCIUM SODIUM LACTATE	A, E, H	
1081	CALCIUM STEARATE	E	
1082	CALCIUM SUCCINATE	A, E, H	
1083	CALCIUM SULFATE	A, E, H	
1084	CALCIUM SULFATE DIHYDRATE	A, E, H	
1085	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1086	CALCIUM THREONINATE	A	
1087	CALENDULA FLOWER DRY	A, E, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1088	CALENDULA FLOWER POWDER	A, H	
1089	CALENDULA OFFICINALIS	A, E, H	
1090	CALLERYA RETICULATA	A, H	
1091	CALLICARPA PEDUNCULATA	A, H	
1092	CALLISTEMON CITRINUS	A, H	
1093	CALLISTEPHUS CHINENSIS	A, H	
1094	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%.
1095	CALLITRIS RHOMBOIDEA	A, H	
1096	CALLUNA VULGARIS	A, E, H	
1097	CALOCHORTUS TOLMIEI	A, H	
1098	CALTHA PALUSTRIS	A, H	
1099	CALUMBA ROOT DRY	A, H	
1100	CALUMBA ROOT POWDER	A, H	
1101	CALVATIA GIGANTEA	A, E, H	
1102	CALYCANTHUS FLORIDUS	A, H	
1103	CALYCANTHUS PRAECOX	A, H	
1104	CAMELLIA JAPONICA	A, H	
1105	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.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1106	CAMELLIA SINENSIS	A, E, H	<p>Caffeine is a mandatory component of Camellia sinensis for oral use.</p> <p>Medicines for oral or sublingual administration that contain caffeine as a component of a herbal substance and that provide a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine require the following warning statement on the medicine label:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine require the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product].'</p> <p>Polyphenols calculated as gallic acid (of Camellia sinensis) is only permitted for use as a component when the plant part is leaf.</p>
1107	CAMPHENE	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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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%.
1108	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%.
1109	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%.
1110	CAMPHOR BENZALKONIUM METHOSULFATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the preparation must be no more than 6%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<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).
1111	CAMPHOR OIL BROWN	A, H	<p>camphor, cineole and saffrole are mandatory components of camphor oil brown.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if</p>

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

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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
1112	CAMPHOR OIL WHITE	A, E, H	<p>Camphor and safrole are mandatory components of camphor oil white.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the</p>

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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 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 - (NTAKEN) 'Not to be taken'. <p>When for internal use then the</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>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>
1113	CAMPSIS GRANDIFLORA	A, H	
1114	CANADA BALSAM	A, H	
1115	CANANGA ODORATA	A, E, H	
1116	CANANGA OIL	A, E, H	
1117	CANARIUM INDICUM	A, H	<p>The plant part must be seed and the plant preparation is oil.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (DERIVED) 'This product contains material derived from nuts' (or words to that effect).</p>
1118	CANARIUM LUZONICUM	A, H	
1119	CANDELILLA WAX	A, E, H	
1120	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1121	CANDIDA UTILIS	A, H	
1122	CANINE MILK	H	Only for use as an active homoeopathic ingredient.

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Item	Ingredient name	Purpose	Specific requirements
1123	CANOLA OIL	A, E, H	<p>Allyl isothiocyanate is a mandatory component of canola oil 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>
1124	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1125	CANTHAXANTHIN	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1126	CAPRIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1127	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</p>

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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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1128	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>
1129	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>
1130	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1131	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC TRIGLYCERIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended</p>

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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 is not to exceed 3%
1132	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1133	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%.
1134	CAPRYLOYL GLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1135	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%.
1136	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%
1137	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%.
1138	CAPSELLA BURSA-PASTORIS	A, H	
1139	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1140	CAPSICUM ANNUUM	A, E, H	

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1141	CAPSICUM DRY	A, E, H	
1142	CAPSICUM FRUIT OLEORESIN	A, E	
1143	CAPSICUM FRUTESCENS	A, E, H	
1144	CAPSICUM POWDER	A, E, H	
1145	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1146	CARAMEL	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1147	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must be no more than 0.2%. Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.
1148	CARAWAY DRY	A, H	
1149	CARAWAY OIL	A, E, H	
1150	CARAWAY POWDER	A, H	
1151	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1152	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.
1153	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1154	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1155	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1156	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1157	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1158	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1159	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			application.
1160	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1161	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1162	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%.
1163	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1164	CARBON BLACK	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1165	CARBON DIOXIDE	E	
1166	CARDAMOM FRUIT DRY	A, H	
1167	CARDAMOM FRUIT POWDER	A, E, H	
1168	CARDAMOM OIL	A, E, H	
1169	CARDIOSPERMUM HALICACABUM	A, H	

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1170	CARICA PAPAYA	A, E, H	
1171	CARLINA ACAULIS	A, H	
1172	CARMELLOSE	E	
1173	CARMELLOSE CALCIUM	E	
1174	CARMELLOSE SODIUM	E	
1175	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1176	CARMOISINE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1177	CARMOISINE ALUMINIUM LAKE	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1178	CARNAUBA WAX	A, E, H	
1179	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%.
1180	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%.

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Item	Ingredient name	Purpose	Specific requirements
1181	CAROB GUM	E	
1182	CAROB POD	E	
1183	CAROTENES	E	Permitted as an excipient ingredient as a colour for oral and topical use.
1184	CARPINUS BETULUS	A, H	
1185	CARPINUS CORDATA	A, H	
1186	CARRAGEENAN	E	
1187	CARROT	E	
1188	CARROT SEED OIL	A, E, H	
1189	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>
1190	CARUM CARVI	A, H	
1191	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			5%.
1192	CARVACRYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1193	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%.
1194	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%.
1195	CARVYL ACETATE	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 or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1196	CARYA ILLINOINENSIS	A, H	
1197	CARYA OVATA	A, H	
1198	CARYOPHYLLENE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1199	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara dry when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

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

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			<p>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’.
1200	CASCARA POWDER	A, H	<p>Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara powder when the route of administration is oral administration.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <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

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			<p>professional before taking this product' (or words to that effect).</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (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'.

