

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
749	BACILLUS COAGULANS	A	<p>Only permitted for use in medicines:</p> <p>(a) limited to oral routes of administration; and</p> <p>(b) when the strain of Bacillus coagulans is confirmed to be:</p> <p>(i) Microbial Type Culture Collection (MTCC) accession number 5260; and/or</p> <p>(ii) MTCC accession number 5856.</p> <p>The strain of Bacillus coagulans must be declared on the label.</p> <p>When the strain of Bacillus coagulans is MTCC accession number 5260:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than 6 billion cfu of Bacillus coagulans strain MTCC accession number 5260; and</p> <p>(b) the following warning statements are required on the medicine label:</p> <p>- (CHILD2) 'Not suitable for children'; and</p> <p>- (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'</p>

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			<p>When the strain of <i>Bacillus coagulans</i> is MTCC accession number 5856:</p> <p>(a) the maximum recommended daily dose of the medicine must not provide more than 2 billion cfu of <i>Bacillus coagulans</i> strain MTCC accession number 5856; and</p> <p>(b) the following warning statements are required 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); - (CHILD2) 'Not suitable for children'; and - (BACCOAG) 'Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'
750	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).
751	BACOPA MONNIERI	A, H	

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752	BALLOTA NIGRA	A, H	
753	BALM OF GILEAD BUD DRY	A, H	
754	BALM OF GILEAD BUD POWDER	A, H	
755	BALSAM COPAIBA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
756	BAMBUSA BREVIFLORA	A, E, H	
757	BAMBUSA TEXTILIS	A, H	
758	BANANA	E	
759	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%.
760	BAPTISIA CONFUSA	A, H	
761	BAPTISIA TINCTORIA	A, H	
762	BARBAREA VULGARIS	A, H	
763	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
764	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
765	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
766	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other than topical and mucosal.
767	BARLEY LEAF	E	

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768	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
769	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
770	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%.
771	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%.
772	BASIL OIL COMOROS	A, E, H	Methyl chavicol is a mandatory component of Basil oil Comoros. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
773	BASIL OIL EUROPEAN	A, E, H	Methyl chavicol is a mandatory component of Basil oil European. When the concentration of Methyl chavicol in the medicine is more

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			<p>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>
774	BASSIA SCOPARIA	A, H	
775	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
776	BAY LEAF	E	
777	BAY OIL	A, E, H	<p>When the total concentration of bay oil in the medicine is more than 25%:</p> <p>(a) the nominal capacity of the container must not be more than 25 mL;</p> <p>(b) the container must be fitted with a restricted flow insert;</p> <p>(c) the following warning statements are required on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect);</p> <p>- (NTAKEN) 'Not to be taken';</p> <p>and</p> <p>(d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.</p>
778	BEEWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
779	BEESWAX ALCOHOLS	A	<p>Only to be used in a medicine where Rainbow and Nature Pty Ltd (Client ID 22307), 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 22 April 2024.</p> <p>The route of administration for medicines that contain beeswax alcohols must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 150 mg beeswax alcohols.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <p>(a) (PREGNT) ‘Not recommended for use by pregnant and lactating women’</p> <p>(b) (CHILD2) ‘Not suitable for children’</p>
780	BEET RED	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
781	BEETROOT	E, H	
782	BEGONIA FIMBRISTIPULA	A, H	
783	BEHENETH-10	E	Only for use in topical medicines

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			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.
784	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
785	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
786	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%.
787	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
788	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%.
789	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are

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			<p>mandatory components of Belladonna herb powder.</p> <p>The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p>
790	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>
791	BELLIS PERENNIS	A, H	
792	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 not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p>

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
793	BENINCASA HISPIDA	A, E, H	
794	BENTONITE	E	
795	BENZALDEHYDE	E	
796	BENZALDEHYDE GLYCERYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
797	BENZALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and nasal sprays. When benzalkonium chloride is used in a topical medicine for dermal application, the concentration in the medicine must not be more than 5%. When benzalkonium chloride is used in a nasal spray dosage form, the concentration of benzalkonium chloride in the medicine must not be more than 0.03%. When benzalkonium chloride is used in a nasal spray dosage form which is either: (i) indicated for use in children; or (ii) not specifically indicated for adults only; the following warning statement is required on the medicine label: - (NTAKEN2) 'Not to be used by children under 2 years old' (or words to that effect).
798	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal

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			application.
799	BENZOIC ACID	E, H	
800	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%.
801	BENZOIN SIAM	A, E, H	
802	BENZOIN SUMATRA	A, E, H	
803	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%.
804	BENZOTHIAZOLE	E	Benzothiazole must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing benzothiazole must not be more than 1% of the total medicine.
805	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
806	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%.
807	BENZYL ALCOHOL	A, E	When used as an active ingredient: a) permitted for use only in medicated throat lozenges; and b) when the maximum recommended daily dose of the medicine provides more than 300mg, the following warning statement must be included on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
808	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application.
809	BENZYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
810	BENZYL CINNAMATE	E	Only for use in: (a) topical medicines for dermal

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			<p>application when the concentration of benzyl cinnamate in the medicine is not greater than 0.15%; or</p> <p>(b) medicines in combination with other permitted ingredients as a constituent of a flavour proprietary excipient formulation when the total flavour proprietary excipient formulation in the medicine is not more than 5%.</p> <p>Not to be included in medicines intended for use in the eye.</p>
811	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
812	BENZYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
813	BENZYL ISOAMYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
814	BENZYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
815	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>
816	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>
817	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 medicine must be no more 1%.</p>
818	BENZYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
819	BENZYL SALICYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
820	BENZYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>
821	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>

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822	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 not be more than 6% (as acid).</p> <p>When used in primary sunscreen products, the following warning statements are required 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).
823	BERBERIS AQUIFOLIUM	A, H	
824	BERBERIS ARISTATA	A	<p>Only for use in oral medicines.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
825	BERBERIS VULGARIS	A, E, H	
826	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 on</p>

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			the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
827	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%.
828	BERGAMOT OIL COLDPRESSED	A, E, H	When for internal use oxedrine is a mandatory component of bergamot oil coldpressed. The maximum recommended daily dose must provide no more than 30 milligrams of oxedrine. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.4 per cent or less of bergamot oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
829	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%.

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830	BERTHOLLETIA EXCELSA	A, E, H	
831	BETA RAPA	A, E, H	
832	BETA VULGARIS	A, E, H	
833	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%.
834	BETA-CARYOPHYLLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
835	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%.
836	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

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			medicine must be no more 1%.
837	BETA-DAMASCONE	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>
838	BETA-HOMO CYCLOCITRAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
839	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
840	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>
841	BETA-IONONE EPOXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>

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842	BETA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
843	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%.
844	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%.
845	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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846	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%.
847	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%.
848	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%.
849	BETA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
850	BETA-TOCOPHEROL	E	
851	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.’
852	BETADEX	E	
853	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%.
854	BETAINE	E	Only for use in topical medicines for dermal application.
855	BETAINE HYDROCHLORIDE	E	
856	BETULA LENTA	A, H	Methyl salicylate is a mandatory component of Betula lenta. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. 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

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packaging.

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

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

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

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

The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%;

- ii) the following warning statements are required on the medicine label:

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

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

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

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

- iii) if the concentration of methyl

			<p>salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
857	BETULA NIGRA	A, H	<p>Cresol, eugenol and methyl salicylate are mandatory components of <i>Betula nigra</i>.</p> <p>For external use only when the total concentration of cresols, 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>

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When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging.

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

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

The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%;
- ii) the following warning statements are required on the medicine label:
 - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
 - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
 - (SENS) 'Application to skin may increase sensitivity to sunlight.'

			<p>(or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);</p> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
858	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> <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.

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The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%
- ii) the following warning statements are required on the medicine label:
 - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
 - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
 - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);
 - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);
- iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:
 - (IRRIT) 'If irritation develops, discontinue use'.