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1201	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1202	CASEIN	E	
1203	CASHEW NUT	E	
1204	CASSIA ALATA LEAF EXTRACT	E	Only for use as an excipient ingredient in sunscreens for dermal application and not to be intended for use in the eye. The extraction ratio of the Cassia alata can only be 1:3 in 62.5% glycerine:water. The concentration in the medicine must be no more than 0.0275%.
1205	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%.
1206	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.
1207	CASSIA FISTULA	A, H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia fistula when the route of

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Item	Ingredient name	Purpose	Specific requirements
			<p>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 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)] or the chemical

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Item	Ingredient name	Purpose	Specific requirements
			<p>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'.
1208	CASSIA OIL	A, E, H	The concentration of Cassia oil in the product must be no more than 2% unless the preparation is for dermal use as a rubefacient, in which case the concentration of cassia oil must be no more than 5%.
1209	CASSIE ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
1210	CASTANEA MOLLISSIMA	A, H	
1211	CASTANEA SATIVA	A, H	
1212	CASTOR OIL	A, E	
1213	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1214	CASUARINA EQUISITIFOLIA	A, H	
1215	CATALPA BIGNONIOIDES	A, H	
1216	CATALPA OVATA	A, H	
1217	CATECHU	A, H	
1218	CATHARANTHUS ROSEUS	A, H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus. The concentration of vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1219	CAULIFLOWER	E	
1220	CAULOPHYLLUM THALICTROIDES	A, E, H	
1221	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.

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1222	CEANOTHUS AMERICANUS	A, H	
1223	CEDAR LEAF OIL	A, E, H	
1224	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%.
1225	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%.
1226	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%.

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1227	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%.
1228	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%.
1229	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%.
1230	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%.

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1231	CEDRUS ATLANTICA	A, E, H	
1232	CEDRUS DEODARA	A, H	
1233	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1234	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%.
1235	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%.
1236	CELERY LEAF	E, H	
1237	CELERY SEED DRY	A, E, H	
1238	CELERY SEED OIL	A, E, H	
1239	CELERY SEED POWDER	A, H	
1240	CELLACEFATE	E	
1241	CELLULASE	A	Must be derived from <i>Trichoderma longibrachiatum</i> only. If used as an undivided preparation, the allowed unit is Cellulase unit per gram or

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Item	Ingredient name	Purpose	Specific requirements
			Thousand cellulase unit per gram. If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.
1242	CELLULOSE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1243	CELOSIA ARGENTEA	A, H	
1244	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1245	CENTAUREA CYANUS	A, E, H	
1246	CENTAURIUM ERYTHRAEA	A, H	
1247	CENTELLA ASIATICA	A, E, H	
1248	CENTELLA ASIATICA MERISTEM CELL CULTURE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.05%.
1249	CENTIPEDA CUNNINGHAMII	A, E, H	
1250	CENTIPEDA MINIMA	A, H	

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1251	CEPHALANOPSIS SEGETUM	A, H	
1252	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1253	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%.
1254	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1255	CERATONIA SILIQUA	A, E, H	
1256	CERATOSTIGMA WILLMOTTIANUM	A, H	
1257	CERESIN	E	Only for use in topical medicines for dermal application.
1258	CESTRUM LATIFOLIUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The plant part must be leaf and must be a water extract. The concentration must be no more than 0.5%.

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1259	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1260	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1261	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1262	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1263	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1264	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.
1265	CETEARYL GLUCOSIDE	E	Only for use in topical

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Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
1266	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1267	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%.
1268	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1269	CETETH-10	E	Only for use in topical medicines for dermal application.
1270	CETETH-2	E	Only for use in topical medicines for dermal application.
1271	CETETH-24	E	Only for use in topical medicines for dermal application.
1272	CETETH-5	E	Only for use in topical medicines for dermal application.

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1273	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1274	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%.
1275	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%.
1276	CETOSTEARYL ALCOHOL	E	
1277	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 %

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Item	Ingredient name	Purpose	Specific requirements
1278	CETRARIA ISLANDICA	A, H	
1279	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1280	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1281	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1282	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1283	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1284	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1285	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%.

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1286	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1287	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%.
1288	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1289	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1290	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1291	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1292	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

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Item	Ingredient name	Purpose	Specific requirements
			8%.
1293	CETYLPYRIDINIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1294	CHAENOMELES LAGENARIA	A, H	
1295	CHAENOMELES SPECIOSA	A, H	
1296	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.
1297	CHAMAECYPARIS LAWSONIANA	A, H	
1298	CHAMAELIRIUM LUTEUM	A, H	
1299	CHAMAEMELUM NOBILE	A, E, H	
1300	CHAMOMILE FLOWER DRY	A, E, H	
1301	CHAMOMILE OIL ENGLISH	A, E, H	
1302	CHAMOMILE OIL GERMAN	A, E, H	
1303	CHANGIUM SMYRNIODES	A, H	
1304	CHEIRANTHUS CHEIRI	A, H	
1305	CHELIDONIUM MAJUS	A, E, H	When for oral or sublingual use, the medicine requires the following warning statement on the medicine label: - (CELAND) 'WARNING:

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			Greater Celandine may harm the liver in some people. Use only under the supervision of a healthcare professional'.
1306	CHELONE GLABRA	A, H	
1307	CHENOPODIUM ALBUM	A, H	
1308	CHENOPODIUM VULVARIA	A, H	
1309	CHERRY	E	
1310	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%.
1311	CHESTNUT SWEET	E, H	
1312	CHICKEN COMB EXTRACT	A	
1313	CHILLI	E, H	
1314	CHIMAPHILA UMBELLATA	A, H	Arbutin is a mandatory component of Chimaphila umbellata. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.

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1315	CHIONANTHUS VIRGINICA	A, H	
1316	CHLORELLA	E	<p>Iodine is a mandatory component of Chlorella.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
1317	CHLORELLA PYRENOIDOSA	E	
1318	CHLORELLA VULGARIS	A, E	<p>Iodine is a mandatory component of Chlorella vulgaris.</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>
1319	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1320	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal

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Item	Ingredient name	Purpose	Specific requirements
			application.
1321	CHLOROACETAMIDE	E	Only for use in topical medicines for dermal application.
1322	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1323	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1324	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%.
1325	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1326	CHLOROPHYLL-COPPER	E	Only for use as a colour in oral

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	COMPLEXES		and topical medicines.
1327	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1328	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1329	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1330	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1331	CHOCOLATE BROWN HT	E	Permitted for use only as a colour for oral and topical use.
1332	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1333	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1334	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1335	CHOLESTERYL/BEHENYL/OCTY	E	Only for use in topical

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	LDODECYL LAUROYL GLUTAMATE		medicines for dermal 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%.
1336	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1337	CHOLINE BITARTRATE	A, E	
1338	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1339	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%.
1340	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.

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1341	CHONDRUS DRY	A, E, H	<p>Iodine is a mandatory component of Chondrus dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
1342	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>
1343	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</p>

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			<p>calculated based on the molecular weight of chromic chloride hexahydrate.</p> <p>The maximum recommended daily dose must provide 50 micrograms or less of chromium from organic sources (i.e. chromium picolinate, chromium nicotinate and high chromium yeast).</p>
1344	CHROMIUM NICOTINATE	A	<p>Chromium is a mandatory component of chromium nicotinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.</p> <p>Chromium nicotinate is considered to be an organic form of chromium.</p>
1345	CHROMIUM PICOLINATE	A	<p>Chromium is a mandatory component of Chromium picolinate.</p> <p>The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.</p> <p>Chromium picolinate is considered to be an organic form of chromium.</p>

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1346	CHRYSANTHEMUM BALSAMITA	A, H	
1347	CHRYSANTHEMUM INDICUM	A, H	
1348	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1349	CHRYSANTHEMUM MARSHALLII	A, H	
1350	CHRYSANTHEMUM SINENSE	A, H	
1351	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1352	CHRYSOSPORIUM PRUINOSUM	A, H	
1353	CIBOTIUM BAROMETZ	A, H	
1354	CICHORIUM INTYBUS	A, E, H	
1355	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1356	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.
1357	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.

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1358	CINCHONA OFFICINALIS	A, H	<p>Quinidine and quinine are mandatory components of Cinchona officinalis.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1359	CINCHONA PUBESCENS	A, H	<p>Quinidine and quinine are mandatory components of Cinchona pubescens.</p> <p>The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.</p>
1360	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</p>

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Permissible ingredients and requirements			
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			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.
1361	CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1362	CINNAMIC 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%.
1363	CINNAMOMUM CAMPHORA	A, E, H	Camphor, cineole and safrole are mandatory components of Cinnamomum camphora. In solid and semi solid preparations, the concentration

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			<p>of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations or distillates, the nominal capacity of the container must be no more than 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'; <p>and</p> <ul style="list-style-type: none"> - 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>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container.</p> <p>In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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</p>

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Item	Ingredient name	Purpose	Specific requirements
			<p>cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.</p> <p>When for internal use then the concentration of safrole in a medicine must be no more than 0.1%.</p> <p>When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.</p>
1364	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>

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1365	CINNAMOMUM VERUM	A, E, H	<p>When used as an active ingredient coumarin is a mandatory component of Cinnamomum verum and the concentration of coumarin in the medicine must be no more than 0.001%.</p> <p>Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is essential oil, distillate, fixed oil or infused oil.</p> <p>The concentration of cinnamon bark oil in the medicine must be no more than 2%.</p> <p>Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the plant part is leaf.</p> <p>When the concentration of cinnamon leaf oil in the preparation is more than 25%:</p> <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</p>

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			<p>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>
1366	CINNAMON BARK OIL	A, E, H	<p>The concentration of cinnamon bark oil in the product must be no more than 2%.</p> <p>When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.</p>
1367	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>

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Item	Ingredient name	Purpose	Specific requirements
1368	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% 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</p>

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			be no more than 0.001%.
1369	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>
1370	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>
1371	CINNAMYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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Item	Ingredient name	Purpose	Specific requirements
1372	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%.
1373	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%.
1374	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%.
1375	CINNAMYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Item	Ingredient name	Purpose	Specific requirements
1376	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%.
1377	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%.
1378	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 must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear

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Item	Ingredient name	Purpose	Specific requirements
			<p>when exposed to the sun' (or words to this effect).</p> <p>When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019:</p> <ul style="list-style-type: none"> - (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).
1379	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>
1380	CIS-3-HEXEN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1381	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%.
1382	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%.
1383	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%.
1384	CIS-3-HEXENYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a

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

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Item	Ingredient name	Purpose	Specific requirements
1388	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%.
1389	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%.
1390	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%.
1391	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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Item	Ingredient name	Purpose	Specific requirements
			1%.
1392	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%.
1393	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%.
1394	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%.

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Item	Ingredient name	Purpose	Specific requirements
1395	CIS-6-NONEN-1-AL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1396	CIS-6-NONENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1397	CIS-BETA-OCIMENE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1398	CIS-HEXAHYDROCUMINYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1399	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%.
1400	CISTANCHE DESERTICOLA	A, H	
1401	CISTANCHE SALSA	A, H	
1402	CISTUS LADANIFERUS	A, E, H	
1403	CITRAL	E	
1404	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%.
1405	CITRAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

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Item	Ingredient name	Purpose	Specific requirements
			fragrance concentration in a medicine must be no more than 1%.
1406	CITRIC ACID	A, E	<p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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'
1407	CITRIC ACID DIHYDRATE	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the

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Item	Ingredient name	Purpose	Specific requirements
			<p>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'
1408	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</p>

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			<p>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.'
1409	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1410	CITROL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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Item	Ingredient name	Purpose	Specific requirements
			5%.
1411	CITRON	E	
1412	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'.
1413	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%.
1414	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 than 1%.
1415	CITRONELLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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Item	Ingredient name	Purpose	Specific requirements
			<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>
1416	CITRONELLOL	E	<p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
1417	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>
1418	CITRONELLYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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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%.
1419	CITRONELLYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1420	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%.
1421	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
1422	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%.
1423	CITRONELLYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1424	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%.
1425	CITRULLUS COLOCYNTHIS	H	Only for use as an active homoeopathic ingredient. When for oral use, the concentration of Citrullus colocynthis must be more than

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			4X (i.e. 1X 2X 3X).
1426	CITRULLUS VULGARIS	A, H	
1427	CITRUS AURANTIFOLIA	A, E, H	<p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1428	CITRUS AURANTIUM	A, E, H	<p>Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg.</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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			1.4% or less of citrus aurantium oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1429	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1430	CITRUS CHACHIENSIS	A, H	
1431	CITRUS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1432	CITRUS FIBRE	E	
1433	CITRUS LIMETTA	A, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1434	CITRUS LIMON	A, E, H	Oxedrine is a mandatory

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>component of Citrus limon when intended for internal use.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus limon oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1435	CITRUS MAXIMA	A, H	
1436	CITRUS MEDICA	A, E, H	<p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus medica oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			the skin.
1437	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%.
1438	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.
1439	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.
1440	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%.
1441	CITRUS UNSHIU	A, E, H	Oxedrine is a mandatory component of Citrus unshiu