859	BETULA PUBESCENS	A, E, H	
860	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
861	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-	E	Permitted for use only in combination with other permitted

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	METHYL-8-(1-METHYLETHYL)-		ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
862	BIFIDOBACTERIUM ADOLESCENTIS	A	
863	BIFIDOBACTERIUM ANIMALIS	A	
864	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
865	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
866	BIFIDOBACTERIUM BIFIDUM	A	
867	BIFIDOBACTERIUM BREVE	A	
868	BIFIDOBACTERIUM INFANTIS	A	
869	BIFIDOBACTERIUM LACTIS	A	
870	BIFIDOBACTERIUM LONGUM	A	
871	BILBERRY	E	
872	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%.
873	BIOTA ORIENTALIS	A, H	
874	BIOTIN	A, E	
875	BIRCH LEAF DRY	A, E, H	Methyl salicylate is a mandatory component of birch leaf dry. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant

packaging.

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

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

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

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

The following warning statement is required on the medicine label:

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

When for use in topical medicines for dermal application:

- i) the concentration of methyl salicylate in the medicine must not be more than 25%

- ii) the following warning statements are required on the medicine label:

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

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

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

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

- iii) if the concentration of methyl salicylate in the medicine is

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			greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
876	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%.
877	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%.
878	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
879	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%.
880	BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2.5%.
881	BIS-PEG-12 DIMETHICONE BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 0.2%.
882	BIS-STEARYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2.30%.
883	BIS-STEARYL ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
884	BISABOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
885	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
886	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.

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

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			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.'
891	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.'
892	BLACK CURRANT	E	
893	BLACK CURRANT ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
894	BLACK CURRANT FRESH	A, E, H	
895	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted

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			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
896	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
897	BLACK PEPPER OIL	A, E, H	
898	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%.
899	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
900	BLACKBERRY	E	
901	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%.
902	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
903	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

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			medicine must be no more than 5%.
904	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%.
905	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, sucrose is a mandatory component of blackstrap molasses.
906	BLADDERWRACK DRY	A, H	Iodine is a mandatory component of Bladderwrack dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
907	BLADDERWRACK POWDER	A, H	Iodine is a mandatory component of Bladderwrack powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
908	BLAINVILLEA ACMELLA	A, E, H	When used as an excipient, permitted for use only in combination with other permitted

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			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
909	BLETILLA STRIATA	A, H	
910	BLUE FLAG RHIZOME DRY	A, H	
911	BLUE FLAG RHIZOME POWDER	A, H	
912	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%.
913	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%.
914	BLUMEA LACERA	A, H	
915	BOEHMERIA NIVEA	A, H	
916	BOERHAVIA DIFFUSA	A, H	
917	BOERHAVIA REPENS	A, H	
918	BOGBEAN LEAF DRY	A, H	
919	BOGBEAN LEAF POWDER	A, H	
920	BOIS DE ROSE OIL	A, E, H	
921	BOMBAX CEIBA	A, H	
922	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> .

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923	BORAX	A, E, H	<p>Boron is a mandatory component of borax.</p> <p>The percentage of boron from borax should be calculated based on the molecular weight of borax.</p> <p>The maximum recommended daily dose must not provide more than 6mg of boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must be no more than 3500 mg/kg or 3500 mg/L or 0.35%.</p> <p>When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none">- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or- (ADULT) 'Adults only' (or words to that effect). <p>When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <ul style="list-style-type: none">- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or- (ADULT) 'Adults only' (or words to that effect). <p>When for excipient use and the maximum recommended daily dose of the medicine provides</p>
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			<p>more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:</p> <p>- (BORON) 'Contains boron' (or words to that effect).</p> <p>When the medicine is for topical use for dermal application, the following warning statement is required on the label:</p> <p>- (BROKEN) 'Use on unbroken skin only' (or words to that effect).</p>
924	BORAX PENTAHYDRATE	A, E	<p>Boron is a mandatory component of borax pentahydrate.</p> <p>The percentage of boron from borax pentahydrate should be calculated based on the molecular weight of borax pentahydrate.</p> <p>The maximum recommended daily dose must not provide more than 6mg of boron from borax pentahydrate.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 g/L or 0.35%.</p> <p>When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:</p> <p>- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>When the maximum</p>

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recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or

- (ADULT) 'Adults only' (or words to that effect).

When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:

- (BORON) 'Contains boron' (or words to that effect).

When the medicine is for topical use for dermal application, the following warning statement is required on the label:

- (BROKEN) 'Use on unbroken skin only' (or words to that effect).

925	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 not provide more than 6mg of boron.</p> <p>In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 mg/L or 0.35%.</p>
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When the maximum recommended daily dose of the medicine provides more than 3 mg of boron and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or
- (ADULT) 'Adults only' (or words to that effect).

When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label:

- (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or
- (ADULT) 'Adults only' (or words to that effect).

When for excipient use and the maximum recommended daily dose of the medicine provides more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label:

- (BORON) 'Contains boron' (or words to that effect).

When the medicine is for topical use for dermal application, the following warning statement is required on the label:

- (BROKEN) 'Use on unbroken skin only' (or words to that effect).
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926	BORNEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
927	BORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
928	BORON NITRIDE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
929	BORONIA ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
930	BORONIA MEGASTIGMA	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%.
931	BOSWELLIA CARTERII	A, E, H	
932	BOSWELLIA SERRATA	A, E, H	
933	BOSWELLIA THURIFERA	A, H	
934	BOVINE CALCIUM CHONDROITIN SULFATE	A	
935	BOVINE CHONDROITIN SULFATE	A	
936	BOVINE COLOSTRUM POWDER	A	The following warning statement is required on the medicine label: - (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).
937	BOVINE LACTOFERRIN	A	
938	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
939	BOVINE SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application; - not to be included in medicines intended for use in the eye; and - the concentration in the medicine must be no more than 0.001%.
940	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The following warning statement is required on the medicine label: - (BABY3) 'Not suitable for use in children under the age of 12 months except on the advice of a health professional.' (or words to that effect).
941	BRANDY	E	
942	BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 1%.
943	BRASSICA CHINENSIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica chinensis when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
944	BRASSICA JUNCEA	A, H	Allyl isothiocyanate is a mandatory component of Brassica juncea when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
945	BRASSICA NAPUS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
946	BRASSICA NIGRA	A, H	Allyl isothiocyanate is a mandatory component of Brassica nigra when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
947	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the

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			<p>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>
948	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>
949	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>
950	BRASSICA OLERACEA VAR. ITALICA	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
951	BRASSICA OLERACEA VAR. VIRIDIS	A, H	<p>Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed.</p> <p>The concentration of allyl isothiocyanate from all ingredients in the product must be no more</p>

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			than 10 mg/kg or 10 mg/L or 0.001%.
952	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%.
953	BRASSICA RAPA	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica rapa when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
954	BRILLIANT BLACK BN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
955	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
956	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
957	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
958	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
959	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.

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960	BRIZA MEDIA	A, H	
961	BROCCOLI	E	
962	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (Ananas comosus).
963	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%.
964	BROMUS CATHARTICUS	A, H	
965	BROMUS INERMIS	A, H	
966	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
967	BRONOPOL	E	Only for use in topical medicines for dermal application.
968	BROUSSONETIA PAPYRIFERA	A, H	
969	BROWN FK	E	Permitted for use only as a colour for topical use.
970	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
971	BRUSSEL SPROUT	E	
972	BRYONIA ALBA	A, H	
973	BRYONIA DIOICA	A, H	
974	BUCHU LEAF DRY	A, H	
975	BUCHU LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
976	BUCHU LEAF POWDER	A, E, H	
977	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
978	BUDDLEJA OFFICINALIS	A, H	
979	BULNESIA SARMIENTI	A, E, H	
980	BUNIAS ORIENTALIS	A, H	
981	BUPLEURUM FALCATUM	A, H	
982	BURDOCK LEAF DRY	A, H	
983	BURDOCK LEAF POWDER	A, H	
984	BURDOCK ROOT DRY	A, H	
985	BURDOCK ROOT POWDER	A, H	
986	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
987	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%.
988	BUTANE	E	Only for use as an excipient propellant ingredient.
989	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%.
990	BUTTER	E	
991	BUTTER ACIDS	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%.
992	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%.
993	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%.
994	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%.
995	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%.
996	BUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
997	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%.
998	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%.
999	BUTYL ESTER OF PVM/MA COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1000	BUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
1001	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
1002	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%.
1003	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%.
1004	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%.
1005	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%.
1006	BUTYL METHOXYDIBENZOYLMETHAN E	A E	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for