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1442	CITRUS X PARADISI	A, E, H	
1443	CITRUS X WILSONII	A, H	
1444	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%.
1445	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%.
1446	CIVET SYNTHETIC	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1447	CIVETONE	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 fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1448	CLARY OIL	A, E, H	
1449	CLEMATIS ARMANDII	A, H	
1450	CLEMATIS CHINENSIS	A, E, H	
1451	CLEMATIS RECTA	A, H	
1452	CLEMATIS VITALBA	A, H	
1453	CLERODENDRUM TRICHOTOMUM	A, H	
1454	CLINOPODION POLYCEPHALUM	A, H	
1455	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1456	CLIVER HERB DRY	A, H	
1457	CLIVER HERB POWDER	A, H	
1458	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. 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>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’
1459	CLOVE DRY	A, E, H	
1460	CLOVE LEAF OIL	A, E, H	<p>When the concentration of Clove Leaf Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration of Clove Leaf Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the</p>

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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 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’
1461	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>
1462	CLOVE POWDER	A, E, H	
1463	CLOVE STEM OIL	A, E, H	<p>When the concentration of Clove Stem Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<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’
1464	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 acids.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1465	CNICUS BENEDICTUS	A, H	
1466	CNICUS JAPONICUS	A, H	
1467	CNIDIUM MONNIERI	A, H	
1468	CNIDIUM OFFICINALE	A, H	
1469	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1470	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1471	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1472	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%.
1473	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be: a) no more than 1% in leave on medicines

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			b) no more than 15% in wash on /wash off medicines c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcoamide; AA) must be controlled to below the level of detection.
1474	COCCOLOBIA UVIFERA	A, H	
1475	COCCULUS ORBICULATUS	A, H	
1476	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1477	COCHLEARIA OFFICINALIS	A, H	
1478	COCILLANA DRY	A, H	
1479	COCILLANA POWDER	A, H	
1480	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1481	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.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1482	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%
1483	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.
1484	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%.
1485	COCOA POWDER	A, E, H	
1486	COCOLYCEERIDES	E	
1487	COCONUT	E	
1488	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1489	COCONUT OIL	A, E, H	
1490	COCOS NUCIFERA	A, E, H	
1491	COD-LIVER OIL	A, E	Vitamin A and colecalciferol

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>are mandatory components of Cod-liver oil.</p> <p>When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%.</p> <p>When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents.</p> <p>When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:</p> <p>- (VITA2) ‘WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’ When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.
1492	CODONOPSIS LANCEOLATA	A, H	
1493	CODONOPSIS PILOSULA	A, H	
1494	CODONOPSIS TANGSHEN	A, H	
1495	COFFEA ARABICA	A, E, H	Caffeine is a mandatory component of Coffea arabica. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]’.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1496	COFFEA CANEPHORA	A, E, H	<p>Caffeine is a mandatory component of Coffea canephora.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1497	COFFEE	E, H	<p>Caffeine is a mandatory component of coffee.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the following warning statement on the medicine label:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1498	COFFEE OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1499	COFFEE SOLID EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1500	COGNAC OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			5%.
1501	COGNAC OIL GREEN	A, E, H	
1502	COGNAC OIL WHITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1503	COIX LACHRYMA-JOBI	A, H	
1504	COLA ACUMINATA	A, E, H	Caffeine is a mandatory component of Cola acuminata. When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of: a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement: - (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.' b) more than 10 mg of caffeine the medicine requires the warning statement: - (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]!'
1505	COLA NITIDA	A, E, H	Caffeine is a mandatory

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>component of Cola nitida.</p> <p>When the route of administration is oral or sublingual and the medicine provides a maximum recommended daily dose of:</p> <p>a) more than 1 mg but no more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFFR) 'The recommended dose of this medicine provides small amounts of caffeine.'</p> <p>b) more than 10 mg of caffeine the medicine requires the warning statement:</p> <p>- (CAFF) 'Contains caffeine [state quantity per dosage unit or per mL or per gram of product]'.</p>
1506	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.
1507	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1508	COLLAGEN	E	
1509	COLLINSONIA CANADENSIS	A, H	
1510	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1511	COLOPHONY	A, E, H	
1512	COMMIPHORA HABESSINICA	A, H	
1513	COMMIPHORA KATAF	A, H	
1514	COMMIPHORA MYRRHA	A, E, H	
1515	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1516	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1517	CONCENTRATED SQUID OMEGA-3 TRIGLYCERIDES	A	Only for oral use. 'Concentrated squid omega-3-triglycerides' must be obtained from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the preparation AND be presented in a therapeutic dosage form for therapeutic use. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
1518	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).
1519	CONIFER PHYTOSTEROL	A	

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Item	Ingredient name	Purpose	Specific requirements
	COMPLEX		
1520	CONIOSELIUM UNIVITTATUM	A, H	
1521	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.
1522	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry Convallaria majalis in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1523	CONYZA CANADENSIS	A, H	
1524	COPAIBA OIL	A, E, H	
1525	COPAIFERA LANGSDORFFII	A, E, H	
1526	COPERNICIA CERIFERA	A, E, H	
1527	COPOVIDONE	E	
1528	COPPER	H	Only for use as an active homoeopathic ingredient. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1529	COPPER (II) ASPARTATE	A, H	Copper is a mandatory component of copper (II)

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>aspartate.</p> <p>The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1530	COPPER (II) GLYCINATE	A, H	<p>Copper is a mandatory component of copper (II) glycinate.</p> <p>The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1531	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			(II) lysinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1532	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1533	COPPER CHLOROPHYLL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1534	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1535	COPPER GLUCONATE	A, E	Copper is a mandatory component of copper gluconate. The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate. When for internal use the maximum daily dose must not contain more than 5 mg of

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1536	COPPER TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1537	COPTIS CHINENSIS	A, H	
1538	COPTIS JAPONICA	A, H	
1539	CORALLINA OFFICINALIS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is to be no more than 1%.
1540	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1541	CORIANDER DRY	A, H	
1542	CORIANDER OIL	A, E, H	
1543	CORIANDER POWDER	A, H	
1544	CORIANDRUM SATIVUM	A, E, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1545	CORN GLYCERIDES	E	
1546	CORN SILK DRY	A, H	
1547	CORN SILK POWDER	A, H	
1548	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%.
1549	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%.
1550	CORNUS FLORIDA	A, H	
1551	CORNUS OFFICINALIS	A, H	
1552	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1553	CORYDALIS AMBIGUA	A, E, H	
1554	CORYDALIS BUNGEANA	A, H	
1555	CORYDALIS CAVA	A, H	
1556	CORYDALIS FABACEA	A, H	
1557	CORYDALIS FORMOSA	A, H	
1558	CORYDALIS TURTSCHANINOVII	A, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1559	CORYLUS AMERICANA	A, H	
1560	CORYLUS AVELLANA	A, H	
1561	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>
1562	CORYMBIA FICIFOLIA	A, H	Cineole is a mandatory component of Corymbia

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>ficifolia.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <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>
1563	COSMOS BIPINNATUS	A, H	
1564	COSTUS ROOT OIL	A, H	
1565	COSTUS SPICATUS	A, H	
1566	COTTONSEED OIL	A, E, H	
1567	COUCH GRASS RHIZOME DRY	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1568	COUCH GRASS RHIZOME POWDER	A, H	
1569	COUMARIN	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
1570	CRANBERRY	E	
1571	CRATAEGUS CUNEATA	A, E, H	
1572	CRATAEGUS LAEVIGATA	A, E, H	
1573	CRATAEGUS MONOGYNA	A, E, H	
1574	CRATAEGUS PINNATIFIDA	A, E, H	
1575	CRATEVA MAGNA	A, E, H	
1576	CREATINE	A, E	
1577	CREATINE MONOHYDRATE	A, E	
1578	CREATINE PHOSPHATE	A, E	
1579	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%.
1580	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

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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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1581	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1582	CRESOL	E	<p>Only for use as a preservative in topical medicines.</p> <p>The concentration of phenols (including cresols and xylenols and any other homologue of phenol) boiling below 220 degrees centigrade must be no more than 3%.</p>
1583	CRESYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1584	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.00341%.</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1585	CROCUS SATIVUS	A, H	
1586	CROSCARMELOSE SODIUM	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) ‘The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).’
1587	CROSPROVIDONE	E	
1588	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1589	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1590	CRYPTOMERIA JAPONICA	A, H	
1591	CUBEB OIL	A, H	
1592	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

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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%.
1593	CUCUMBER	E	
1594	CUCUMIS MELO	A, H	
1595	CUCUMIS SATIVUS	A, E, H	
1596	CUCURBITA MAXIMA	A, E, H	
1597	CUCURBITA MOSCHATA	A, H	
1598	CUCURBITA PEPO	A, E, H	
1599	CULLEN CORYLIFOLIUM	A, H	
1600	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%.
1601	CUMIN OIL	A, E, H	
1602	CUMINALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1603	CUMINUM CYMINUM	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1604	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%.
1605	CUPRESSUS ARIZONICA	A, H	
1606	CUPRESSUS FUNEBRIS	A, E, H	
1607	CUPRESSUS MACROCARPA	A, H	
1608	CUPRESSUS SEMPERVIRENS	A, E, H	
1609	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1610	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1611	CUPRIC CITRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate. The percentage of copper from cupric citrate should be calculated based on the molecular weight of cupric citrate. The medicine must not contain more than 750 micrograms of copper from cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily dose.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1612	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate.</p> <p>The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate.</p> <p>The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.</p>
1613	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>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1614	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>
1615	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			component of cupric sulfate monohydrate.
1616	CUPRIC SULFATE PENTAHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate.</p> <p>The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.</p>
1617	CURCULIGO ORCHIOIDES	A, H	
1618	CURCUMA AROMATICA	A, H	
1619	CURCUMA LONGA	A, E, H	
1620	CURCUMA XANTHORRHIZA	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1621	CURCUMA ZEDOARIA	A, H	
1622	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1623	CUSCUTA EPITHYMUM	A, H	
1624	CUSCUTA EUROPAEA	A, H	
1625	CUSCUTA HYGROPHILAE	A, H	
1626	CUSCUTA RACEMOSA	A, H	
1627	CUSPARIA FEBRIFUGA	A, H	
1628	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1629	CYANOCOBALAMIN	A, E, H	
1630	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1631	CYATHULA OFFICINALIS	A, H	
1632	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1633	CYCLAMEN PURPURASCENS	A, H	
1634	CYCLOHEXADECENONE-8	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%.
1635	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%.
1636	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%.
1637	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%.
1638	CYCLOHEXYL ACETATE	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%.
1639	CYCLOHEXYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1640	CYCLOHEXYL PHENETHYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1641	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</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			1%.
1642	CYCLOHEXYLETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1643	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1644	CYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1645	CYDONIA OBLONGA	A, H	
1646	CYMBOPOGON FLEXUOSUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1647	CYMBOPOGON MARTINI	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1648	CYMBOPOGON NARDUS	A, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1649	CYMBOPOGON SCHOENANTHUS	A, E, H	The concentration or Aldehydes calculated as citral in the medicine must be no more than 5% for topical use.
1650	CYNANCHUM ATRATUM	A, H	
1651	CYNANCHUM STAUNTONII	A, E, H	
1652	CYNARA SCOLYMUS	A, E, H	
1653	CYNODON DACTYLON	A, E, H	
1654	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1655	CYPERUS LONGUS	A, H	
1656	CYPERUS ROTUNDUS	A, H	
1657	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%.

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1658	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1659	CYSTEINE	A	<p>When the ingredient is included in a medicine for internal use that is listed in the Register:</p> <ul style="list-style-type: none"> - 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 450 mg of cysteine.</p> <p>b) When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.</p>
1660	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);

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements 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 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>
1661	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	<p>When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient and the total flavour proprietary excipient formulation concentration in a medicine must not be more than 5%.</p> <p>In addition, when the ingredient is included in a medicine for internal use that is listed in the Register:</p> <p>- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements 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 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>
1662	CYSTINE	A	<p>When the ingredient is included in a medicine for internal use that is listed in the Register:</p> <p>- on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b);</p> <p>- before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or</p> <p>- before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements</p>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			under (a) & (b). a) The maximum recommended daily dose must contain no more than 450 mg of cystine. 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.
1663	CYTISUS SCOPARIUS	A, H	Sparteine is a mandatory component of Cytisus scoparius. The concentration of Sparteine in the medicine must be no more than 0.001%.
1664	D-ALPHA-TOCOPHEROL	A, E	
1665	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1666	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1667	D-ALPHA-TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1668	D-BORNEOL	E	Permitted for use only in

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1669	D-CARVONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1670	D-FENCHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1671	D-LIMONENE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1672	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%.
1673	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.
1674	DACTYLIS GLOMERATA	A, H	
1675	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1676	DAEMONOROPS DRACO	A, E, H	
1677	DAHLIA PINNATA	A, H	
1678	DALBERGIA ODORIFERA	A, H	
1679	DAMIANA LEAF POWDER	A	
1680	DANDELION LEAF DRY	A, H	
1681	DANDELION LEAF POWDER	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1682	DANDELION ROOT DRY	A, H	
1683	DANDELION ROOT POWDER	A, H	
1684	DAPHNE GENKWA	A, H	
1685	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1686	DATE	E	
1687	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%.
1688	DAUCUS CAROTA	A, E, H	
1689	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%.
1690	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>medicines for dermal application and not be included in topical medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 1%.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1691	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>
1692	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>
1693	DECAHYDRO-BETA-NAPHTHYLFORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1694	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%.
1695	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%.
1696	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%.
1697	DECANAL DIMETHYL ACETAL	E	Permitted for use only in