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			<p>use in the eye.</p> <p>The concentration in preparation must not be more than 5%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
1007	BUTYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1008	BUTYL STEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
1009	BUTYL UNDECYLENATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1010	BUTYLATED HYDROXYANISOLE	E	
1011	BUTYLATED HYDROXYTOLUENE	E	
1012	BUTYLENE GLYCOL	E	<p>Only for use in topical medicines</p>

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	DICAPRYLATE/DICAPRATE		for dermal 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%.
1013	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%.
1014	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%.
1015	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%.
1016	BUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1017	BUTYRIC ACID	E	Permitted for use only in combination with other permitted

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1018	C1-8 ALKYL TETRAHYDROXYCYCLOHEXAN OATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.012%.</p>
1019	C10-12 ALKANE/CYCLOALKANE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1020	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	<p>Only for use in topical medicines for dermal application.</p>
1021	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>
1022	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>

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1023	C12-13 PARETH-3	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
1024	C12-13 PARETH-3	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.125%.</p> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
1025	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>
1026	C12-15 ALKYL OCTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
1027	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>
1028	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>

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			The concentration in the medicine must be no more than 0.75%.
1029	C12-22 ALKYL ACRYLATE/HYDROXYETHYL ACRYLATE COPOLYMER	E	<p>Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin.</p> <p>The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.</p>
1030	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1031	C14-22 ALCOHOLS	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 2.55%.</p>
1032	C15-16 ISOPARAFFIN	E	<p>C15-16 isoparaffin must only be included in topical medicines:</p> <p>(a) for dermal application; and</p> <p>(b) where the dosage form of the medicine is not spray.</p> <p>The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.</p> <p>When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%.</p>
1033	C15-19 ALKANE	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
1034	C17-18 ISOPARAFFIN	E	C17-18 isoparaffin must only be included in topical medicines: (a) for dermal application; and (b) where the dosage form of the medicine is not spray. The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%. When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C17-18 isoparaffin) in the medicine must not be more than 25%.
1035	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1036	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1037	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%.
1038	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1039	C20-40 ALKYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 2%.
1040	C20-40 PARETH-24	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%.
1041	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%.
1042	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%.
1043	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1044	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1045	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%
1046	CABBAGE	E	
1047	CABREUVA OIL	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%.
1048	CADE OIL	A, E, H	
1049	CAESALPINIA SAPPAN	A, H	
1050	CAFFEINE	A, E, H	<p>When used as an excipient, only for use in topical medicines for dermal application.</p> <p>Only for use as an active ingredient for:</p> <p>(a) oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and</p> <p>(b) Topical medicines for dermal application that are directed for use in adults only.</p> <p>When for topical application:</p> <p>(a) the concentration of total caffeine in the medicine must not be more than 1%; and</p> <p>(b) the medicine must not be intended for use on broken skin.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100 mg of caffeine from this ingredient.</p> <p>When for internal use or oral application, the following warning statement is required on the medicine label:</p> <p>- (ADULT) 'Adults only' (or words to that effect).</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total</p>

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caffeine greater than 33%.

When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver.'

			Consult your health professional before taking with other medicines' (or words to that effect).
1051	CAJUPUT OIL	A, E, H	<p>Cineole is a mandatory component of Cajuput oil.</p> <p>When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container.</p> <p>When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container.</p> <p>When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label:</p> <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</p>

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			<p>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 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'.
1052	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>
1053	CALANUS FINMARCHICUS OIL	A	<p>Only to be used in a medicine where Blackmores Ltd (Client ID 10576), 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 1 March 2025.</p> <p>The route of administration for medicines that contain Calanus</p>

			<p>finmarchicus oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2.3 g of <i>Calanus finmarchicus</i> oil.</p> <p>The following warning statements (or words to that effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
1054	CALCIFEDIOL MONOHYDRATE	A	<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).
1055	CALCIFIED LITHOTHAMNION	A	Only for use in oral medicines.

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1056	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1057	CALCIUM ALGINATE	E	
1058	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.
1059	CALCIUM ASCORBATE	A, E, H	
1060	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1061	CALCIUM ASPARTATE	A	
1062	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1063	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.
1064	CALCIUM BETA-HYDROXY- BETA-METHYLBUTYRATE	A, H	
1065	CALCIUM BETA-HYDROXY- BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1066	CALCIUM CARBONATE	A, E, H	
1067	CALCIUM CASEINATE	E	
1068	CALCIUM CHLORIDE DIHYDRATE	E	
1069	CALCIUM CITRATE	A, E, H	
1070	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1071	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1072	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular

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			<p>weight of Calcium fluoride.</p> <p>The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.</p>
1073	CALCIUM FOLINATE	A	<p>Folinic acid is a mandatory component of calcium folinate.</p> <p>The maximum recommended daily dose must not provide more than 500 micrograms of folinic acid.</p> <p>When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.</p>
1074	CALCIUM FRUCTOBORATE TETRAHYDRATE	A	<p>Only to be used in a medicine where VDF FutureCeuticals Inc (Client ID 62256), 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 25 October 2025.</p> <p>Boron is a mandatory component of calcium fructoborate tetrahydrate.</p> <p>The percentage of boron from calcium fructoborate tetrahydrate should be calculated based on the molecular weight of calcium fructoborate tetrahydrate.</p> <p>The route of administration for medicines that contain calcium fructoborate tetrahydrate must be</p>

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			limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 220 mg of calcium fructoborate tetrahydrate; and (b) 6 mg of boron. The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
1075	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1076	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1077	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1078	CALCIUM GLYCINATE DIHYDRATE	A	
1079	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1080	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1081	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1082	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1083	CALCIUM HYDROXIDE	A, E, H	When used as a standard active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia as in force or existing from time to time.

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1084	CALCIUM HYDROXYCITRATE	A, H	
1085	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1086	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1087	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%
1088	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1089	CALCIUM LACTATE	A, E, H	
1090	CALCIUM LACTATE GLUCONATE	A, E, H	
1091	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1092	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1093	CALCIUM LYSINATE	A	Only for use in oral medicines.
1094	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1095	CALCIUM OROTATE	A, E, H	
1096	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1097	CALCIUM PANTOTHENATE	A, E, H	
1098	CALCIUM PHOSPHATE	A, E, H	
1099	CALCIUM PYRUVATE	A	
1100	CALCIUM SACCHARATE	E	
1101	CALCIUM SILICATE	E	
1102	CALCIUM SODIUM CASEINATE	A, H	
1103	CALCIUM SODIUM LACTATE	A, E, H	
1104	CALCIUM STEARATE	E	

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1105	CALCIUM SUCCINATE	A, E, H	
1106	CALCIUM SULFATE	A, E, H	
1107	CALCIUM SULFATE DIHYDRATE	A, E, H	
1108	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1109	CALCIUM THREONINATE	A	
1110	CALENDULA FLOWER DRY	A, E, H	
1111	CALENDULA FLOWER POWDER	A, H	
1112	CALENDULA OFFICINALIS	A, E, H	
1113	CALLERYA RETICULATA	A, H	
1114	CALLICARPA PEDUNCULATA	A, H	
1115	CALLISTEPHUS CHINENSIS	A, H	
1116	CALLITRIS COLUMELLARIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1117	CALLITRIS COLUMELLARIS SUBSP. INTRATROPICA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1118	CALLITRIS RHOMBOIDEA	A, H	
1119	CALLUNA VULGARIS	A, E, H	
1120	CALOCHORTUS TOLMIEI	A, H	
1121	CALTHA PALUSTRIS	A, H	
1122	CALUMBA ROOT DRY	A, H	
1123	CALUMBA ROOT POWDER	A, H	
1124	CALVATIA GIGANTEA	A, E, H	
1125	CALYCANTHUS FLORIDUS	A, H	
1126	CALYCANTHUS PRAECOX	A, H	
1127	CAMELLIA JAPONICA	A, H	

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1128	CAMELLIA OLEIFERA	A, E, H	If <i>Camellia oleifera</i> (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only.
1129	CAMELLIA SINENSIS	A, E, H	<p>Caffeine is a mandatory component of <i>Camellia sinensis</i>.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee

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			<p>contains approximately 80mg of caffeine.'</p> <p>- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'</p> <p>When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <p>- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'</p> <p>- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).</p>
1130	CAMPHENE	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1131	CAMPHOLENIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p>

1132	CAMPHOR	A, E, H	<p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations, the concentration of camphor must be no more than 2.5%.</p>
1133	CAMPHOR BENZALKONIUM METHOSULFATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the preparation must not be more than 6%.</p> <p>When used in primary sunscreen products, the following warning statements are required 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).
1134	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 the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of</p>

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the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

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

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

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

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

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

- (NTAKEN) 'Not to be taken'.

When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.

When the concentration of cineole in the preparation is more than

			<p>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 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>
1135	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</p>

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12.5%.

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

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

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

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

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

- (NTAKEN) 'Not to be taken'.

In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

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

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			and - (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.
1136	CAMPSIS GRANDIFLORA	A, H	
1137	CANADA BALSAM	A, H	
1138	CANANGA ODORATA	A, E, H	
1139	CANANGA OIL	A, E, H	
1140	CANARIUM INDICUM	A, H	Only for use when the plant part is seed and the plant preparation is oil.
1141	CANARIUM LUZONICUM	A, H	
1142	CANDELILLA WAX	A, E, H	
1143	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1144	CANDIDA UTILIS	A, E, H	When used as an excipient, only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
1145	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1146	CANOLA OIL	A, E, H	Allyl isothiocyanate is a

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			<p>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>
1147	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1148	CANTHAXANTHIN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1149	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>
1150	CAPROIC ALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1151	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</p>

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1152	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIIC TRIGLYCERIDE	E	
1153	CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3%
1154	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1155	CAPRYLOYL GLYCERIN/SEBACIC 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. The concentration in the medicine must not be more than 10%.
1156	CAPRYLOYL GLYCINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2%
1157	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%.
1158	CAPRYLYL GLYCOL	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%
1159	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%.
1160	CAPSELLA BURSA-PASTORIS	A, H	
1161	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1162	CAPSICUM ANNUUM	A, E, H	
1163	CAPSICUM DRY	A, E, H	
1164	CAPSICUM FRUIT OLEORESIN	A, E	
1165	CAPSICUM FRUTESCENS	A, E, H	
1166	CAPSICUM POWDER	A, E, H	
1167	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1168	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1169	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must not be more than 0.2%.
1170	CARAWAY DRY	A, H	
1171	CARAWAY OIL	A, E, H	
1172	CARAWAY POWDER	A, H	
1173	CARBOMER 1342	E	Only for use as an excipient in

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				topical medicines for dermal application.
1174	CARBOMER 2001	E		Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.
1175	CARBOMER 934	E		Only for use in topical medicines for dermal application.
1176	CARBOMER 934P	E		Only for use in topical medicines for dermal application.
1177	CARBOMER 940	E		Only for use in topical medicines for dermal application.
1178	CARBOMER 941	E		Only for use as an excipient in topical medicines for dermal application.
1179	CARBOMER 954	E		Only for use as an excipient in topical medicines for dermal application.
1180	CARBOMER 980	E		Only for use as an excipient in topical medicines for dermal application.
1181	CARBOMER 981	E		Only for use as an excipient in topical medicines for dermal application.
1182	CARBOMER COPOLYMER (TYPE B)	E		Only for use as an excipient in topical medicines for dermal application.

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1183	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1184	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%.
1185	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1186	CARBON BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1187	CARBON DIOXIDE	E	
1188	CARDAMOM FRUIT DRY	A, H	
1189	CARDAMOM FRUIT POWDER	A, E, H	
1190	CARDAMOM OIL	A, E, H	
1191	CARDIOSPERMUM HALICACABUM	A, H	
1192	CARICA PAPAYA	A, E, H	
1193	CARLINA ACAULIS	A, H	
1194	CARMELLOSE	E	
1195	CARMELLOSE CALCIUM	E	
1196	CARMELLOSE SODIUM	E	
1197	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1198	CARMOISINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1199	CARMOISINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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1200	CARNAUBA WAX	A, E, H	
1201	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%.
1202	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%.
1203	CAROB GUM	E	
1204	CAROB POD	E	
1205	CAROTENES	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1206	CARPINUS BETULUS	A, H	
1207	CARPINUS CORDATA	A, H	
1208	CARRAGEENAN	E	
1209	CARROT	E	
1210	CARROT SEED OIL	A, E, H	
1211	CARTHAMUS TINCTORIUS	A, E, H	Carthamus tinctorius (safflower oil) when used as a solvent is restricted to topical or sunscreen preparations for dermal application only. If for oral use, the medicine requires the following warning statement on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect).
1212	CARUM CARVI	A, H	

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1213	CARVACROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1214	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%.
1215	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%.
1216	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%.
1217	CARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1218	CARYA ILLINOINENSIS	A, H	
1219	CARYA OVATA	A, H	
1220	CARYOPHYLLENE OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1221	CASCARA DRY	A, H	<p>Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD3) ‘Use in children under 12 years is not recommended’; - (LAX2) ‘Prolonged use may cause serious bowel problems’; and - (LAX3) ‘Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are

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			<p>pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect].</p> <p>When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect].</p> <p>When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and</p> <p>- (LAX4) 'This product may have laxative effect'.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended';</p> <p>- (LAX1) 'Drink plenty of water' [or words to that effect]; and</p> <p>- (LAX2) 'Prolonged use may cause serious bowel problems'.</p>
1222	CASCARA POWDER	A, H	<p>Hydroxyanthracene derivatives calculated as cascarioside A is a mandatory component of cascara powder when the route of administration is oral administration.</p> <p>When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the</p>

medicine requires the following warning statements on the medicine label:

- (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).

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

- (LAX1) 'Drink plenty of water' (or words to that effect).

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

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

- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:

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

- (LAX1) 'Drink plenty of water' (or words to that effect); and

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			- (LAX2) 'Prolonged use may cause serious bowel problems'.
1223	CASCARILLA OIL	A, E, H	The medicine must not contain more than 1 mg of the equivalent dry herbal material per the maximum recommended daily dose. When for use as an excipient ingredient, cascarilla oil must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing cascarilla oil must not be more than 5% of the total medicine.
1224	CASEIN	E	
1225	CASHEW NUT	E	
1226	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%.
1227	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%.
1228	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.
1229	CASSIA FISTULA	A, E, H	Hydroxyanthracene glycosides

calculated as sennoside B is a mandatory component of Cassia fistula when the route of administration is oral.

When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label:

- (CHILD3) 'Use in children 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).

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

- (LAX1) 'Drink plenty of water' (or words to that effect).

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

- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and
- (LAX4) 'This product may have laxative effect'.

When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as

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			<p>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’. <p>When Cassia fistula is for use as an excipient:</p> <ul style="list-style-type: none"> (a) the plant part must be fruit; and (b) must only be included in medicines when in combination with other permitted ingredients as a: <ul style="list-style-type: none"> (i) flavour proprietary excipient formulation when the plant preparation is an extract; and/or (ii) fragrance proprietary excipient formulation when the plant preparation is an essential oil. <p>The total concentration of flavour proprietary excipient formulations containing Cassia fistula must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing Cassia fistula must not be more than 1% of the total medicine.</p>
1230	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%.
1231	CASSIE ABSOLUTE	E	Permitted for use only in combination with other permitted

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			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1232	CASTANEA MOLLISSIMA	A, H	
1233	CASTANEA SATIVA	A, H	
1234	CASTOR OIL	A, E	
1235	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1236	CASUARINA EQUISETIFOLIA	A, H	
1237	CATALPA BIGNONIOIDES	A, H	
1238	CATALPA OVATA	A, H	
1239	CATECHU	A, H	
1240	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%.
1241	CAULIFLOWER	E	
1242	CAULOPHYLLUM THALICTROIDES	A, E, H	
1243	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1244	CEANOTHUS AMERICANUS	A, H	
1245	CEDAR LEAF OIL	A, E, H	
1246	CEDARWOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1247	CEDARWOOD OIL TERPENES	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1248	CEDARWOOD OIL VIRGINIA	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>
1249	CEDRENOL	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>
1250	CEDRENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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1251	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%.
1252	CEDRUS ATLANTICA	A, E, H	
1253	CEDRUS ATLANTICA WOOD 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%.
1254	CEDRUS DEODARA	A, H	
1255	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1256	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%.
1257	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%.
1258	CELERY SEED DRY	A, E, H	
1259	CELERY SEED OIL	A, E, H	
1260	CELERY SEED POWDER	A, H	
1261	CELLACEFATE	E	

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1262	CELLULASE	A	Must be derived from <i>Trichoderma longibrachiatum</i> only.
1263	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%.
1264	CELOSIA ARGENTEA	A, H	
1265	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1266	CENTAUREA CYANUS	A, E, H	
1267	CENTAURIUM ERYTHRAEA	A, H	
1268	CENTELLA ASIATICA	A, E, H	
1269	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%.
1270	CENTIPEDA CUNNINGHAMII	A, E, H	
1271	CENTIPEDA MINIMA	A, H	
1272	CEPHALANOPSIS SEGETUM	A, H	
1273	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1274	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%.
1275	CERAMIDE 3	E	Only for use in topical medicines for dermal application.