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<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>
1698	DECARBOXY CARNOISINE DIHYDROCHLORIDE	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>
1699	DECENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1700	DECYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1701	DECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1702	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1703	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1704	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%.
1705	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1706	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>therapeutically active ingredient are subject to the following conditions:</p> <p>a) the medicines are for oral use only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p>
1707	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>

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Item	Ingredient name	Purpose	Specific requirements
			<p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.</p>
1708	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>
1709	DEHYDROACETIC ACID	E	<p>Only for use in topical medicines for dermal application.</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1710	DEHYDROMENTHOFUROLACT ONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1711	DEHYDROXANTHAN GUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1712	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1713	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%.
1714	DELTA-DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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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%.
1715	DELTA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1716	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%.
1717	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1718	DELTA-TETRADECALACTONE	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>
1719	DELTA-TOCOPHEROL	E	
1720	DELTA-UNDECALACTONE	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>
1721	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1722	DENATONIUM BENZOATE	E	
1723	DENDROBIUM NOBILE	A, H	
1724	DESCURAINIA SOPHIA	A, H	
1725	DESMODIUM STYRACIFOLIUM	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1726	DESMODIUM TRIQUETUM	A, H	
1727	DEVIL'S CLAW TUBER DRY	A, H	
1728	DEVIL'S CLAW TUBER POWDER	A, H	
1729	DEXPANTHENOL	A, E	
1730	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%.
1731	DEXTRAN 40	A, E	
1732	DEXTRATES	E	
1733	DEXTRIN	E	
1734	DEXTRIN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1735	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A	Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil. Only for use in oral medicines when in combination with other active or excipient

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			ingredients. The ratio of DHA to EPA must be 2:1.
1736	DI-C12-13 ALKYL MALATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1737	DI-C12-15 ALKYL FUMARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1738	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%.
1739	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			15%.
1740	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%.
1741	DIACETYL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1742	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%.
1743	DIACETYLATED	E	Permitted for use only in combination with other

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Item	Ingredient name	Purpose	Specific requirements
	MONOGLYCERIDES		permitted ingredients as a coating solution.
1744	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1745	DIANTHUS SUPERBUS	A, H	
1746	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1747	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1748	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate. The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.
1749	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

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1750	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.
1751	DIBASIC SODIUM PHOSPHATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate. 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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
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>
1752	DIBASIC SODIUM PHOSPHATE DIHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate dihydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1753	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: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1754	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	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 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>
1755	DIBASIC SODIUM PHOSPHATE MONOHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			<p>more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p> <p>When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label:</p> <p>- (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'</p>
1756	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>
1757	DIBUTYL ADIPATE	E	<p>Only for use in topical medicines for dermal application.</p>
1758	DIBUTYL PHTHALATE	E	<p>Only for use in topical</p>

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
1759	DIBUTYL SEBACATE	E	
1760	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%.
1761	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1762	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1763	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%.
1764	DICETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be

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Item	Ingredient name	Purpose	Specific requirements
			included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1765	DICHLOROBENZYL ALCOHOL	E	
1766	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.
1767	DICTAMNUS ALBUS	A, H	
1768	DICTAMNUS DESYCARPUS	A, H	
1769	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%.
1770	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1771	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			
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Item	Ingredient name	Purpose	Specific requirements
1772	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%.
1773	DIETHYL MALONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1774	DIETHYL PHTHALATE	E	
1775	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%.
1776	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			<p>be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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).
1777	DIETHYLAMINOMETHYLCOUM ARIN	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
			The concentration in the medicine must be no more than 0.1%.
1778	DIETHYLDIMETHYL-2-CYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1779	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%.
1780	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1781	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%.
1782	DIETHYLHEXYL SEBACATE	E	Only for use in topical

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Item	Ingredient name	Purpose	Specific requirements
			medicines for dermal application.
1783	DIETHYLHEXYL SYRINGYLIDENEMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1784	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).
1785	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

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Item	Ingredient name	Purpose	Specific requirements
			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.'
1786	DIGITALIS LEAF DRY	A, H	The concentration of Digitalis leaf dry in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1787	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%.
1788	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%.
1789	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1790	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%.
1791	DIHYDRO JASMONE	E	Permitted for use only in

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Item	Ingredient name	Purpose	Specific requirements
			<p>combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1792	DIHYDRO TERPINYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1793	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>
1794	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>

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1795	DIHYDRO-ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1796	DIHYDROACTINIDIOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1797	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%.
1798	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1799	DIHYDROCOUMARIN	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>
1800	DIHYDROCUMINYL ALCOHOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
1801	DIHYDROEUGENOL	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>
1802	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	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			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 5%.
1803	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%.
1804	DIHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1805	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%.
1806	DIHYDROMYRCENYL ACETATE	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%.
1807	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1808	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%.
1809	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%.
1810	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1811	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1812	DILL HERB OIL	A, E, H	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1813	DILL SEED OIL	A, E, H	
1814	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%.
1815	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%.
1816	DIMETHICONE 12500	E	
1817	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%.
1818	DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 15%.
1819	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%.
1820	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%.
1821	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%.
1822	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
1823	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%.
1824	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%.
1825	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%.
1826	DIMETHYL BENZYL CARBINYL	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
	BUTYRATE		permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
1827	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%.
1828	DIMETHYL PHENYLETHYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1829	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1830	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%.
1831	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%.
1832	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%.
1833	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