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1276	CERATONIA SILIQUA	A, E, H	
1277	CERATOSTIGMA WILLMOTTIANUM	A, H	
1278	CERESIN	E	Only for use in topical medicines for dermal application.
1279	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%.
1280	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1281	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1282	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1283	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1284	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1285	CETEARETH-33	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. Residual levels of 1,4-dioxane oxide (and related substances) are to be kept below the level of detection.

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1286	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1287	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1288	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%.
1289	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1290	CETETH-10	E	Only for use in topical medicines for dermal application.
1291	CETETH-2	E	Only for use in topical medicines for dermal application.
1292	CETETH-24	E	Only for use in topical medicines for dermal application.
1293	CETETH-5	E	Only for use in topical medicines for dermal application.
1294	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1295	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%.
1296	CETOMACROGOL 500 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to

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			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%.
1297	CETOSTEARYL ALCOHOL	E	
1298	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 %
1299	CETRARIA ISLANDICA	A, H	
1300	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1301	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1302	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1303	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1304	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1305	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1306	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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1307	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1308	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%.
1309	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1310	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1311	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1312	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1313	CETYL-PG HYDROXYETHYL PALMITAMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 8%.
1314	CETYLPYRIDINIUM CHLORIDE	A, E	When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient: a) permitted for use only in medicated throat lozenges; b) the medicine must not contain more than 2 mg of cetylpyridinium chloride per lozenge; c) the maximum recommended daily dose of the medicine must not provide more than 24 mg of

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			cetylpyridinium chloride; and d) the medicine label must specify that the medicine is only to be used for 7 days (or less).
1315	CHAENOMELES LAGENARIA	A, H	
1316	CHAENOMELES SPECIOSA	A, H	
1317	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.
1318	CHAMAECYPARIS LAWSONIANA	A, H	
1319	CHAMAELIRIUM LUTEUM	A, H	
1320	CHAMAEMELUM NOBILE	A, E, H	
1321	CHAMOMILE FLOWER DRY	A, E, H	
1322	CHAMOMILE OIL ENGLISH	A, E, H	
1323	CHAMOMILE OIL GERMAN	A, E, H	
1324	CHANGIUM SMYRNIODES	A, H	
1325	CHEIRANTHUS CHEIRI	A, H	
1326	CHELIDONIUM MAJUS	A, E, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2023; and - released for supply before 1 March 2024: (a) When the medicine is for oral or sublingual use, one of the following warning statements is required on the medicine label: (i) (CELAND) 'WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a

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			healthcare professional'; or
			(ii) (CELAND1) 'In rare cases, Chelidonium majus may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain or dark urine.'
			The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is:
			- listed in the Register on or after 1 March 2023; or
			- released for supply on or after 1 March 2024:
			(b) When the medicine is for oral or sublingual use, the following warning statement is required on the medicine label:
			(CELAND1) 'In rare cases, Chelidonium majus may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain or dark urine.'
1327	CHELONE GLABRA	A, H	
1328	CHENOPODIUM ALBUM	A, H	
1329	CHENOPODIUM VULVARIA	A, H	
1330	CHERRY	E	
1331	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%.
1332	CHESTNUT SWEET	E, H	
1333	CHICKEN COMB EXTRACT	A	
1334	CHICKEN STERNUM	A	Only to be used in a medicine

	<p>CARTILAGE POWDER</p>		<p>where Capsugel Australia Pty Ltd (Client ID 43174), 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 3 July 2025.</p> <p>The route of administration for medicines that contain chicken sternum cartilage powder must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 40 mg of chicken sternum cartilage powder.</p> <p>The following warning statement (or words to that effect) is required on the medicine label: - (ADULT) 'Adults only'.</p>
<p>1335</p>	<p>CHIMAPHILA UMBELLATA</p>	<p>A, H</p>	<p>Beta-arbutin is a mandatory component of Chimaphila umbellata.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to</p>

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			the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
1336	CHIONANTHUS VIRGINICA	A, H	
1337	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>
1338	CHLORELLA PYRENOIDOSA	E	
1339	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>
1340	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1341	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1342	CHLOROBUTANOL HEMIHYDRATE	E	<p>Only for use in topical preparations for dermal application.</p> <p>The concentration in the medicine</p>

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			must be no more than 0.5%.
1343	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1344	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%.
1345	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1346	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1347	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1348	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1349	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1350	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1351	CHOCOLATE BROWN HT	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1352	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1353	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.

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1354	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1355	CHOLESTERYL/BEHENYL/OCTYL LDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
1356	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1357	CHOLINE BITARTRATE	A, E	
1358	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1359	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%.
1360	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.
1361	CHONDRUS DRY	A, E, H	Iodine is a mandatory component of Chondrus dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.

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			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1362	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>
1363	CHROMIC CHLORIDE HEXAHYDRATE	A, H	<p>When used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic chloride hexahydrate.</p> <p>The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate.</p> <p>The maximum recommended daily dose must provide 50 micrograms or less of chromium from organic sources (i.e. chromium picolinate, chromium nicotinate and high chromium yeast).</p>
1364	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>

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			Chromium nicotinate is considered to be an organic form of chromium.
1365	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources. Chromium picolinate is considered to be an organic form of chromium.
1366	CHRYSANTHEMUM BALSAMITA	A, H	
1367	CHRYSANTHEMUM INDICUM	A, H	
1368	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1369	CHRYSANTHEMUM SINENSE	A, H	
1370	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1371	CHRYSOSPORIUM PRUINOSUM	A, H	
1372	CIBOTIUM BAROMETZ	A, H	
1373	CICHORIUM INTYBUS	A, E, H	
1374	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1375	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.
1376	CINCHONA BARK POWDER	A, H	Quinidine and quinine are mandatory components of Cinchona bark powder.

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			The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1377	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>
1378	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>
1379	CINEOLE	E	<p>In liquid preparations when the concentration of cineole in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15</p>

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			millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1380	CINNAMALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1381	CINNAMIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1382	CINNAMOMUM CAMPHORA	A, E, H	<p>Camphor, cineole and safrole are mandatory components of Cinnamomum camphora.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>In essential oil preparations or distillates and the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25</p>

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

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

- Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist'.

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

In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.

In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container.

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

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

- (NTAKEN) 'Not to be taken'.

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

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container.

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

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

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

1383	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>
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			When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1384	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 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</p>

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			<p>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>
1385	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>
1386	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>
1387	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</p>

			<p>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 be no more than 0.001%.</p>
1388	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>
1389	CINNAMYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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1390	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>
1391	CINNAMYL BUTYRATE	E	<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>Permitted for use only in combination with other permitted ingredients as a flavour.</p>
1392	CINNAMYL CINNAMATE	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>
1393	CINNAMYL 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>
1394	CINNAMYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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1395	CINNAMYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used as a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1396	CINNAMYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1397	CINOXATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 6%.</p> <p>When used in primary sunscreen products, the following warning statements are required 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).
1398	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</p>

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			fragrance concentration in a medicine must be no more 1%.
1399	CIS-3-HEXEN-1-OL	E	<p>cis-3-Hexen-1-ol must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 1% of the total medicine.</p>
1400	CIS-3-HEXENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1401	CIS-3-HEXENYL 2-METHYLBUTYRATE	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>
1402	CIS-3-HEXENYL 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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1403	CIS-3-HEXENYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1404	CIS-3-HEXENYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1405	CIS-3-HEXENYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1406	CIS-3-HEXENYL HEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1407	CIS-3-HEXENYL ISOBUTYRATE	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%.
1408	CIS-3-HEXENYL ISOVALERATE	E	<p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>
1409	CIS-3-HEXENYL LACTATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1410	CIS-3-HEXENYL METHYL CARBONATE	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>
1411	CIS-3-HEXENYL SALICYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1412	CIS-3-HEXENYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or

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			<p>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>
1413	CIS-4-HEPTENAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1414	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>
1415	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>
1416	CIS-BETA-OCIMENE	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%.
1417	CIS-HEXAHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1418	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%.
1419	CISTANCHE DESERTICOLA	A, H	
1420	CISTANCHE SALSA	A, H	
1421	CISTUS LADANIFER	A, E, H	
1422	CITRAL	E	
1423	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%.
1424	CITRAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

			fragrance concentration in a medicine must be no more than 1%.
1425	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'
1426	CITRIC ACID DIHYDRATE	A, E	<p>Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.</p> <p>When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:</p>

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- (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'

1427 CITRIC ACID MONOHYDRATE A, E

Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose.

When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label:

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

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1428	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1429	CITROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1430	CITRON	E	
1431	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'.
1432	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%.
1433	CITRONELLAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1434	CITRONELLIC ACID	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1435	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>
1436	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>
1437	CITRONELLYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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1438	CITRONELLYL FORMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1439	CITRONELLYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1440	CITRONELLYL NITRILE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1441	CITRONELLYL OXYACETALDEHYDE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1442	CITRONELLYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted</p>

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			<p>ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1443	CITRONELLYL TIGLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1444	CITRULLINE	A	<p>Only permitted for use in medicines:</p> <p>(a) limited to oral routes of administration; and</p> <p>(b) when the maximum recommended daily dose does not provide more than 6 g of citrulline.</p>
1445	CITRULLUS COLOCYNTHIS	H	<p>Citrullus colocynthis can only be included in medicines for oral use when the dilution of the mother tincture is 10,000 fold (4X) or more.</p>
1446	CITRULLUS VULGARIS	A, H	
1447	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</p>

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			distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1448	CITRUS AURANTIUM	A, E, H	Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1449	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1450	CITRUS CHACHIENSIS	A, H	
1451	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%.
1452	CITRUS FIBRE	E	
1453	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

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			<p>included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1454	CITRUS LIMON	A, E, H	<p>Oxedrine is a mandatory component of Citrus limon when intended for internal use.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:</p> <p>a) for internal use; or</p> <p>b) in preparations containing 0.05% or less of citrus limon oil or distillate; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
1455	CITRUS MAXIMA	A, H	
1456	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>

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			c) for use in soaps or bath or shower gels that are washed off the skin.
1457	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%.
1458	CITRUS OIL TERPENES AND TERPENOIDS	E	Citrus oil terpenes and terpenoids must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing citrus oil terpenes and terpenoids must not be more than 1% of the total medicine.
1459	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.
1460	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.
1461	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

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			flavour concentration in a medicine must be no more than 5%.
1462	CITRUS UNSHIU	A, E, H	Oxedrine is a mandatory component of Citrus unshiu when intended for internal use. The quantity of Oxedrine in the recommended daily dose must be no more than 30 mg.
1463	CITRUS X PARADISI	A, E, H	
1464	CITRUS X WILSONII	A, H	
1465	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%.
1466	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%.
1467	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%.
1468	CIVETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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			1%.
1469	CLARY OIL	A, E, H	
1470	CLEMATIS ARMANDII	A, H	
1471	CLEMATIS CHINENSIS	A, E, H	
1472	CLEMATIS RECTA	A, H	
1473	CLEMATIS VITALBA	A, H	
1474	CLERODENDRUM TRICHOTOMUM	A, H	
1475	CLINOPODION POLYCEPHALUM	A, H	
1476	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1477	CLIVER HERB DRY	A, H	
1478	CLIVER HERB POWDER	A, H	
1479	CLOVE BUD OIL	A, E, H	When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) a restricted flow insert must be fitted on the container; (c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'; and (d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container.
1480	CLOVE DRY	A, E, H	
1481	CLOVE LEAF OIL	A, E, H	When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%: (a) the nominal capacity of the

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			<p>container must not be more than 25 mL;</p> <p>(b) a restricted flow insert must be fitted on the container;</p> <p>(c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’; <p>and</p> <p>(d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container.</p>
1482	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>
1483	CLOVE POWDER	A, E, H	
1484	CLOVE STEM OIL	A, E, H	<p>When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%:</p> <p>(a) the nominal capacity of the container must not be more than 25 mL;</p> <p>(b) a restricted flow insert must be fitted on the container;</p> <p>(c) the container must include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’; <p>and</p> <p>(d) When the nominal capacity of the container is more than 15 mL,</p>

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			a child resistant closure must also be fitted on the container.
1485	CLUPEA HARENGUS LIPID EXTRACT	A	Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.
1486	CNICUS BENEDICTUS	A, H	
1487	CNICUS JAPONICUS	A, H	
1488	CNIDIUM MONNIERI	A, H	
1489	CNIDIUM OFFICINALE	A, H	
1490	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1491	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1492	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1493	COCAMIDOPROPYL BETAINE 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%.
1494	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be: a) no more than 1% in leave on medicines b) no more than 15% in wash on /wash off medicines

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			c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection.
1495	COCCOLOBIA UVIFERA	A, H	
1496	COCCULUS ORBICULATUS	A, H	
1497	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1498	COCHLEARIA OFFICINALIS	A, H	
1499	COCILLANA DRY	A, H	
1500	COCILLANA POWDER	A, H	
1501	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1502	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.
1503	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%
1504	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.
1505	COCOA EXTRACT	E	Permitted for use only in

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			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1506	COCOA POWDER	A, E, H	
1507	COCOGLYCERIDES	E	
1508	COCONUT	E	
1509	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1510	COCONUT OIL	A, E, H	
1511	COCOS NUCIFERA	A, E, H	
1512	COD-LIVER OIL	A, E	Vitamin A and colecalciferol are mandatory components of Cod-liver oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (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.

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			<p>- (VITA4) ‘WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.’ NOTE: Position this warning at the beginning of the directions for use.</p> <p>- (VITA3) ‘The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.’</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.</p>
1513	CODONOPSIS LANCEOLATA	A, H	
1514	CODONOPSIS PILOSULA	A, H	
1515	CODONOPSIS TANGSHEN	A, H	
1516	COFFEA ARABICA	A, E, H	<p>Caffeine is a mandatory component of Coffea arabica.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide</p>

			<p>more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <p>When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1517	COFFEA CANEPHORA	A, E, H	<p>Caffeine is a mandatory component of Coffea canephora.</p> <p>When the medicine is packaged</p>

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for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.

When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.

When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.

When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80

			<p>mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1518	COFFEE	E, H	<p>Caffeine is a mandatory component of coffee.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the</p>

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			<p>medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' <p>When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1519	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>
1520	COFFEE SOLID EXTRACT	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1521	COGNAC OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1522	COGNAC OIL GREEN	A, E, H	
1523	COGNAC OIL WHITE	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>
1524	COIX LACHRYMA-JOBI	A, H	
1525	COLA ACUMINATA	A, E, H	<p>Caffeine is a mandatory component of Cola acuminata.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p>

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When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:

- (ADULT) 'Adults only' (or words to that effect).

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.'

- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'

- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).