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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%.
1834	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1835	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%.
1836	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%.
1837	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1838	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1839	DIMETHYLOL DIMETHYL	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
	HYDANTOIN		application.
1840	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%.
1841	DIMETICONE 10	E	
1842	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1843	DIMETICONE 1000	E	
1844	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%
1845	DIMETICONE 2	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 9.602%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1846	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1847	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1848	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%.
1849	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.
1850	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1851	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1852	DIMETICONE 5	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. The concentration in the medicine must be no more than 10%.
1853	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1854	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1855	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%.
1856	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1857	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1858	DIMETICONE CROSSPOLYMER-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The concentration in the medicine must be no more than 15%.
1859	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%.
1860	DIMETICONOL	E	Only for use in topical medicines for dermal application.
1861	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%.
1862	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
1863	DIMOCARPUS LONGAN	A, H	
1864	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1865	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1866	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1867	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%.
1868	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%
1869	DIOLAMINE CETYL	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
	PHOSPHATE		application and not be included in topical medicines intended for use in the eye.
1870	DIOSCOREA COLLETTII	A, H	
1871	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1872	DIOSCOREA JAPONICA	A, H	
1873	DIOSCOREA OPPOSITIFOLIA	A, H	
1874	DIOSCOREA POLYSTACHYA	A, H	
1875	DIOSCOREA SEPTEMLOBA	A, H	
1876	DIOSCOREA VILLOSA	A, E, H	
1877	DIOSPYROS KAKI	A, E, H	
1878	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).
1879	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA	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
	TE		application and not to be included in medicines intended for use on damaged skin. The concentration in the medicine must be no more than 0.5%.
1880	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAIOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1881	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%.
1882	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1883	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1884	DIPHENYL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1885	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%.
1886	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%.
1887	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1888	DIPROPYLENE GLYCOL	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	DIBENZOATE		medicines for dermal 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%.
1889	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1890	DIPSACUS ASPER	A, H	
1891	DIPSACUS JAPONICUS	A, H	
1892	DIPTERYX ODORATA	A, E, H	When used as an active ingredient coumarin is a mandatory component of Dipteryx odorata and the concentration of coumarin in the medicine must be no more than 0.001%.
1893	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1894	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1895	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.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The concentration in the medicine must be no more than 2%.
1896	DISODIUM DIMETICONE COPOLYOL SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 14%.
1897	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).’
1898	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1899	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%.
1900	DISODIUM INOSINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1901	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%.
1902	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
1903	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1904	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%.
1905	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1906	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	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. The concentration in the medicine must be no more than 3%.
1907	DISODIUM RUTINYL DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
1908	DISODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1909	DISPERSIBLE CELLULOSE	E	
1910	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%.
1911	DISTEARDIMONIUM	E	Only for use in topical

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	HECTORITE		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%.
1912	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1913	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%.
1914	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%.
1915	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1.5%.
1916	DL-ALPHA-TOCOPHEROL	A, E	
1917	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1918	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1919	DL-BORNEOL	E	
1920	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1921	DL-THREONINE	A, E	
1922	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.
1923	DOCUSATE SODIUM	E	
1924	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%.
1925	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

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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%.
1926	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%.
1927	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%.
1928	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%.
1929	DODECYL ISOBUTYRATE	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%.
1930	DOLICHOS LABLAB	A, H	
1931	DOLOMITE	A, E, H	
1932	DRACAENA DRACO	A, H	
1933	DRIED BUTTERMILK	E	
1934	DRIED CALCIUM SULFATE	A, E, H	
1935	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
1936	DRIMIA INDICA	A, H	
1937	DRIMIA MARITIMA	A, H	
1938	DROMETRIZOLE TRISILOXANE	A	<p>Only for use as an active ingredient in sunscreens for dermal application.</p> <p>The concentration in a medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			when exposed to the sun' (or words to this effect).
1939	DROSERANGLICA	A, H	
1940	DROSERABURMANNI	A, H	
1941	DROSERAINTERMEDIA	A, H	
1942	DROSERARAMENTACIA	A, H	
1943	DROSERAROTUNDIFOLIA	A, E, H	
1944	DROSERAROTUNDIFOLIAMIS	A, H	
1945	DRYNARIAFORTUNEI	A, H	
1946	DRYOBALANOPSAROMATICA	A, H	
1947	DRYOPTERISFILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1948	DULACIAINOPIFLORA	A, H	
1949	DUNALIELLASALINA	A, E, H	
1950	DUPICAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1951	DURVILLAEAANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			medicine must be no more than 0.1%.
1952	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%.
1953	DYSPHANIA AMBROSIODES	A, H	Volatile oil components (of <i>Dysphania ambrosioides</i>) are mandatory components of <i>Dysphania ambrosioides</i> .
1954	ECAMSULE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear'

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			when exposed to the sun' (or words to this effect).
1955	ECHINACEA ANGUSTIFOLIA	A, E, H	
1956	ECHINACEA PALLIDA	A, E, H	
1957	ECHINACEA PURPUREA	A, E, H	
1958	ECHINOPA SPINOSISSIMUS	A, H	
1959	ECLIPTA PROSTRATA	A, H	
1960	ECTOIN	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1961	EDETATE SODIUM	E	Only for use in topical medicines for dermal application and nasal medicines. The concentration in the medicine must be no more than 0.2%.
1962	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1963	EGG LECITHIN	A, E	
1964	EGGSHELL MEMBRANE HYDROLYSATE	A	
1965	EGGSHELL MEMBRANE	A	

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
	POWDER		
1966	EICHHORNIA CRASSIPES	A, H	
1967	ELAEAGNUS ANGUSTIFOLIA	A, H	
1968	ELAEIS GUINEENSIS	A, E, H	
1969	ELASTIN	E	Only for use in topical medicines for dermal application.
1970	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%.
1971	ELDER FLOWER BLACK DRY	A, E, H	
1972	ELDER FLOWER BLACK POWDER	A, H	
1973	ELECAMPANE RHIZOME DRY	A, H	
1974	ELECAMPANE RHIZOME POWDER	A, H	
1975	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%.
1976	ELEMI RESINOID	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 fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1977	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%.
1978	ELEOCHARIS DULCIS	A, H	
1979	ELETTARIA CARDAMOMUM	A, E, H	
1980	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1981	ELEUTHEROCOCCUS ROOT DRY	A, H	
1982	ELEUTHEROCOCCUS ROOT POWDER	A, H	
1983	ELEUTHEROCOCCUS SENTICOSUS	A, H	
1984	ELSHOLTZIA SPLENDENS	A, H	
1985	ELYMUS REPENS	A, E, H	
1986	EMU OIL	A, E	Emu oil ingredients must meet the following two requirements: 1) the manufacturing process is to include steps such as cooking, fat drying or

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and 2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption.
1987	EMULSIFYING WAX	E	
1988	ENOXOLONE	E	Only for use in topical medicines for dermal application.
1989	ENZYME MODIFIED CREAM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1990	EPHEDRA DISTACHYA	A, H	Ephedrine and Pseudoephedrine (of Ephedra distachya) are mandatory components of Ephedra distachya and must be declared in the application. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			0.001%.
1991	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%.
1992	EPIGAEA REPENS	A, H	
1993	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.
1994	EPILOBIUM PALUSTRE	A, H	
1995	EPILOBIUM PARVIFLORUM	A, H	
1996	EPIEDIUM BREVICORNU	A, H	