1526	COLA NITIDA	A, E, H	<p>Caffeine is a mandatory component of Cola nitida.</p> <p>When the medicine is packaged for supply as a divided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 33%.</p> <p>When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400 mg of total caffeine.</p> <p>When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%.</p> <p>When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.</p> <p>When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not
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			recommended during pregnancy or breastfeeding.’ When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) ‘Limit the use of caffeine-containing products (including tea and coffee) when taking this product.’ - (CAFFCYP) ‘Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines’ (or words to that effect).
1527	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient. The total concentration of Colchicum autumnale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
1528	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1529	COLLAGEN	E	
1530	COLLINSONIA CANADENSIS	A, H	
1531	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1532	COLOPHONY	A, E, H	
1533	COMMIPHORA HABESSINICA	A, H	
1534	COMMIPHORA KATAF	A, H	
1535	COMMIPHORA MYRRHA	A, E, H	

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1536	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1537	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1538	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 following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
1539	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).
1540	CONIFER PHYTOSTEROL COMPLEX	A	
1541	CONIOSELINUM TATARICUM	A, H	
1542	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The homoeopathic potency of <i>Conium maculatum</i> in the final medicine must be 12X or greater.
1543	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry <i>Convallaria majalis</i> in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1544	CONYZA CANADENSIS	A, H	
1545	COPAIBA OIL	A, E, H	

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1546	COPAIFERA LANGSDORFFII	A, E, H	
1547	COPERNICIA CERIFERA	A, E, H	
1548	COPOVIDONE	E	
1549	COPPER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>
1550	COPPER (II) ASPARTATE	A, H	<p>Copper is a mandatory component of copper (II) aspartate.</p> <p>The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate.</p> <p>The concentration of copper compounds in products must be no more than 5%.</p> <p>The maximum daily dose must not contain more than 5mg of copper.</p>
1551	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>
1552	COPPER (II) LYSINATE	A, H	<p>Copper is a mandatory component of copper (II) lysinate.</p> <p>The percentage of copper from copper (II) lysinate should be calculated based on the molecular weight of Copper (II) lysinate.</p>

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			<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>
1553	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1554	COPPER CHLOROPHYLL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1555	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1556	COPPER GLUCONATE	A, E	<p>Copper is a mandatory component of copper gluconate.</p> <p>The percentage of copper from copper gluconate should be calculated based on the molecular weight of copper gluconate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p>
1557	COPPER TRIPEPTIDE-1	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1558	COPTIS CHINENSIS	A, H	
1559	COPTIS JAPONICA	A, H	
1560	CORALLINA OFFICINALIS	E	Only for use in topical medicines

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			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%.
1561	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1562	CORIANDER DRY	A, H	
1563	CORIANDER OIL	A, E, H	
1564	CORIANDER POWDER	A, H	
1565	CORIANDRUM SATIVUM	A, E, H	
1566	CORMUS DOMESTICA	A, H	
1567	CORN GLYCERIDES	E	
1568	CORN SILK DRY	A, H	
1569	CORN SILK POWDER	A, H	
1570	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%.
1571	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%.
1572	CORNUS FLORIDA	A, H	
1573	CORNUS OFFICINALIS	A, H	
1574	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1575	CORYDALIS AMBIGUA	A, E, H	
1576	CORYDALIS BUNGEANA	A, H	

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1577	CORYDALIS CAVA	A, H	
1578	CORYDALIS FABACEA	A, H	
1579	CORYDALIS FORMOSA	A, H	
1580	CORYDALIS TURTSCHANINOVII	A, H	
1581	CORYLUS AMERICANA	A, H	
1582	CORYLUS AVELLANA	A, H	
1583	CORYMBIA CITRIODORA	A, E, H	<p>Cineole is a mandatory component of <i>Corymbia citriodora</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
1584	CORYMBIA FICIFOLIA	A, H	<p>Cineole is a mandatory component of <i>Corymbia ficifolia</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p>

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			<p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <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>
1585	COSMOS BIPINNATUS	A, H	
1586	COSTUS ROOT OIL	A, H	
1587	COSTUS SPICATUS	A, H	
1588	COTTONSEED OIL	A, E, H	
1589	COUCH GRASS RHIZOME DRY	A, H	
1590	COUCH GRASS RHIZOME POWDER	A, H	
1591	COUMARIN	E, H	<p>Only for use as an active homoeopathic ingredient or excipient ingredient.</p> <p>The concentration of coumarin in the medicine must not be more than 0.001%.</p> <p>When used as an excipient:</p> <p>(a) must only be used in topical medicines for dermal application; and</p> <p>(b) the label of the medicine must specify that the product should only be used by adults.</p>
1592	CRANBERRY	E	
1593	CRATAEGUS CUNEATA	A, E, H	

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1594	CRATAEGUS GERMANICA	A, H	
1595	CRATAEGUS LAEVIGATA	A, E, H	
1596	CRATAEGUS MONOGYNA	A, E, H	
1597	CRATAEGUS PINNATIFIDA	A, E, H	
1598	CRATEVA MAGNA	A, E, H	
1599	CREATINE	A, E	
1600	CREATINE MONOHYDRATE	A, E	
1601	CREATINE PHOSPHATE	A, E	
1602	CREATININE	E	<p>Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.2%.</p>
1603	CREOSOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1604	CREOSOTE	H	<p>Only for use as an active homoeopathic ingredient.</p>
1605	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>
1606	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended</p>

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			for use in the eye. The concentration in the medicine must be no more than 0.00341%.
1607	CROCUS SATIVUS	A, E, H	When Crocus sativus is used as an excipient: (a) the ingredient must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation; (b) the plant part must be stigma and/or style; (c) the plant preparation must be fresh or dry; and (d) the total concentration of flavour proprietary excipient formulations containing the ingredient must not be more than 5% of the total medicine.
1608	CROSCARMELLOSE SODIUM	E	
1609	CROSPVIDONE	E	
1610	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1611	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1612	CRYPTOMERIA JAPONICA	A, H	
1613	CUBEB OIL	A, H	
1614	CUBEBENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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1615	CUCUMBER	E	
1616	CUCUMIS MELO	A, H	
1617	CUCUMIS SATIVUS	A, E, H	
1618	CUCURBITA MAXIMA	A, E, H	
1619	CUCURBITA MOSCHATA	A, H	
1620	CUCURBITA PEPO	A, E, H	
1621	CULLEN CORYLIFOLIUM	A, H	
1622	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%.
1623	CUMIN OIL	A, E, H	
1624	CUMINALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1625	CUMINUM CYMINUM	A, H	
1626	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%.
1627	CUPRESSUS ARIZONICA	A, H	
1628	CUPRESSUS FUNEBRIS	A, E, H	
1629	CUPRESSUS SEMPERVIRENS	A, E, H	
1630	CUPRIC ACETATE	H	Only for use as an active

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	MONOHYDRATE		homoeopathic ingredient.
1631	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1632	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.
1633	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate. The percentage of copper from cupric citrate hemipentahydrate should be calculated based on the molecular weight of cupric citrate hemipentahydrate. 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.
1634	CUPRIC OXIDE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric oxide. The percentage of copper from

			<p>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>
1635	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>
1636	CUPRIC SULFATE MONOHYDRATE	A, E, H	<p>When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate.</p> <p>The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate.</p> <p>When for internal use the maximum daily dose must not contain more than 5 mg of copper.</p> <p>When for other than internal use, the concentration of copper compounds must be no more than 5%.</p> <p>When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.</p>

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1637	CUPRIC SULFATE PENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate. The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate. The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.
1638	CURCULIGO ORCHIOIDES	A, H	
1639	CURCUMA AROMATICA	A, H	
1640	CURCUMA LONGA	A, E, H	
1641	CURCUMA ZANTHORRHIZA	A, H	
1642	CURCUMA ZEDOARIA	A, H	
1643	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1644	CUSCUTA EPITHYMUM	A, H	
1645	CUSCUTA EUROPAEA	A, H	
1646	CUSCUTA HYGROPHILAE	A, H	
1647	CUSCUTA RACEMOSA	A, H	
1648	CUSPARIA FEBRIFUGA	A, H	
1649	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1650	CYANOCOBALAMIN	A, E, H	
1651	CYANOMETHYLPHENYL	E	For dental use only in proprietary

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	MENTHANE CARBOXAMIDE		<p>ingredients.</p> <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 the medicine must be no more than 5%.</p>
1652	CYATHULA OFFICINALIS	A, H	
1653	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1654	CYCLAMEN PURPURASCENS	A, H	
1655	CYCLOCARYA PALIURUS LEAF EXTRACT DRY	A	<p>Only to be used in a medicine where Infinitus (China) Company Ltd (Client ID 81208), 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 25 October 2025.</p> <p>The route of administration for medicines that contain Cyclocarya paliurus leaf extract dry must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2 g of Cyclocarya paliurus leaf extract dry.</p> <p>The recommend duration of use for a medicine containing Cyclocarya paliurus leaf extract dry must be limited to 12 weeks or less.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended</p>

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			for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
1656	CYCLOHEXADECENONE-8	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1657	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%.
1658	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%.
1659	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%.
1660	CYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1661	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>
1662	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>
1663	CYCLOHEXYL SALICYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1664	CYCLOHEXYLETHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>

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1665	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1666	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%.
1667	CYDONIA OBLONGA	A, H	
1668	CYMBOPOGON FLEXUOSUS	A, E, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon flexuosus and the concentration of aldehydes calculated as citral in the medicine must not be more than 5%.
1669	CYMBOPOGON MARTINI	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon martini and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1670	CYMBOPOGON NARDUS	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon nardus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1671	CYMBOPOGON SCHOENANTHUS	A, E, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon schoenanthus and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.