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
1997	EPIMEDIUM GRANDIFLORUM	A, H	
1998	EPIMEDIUM SAGITTATUM	A, H	
1999	EPOXY CEDRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2000	EQUISETUM ARVENSE	A, E, H	
2001	EQUISETUM HIEMALE	A, H	
2002	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2003	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%.
2004	ERIGERON BREVISCAPUS	A, H	
2005	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components. The concentration of amygdalin in the medicine must be 0%. The concentration of

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Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
2006	ERIOCAULON BUERGERIANUM	A, H	
2007	ERIODICTYON CRASSIFOLIUM	A, H	
2008	ERIODICTYON GLUTINOSUM	A, H	
2009	ERODIUM CICUTARIUM	A, H	
2010	ERUCA SATIVA	A, H	
2011	ERYTHORBIC ACID	E	
2012	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%.
2013	ERYTHROSINE	E	Only for use as a colour for oral and topical use.
2014	ERYTHROSINE ALUMINIUM LAKE	E	Only for use as a colour for oral and topical use.
2015	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
2016	ESCHSCHOLZIA CALIFORNICA	A, H	
2017	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2018	ETHANOL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2019	ETHANOL ABSOLUTE	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in

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Permissible ingredients and requirements			
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Item	Ingredient name	Purpose	Specific requirements
			force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'
2020	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2021	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).
2022	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2023	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2024	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%.
2025	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%.
2026	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%.
2027	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			1%.
2028	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%.
2029	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2030	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%.
2031	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2032	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%.
2033	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2034	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%.
2035	ETHYL 3-HYDROXYBUTYRATE	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
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2036	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%.
2037	ETHYL 3-MERCAPTOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2038	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%.
2039	ETHYL 4,7-OCTADIENOATE	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%.
2040	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%.
2041	ETHYL ACETOACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2042	ETHYL ACRYLATE	E	
2043	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%.

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2044	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%.
2045	ETHYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2046	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%.
2047	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

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Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
			following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes (or words to that effect)'.
2048	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%.
2049	ETHYL CAPRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2050	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%.

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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%.
2051	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%.
2052	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%.
2053	ETHYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2054	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

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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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2055	ETHYL 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>
2056	ETHYL HYDROXYBENZOATE	E	<p>Medicines containing hydroxybenzoates require the following warning statement on the medicine label:</p> <p>- (TOTBNZ) ‘Contains hydroxybenzoates’ (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR ‘Contains [insert the approved name of hydroxybenzoate used]’ (or words to this effect) if product contains one hydroxybenzoate source.</p>
2057	ETHYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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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%.
2058	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%.
2059	ETHYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2060	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%.

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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%.
2061	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%.
2062	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%.
2063	ETHYL LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2064	ETHYL LINALYL ACETATE	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
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2065	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2066	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2067	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%.
2068	ETHYL MALTOL	E	
2069	ETHYL MENTHANE CARBOXAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2070	ETHYL METHACRYLATE	E	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
2071	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%.
2072	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%.
2073	ETHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2074	ETHYL OLEATE	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
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2075	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%.
2076	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%.
2077	ETHYL PALMITATE	E	Permitted for use only in combination with other permitted 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%.
2078	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%.
2079	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%.
2080	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 fragrance concentration in a medicine must be no more 1%.

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2081	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 than 1%.
2082	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%.
2083	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 than 1%.
2084	ETHYL SEBACATE	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%.
2085	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%.
2086	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%.
2087	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%.
2088	ETHYL TRANS-2, CIS-4-DECADIENOATE	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%.
2089	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%.
2090	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%.
2091	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%.
2092	ETHYL VANILLIN	E	
2093	ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2094	ETHYL-2-METHYL-4-PENTENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2095	ETHYL-2-METHYLPENTENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2096	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.002%.</p>
2097	ETHYLCELLULOSE	E	
2098	ETHYLENE BRASSYLATE	E	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%.
2099	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%.
2100	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2101	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%.
2102	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%.

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2103	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2104	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
2105	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%.
2106	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%.
2107	ETHYLHEXYL METHOXYCRYLENE	E	Only for use in topical medicines for dermal application and not to be

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			<p>included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p>
2108	ETHYLHEXYL TRIAZONE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p> <p>When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label:</p> <ul style="list-style-type: none"> - (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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			to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2109	ETHYLHEXYLGLYCERIN	E	Only for use in topical medicines for dermal 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%.
2110	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2111	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

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			<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>
2112	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> <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

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			<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>
2113	EUCALYPTUS GLOBULUS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus globulus.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is</p>

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			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.
2114	EUCALYPTUS MACRORHYNCHA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus macrorhyncha.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine</p>

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			must also have a child resistant closure.
2115	EUCALYPTUS OIL	A, E, H	<p>Cineole is a mandatory component of Eucalyptus oil.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (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

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			of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2116	EUCALYPTUS RADIATA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus radiata.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>

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2117	EUCALYPTUS ROSTRATA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus rostrata.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include 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 TERETICORNIS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus tereticornis.</p> <p>In liquid preparations when the concentration of cineole OR</p>

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			<p>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>
2119	EUCOMMIA ULMOIDES	A, H	
2120	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</p>

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			<p>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 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’
2121	EUGENYL ACETATE	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%.
2122	EUONYMUS ATROPURPUREUS	A, H	
2123	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2124	EUPATORIUM FORTUNEI	A, H	
2125	EUPATORIUM JAPONICUM	A, H	
2126	EUPATORIUM PERFOLIATUM	A, H	
2127	EUPATORIUM PURPUREUM	A, H	
2128	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood' or - (SHELL) 'Contains crustacean shellfish'.
2129	EUPHORBIA CYPARISSIAS	A, H	
2130	EUPHORBIA DRY	A, H	
2131	EUPHORBIA HETERODOXA	A, H	

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2132	EUPHORBIA HIRTA	A, H	
2133	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%.
2134	EUPHORBIA PEKINENSIS	A, H	
2135	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2136	EUPHORBIA POWDER	A, H	
2137	EUPHORBIA RESINIFERA	A, H	
2138	EUPHORBIA SIEBOLDIANA	A, H	
2139	EUPHRASIA OFFICINALIS	A, H	
2140	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2141	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2142	EURYALE FEROX	A, H	
2143	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

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			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'.
2144	EVENING PRIMROSE OIL	A, E, H	
2145	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%.