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1672	CYNANCHUM ATRATUM	A, H	
1673	CYNANCHUM STAUNTONII	A, E, H	
1674	CYNARA SCOLYMUS	A, E, H	
1675	CYNODON DACTYLON	A, E, H	
1676	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1677	CYPERUS LONGUS	A, H	
1678	CYPERUS ROTUNDUS	A, H	
1679	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%.
1680	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1681	CYSTEINE	A	The maximum recommended daily dose must not contain more than 450 mg of cysteine. When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.
1682	CYSTEINE HYDROCHLORIDE	A	The maximum recommended daily dose must contain no more than 585 mg of cysteine hydrochloride. When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.
1683	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	When used as an excipient, permitted for use only in

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			<p>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>The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate.</p> <p>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>
1684	CYSTINE	A	<p>The maximum recommended daily dose must contain no more than 450 mg of cystine.</p> <p>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>
1685	CYTISUS SCOPARIUS	A, H	<p>Sparteine is a mandatory component of Cytisus scoparius.</p> <p>The concentration of Sparteine in the medicine must be no more than 0.001%.</p>
1686	D-ALPHA-TOCOPHEROL	A, E	
1687	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1688	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1689	D-ALPHA-TOCOPHERYL PHOSPHATES	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p>

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			The concentration in the medicine must be no more than 3%.
1690	D-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1691	D-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1692	D-FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1693	D-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1694	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%.
1695	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.
1696	DACTYLIS GLOMERATA	A, H	
1697	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1698	DAEMONOROPS DRACO	A, E, H	
1699	DAHLIA PINNATA	A, H	
1700	DALBERGIA ODORIFERA	A, H	
1701	DAMIANA LEAF POWDER	A	
1702	DANDELION LEAF DRY	A, H	
1703	DANDELION LEAF POWDER	A, H	
1704	DANDELION ROOT DRY	A, H	
1705	DANDELION ROOT POWDER	A, H	
1706	DAPHNE GENKWA	A, H	
1707	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1708	DATURA STRAMONIUM	A, H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium.

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			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%.
1709	DAUCUS CAROTA	A, E, H	
1710	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%.
1711	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1712	DECAHYDRO-1,1,7-TRIMETHYL-3A,7-METHANO-3AH-CYCLOPENTACYCLOOCT-3-YL FORMATE	E	Decahydro-1,1,7-trimethyl-3a,7-methano-3ah-cyclopentacyclooct-3-yl formate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing decahydro-1,1,7-trimethyl-3a,7-methano-3ah-

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			cyclopentacyclooct-3-yl formate must not be more than 1% of the total medicine.
1713	DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1714	DECAHYDRO-BETA-NAPHTHYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1715	DECAHYDRO-BETA-NAPHTHYLFORMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1716	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%.
1717	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

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				fragrance concentration in a medicine must be no more 1%.
1718	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%.
1719	DECANAL DIMETHYL ACETAL	E		Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1720	DECARBOXY CARNOISINE DIHYDROCHLORIDE	E		Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05.
1721	DECENAL	E		Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1722	DECYL ACETATE	E		Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1723	DECYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1724	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1725	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1726	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%.
1727	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1728	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only;

		<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>
1729	DEER VELVET ANTLER SLICE A	<p>Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions:</p> <p>a) the medicines are for oral use only;</p> <p>b) the antlers (including the velvet) are sourced only from red deer (<i>Cervus elaphus</i>), elk/wapiti (<i>Cervus canadensis</i>), or a crossbreed of these species;</p> <p>c) the deer are sourced only from farmed stock bred and raised in New Zealand;</p> <p>d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time;</p> <p>e) the antlers are removed from the deer only according to the</p>

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			Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1730	DEERTONGUE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1731	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1732	DEHYDROMENTHOFUROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1733	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%.
1734	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1735	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%.

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1736	DELTA-DECALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1737	DELTA-DODECALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1738	DELTA-NONALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1739	DELTA-OCTALACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1740	DELTA-TETRADECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1741	DELTA-TOCOPHEROL	E	
1742	DELTA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1743	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1744	DENATONIUM BENZOATE	E	
1745	DENDROBIUM NOBILE	A, H	
1746	DESCURAINIA SOPHIA	A, H	
1747	DESMODIUM STYRACIFOLIUM	A, H	
1748	DEVIL'S CLAW TUBER DRY	A, H	
1749	DEVIL'S CLAW TUBER POWDER	A, H	
1750	DEXPANTHENOL	A, E	
1751	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

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				must be no more than 0.3%.
1752	DEXTRAN 40	A, E		
1753	DEXTRATES	E		
1754	DEXTRIN	E		
1755	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%.
1756	DHA/EPA RICH SCHIZOCHYTRIUM ALGAL OIL	A		Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are mandatory components of DHA/EPA rich schizochytrium algal oil. Only for use in oral medicines when in combination with other active or excipient ingredients. The ratio of DHA to EPA must be 2:1.
1757	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%.
1758	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%.
1759	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%.

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1760	DI-PPG-3 MYRISTYL ETHER ADIPATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 15%.</p>
1761	DIACETIN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1762	DIACETYL	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>
1763	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	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>
1764	DIACETYLATED MONOGLYCERIDES	E	<p>Permitted for use only in combination with other permitted ingredients as a coating solution.</p>

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1765	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1766	DIANTHUS SUPERBUS	A, H	
1767	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1768	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1769	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	<p>Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate.</p> <p>The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p>

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			When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
1770	DIBASIC POTASSIUM PHOSPHATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
1771	DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE	A, E, H	<p>When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate trihydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>
1772	DIBASIC SODIUM PHOSPHATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the</p>

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			preparation must not exceed 11.5.
1773	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>
1774	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>
1775	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	<p>When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate.</p> <p>When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.</p> <p>When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.</p>

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1776	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 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>
1777	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>
1778	DIBUTYL ADIPATE	E	<p>Only for use in topical medicines for dermal application.</p>
1779	DIBUTYL SEBACATE	E	
1780	DIBUTYLAMINE	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 the medicine must be no more than 5%.</p>
1781	DICAPRYLYL CARBONATE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 34%.</p>

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1782	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1783	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%.
1784	DICETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1785	DICHLOROBENZYL ALCOHOL	E	
1786	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.
1787	DICTAMNUS ALBUS	A, H	
1788	DICTAMNUS DASYCARPUS	A, H	
1789	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%.
1790	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1791	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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1792	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%.
1793	DIETHYL HYDROGEN 2-HYDROXYPROPANE-1,2,3-TRICARBOXYLATE	E	Diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing diethyl hydrogen 2-hydroxypropane-1,2,3-tricarboxylate must not be more than 1% of the total medicine.
1794	DIETHYL MALONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1795	DIETHYL PHTHALATE	E	
1796	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%.

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1797	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required 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).
1798	DIETHYLAMINOMETHYLCOUM ARIN	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
1799	DIETHYLDIMETHYL-2- CYCLOHEXENONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1800	DIETHYLENE GLYCOL	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1801	DIETHYLENE GLYCOL MONOETHYL ETHER	E	<p>Only for use in topical medicines for dermal application.</p>

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1802	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%.
1803	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1804	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%.
1805	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).
1806	DIETHYLTOLUAMIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 20%. The medicine requires the following warning statement on the medicine label: - (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for

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			a long time.'
1807	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%.
1808	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%.
1809	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%.
1810	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1811	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%.
1812	DIHYDRO JASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1813	DIHYDRO TERPINYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1814	DIHYDRO-ALPHA-TERPINEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1815	DIHYDRO-BETA-IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1816	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%.
1817	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%.
1818	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%.

1819	DIHYDROCAPSIATE	A	<p>Only to be used in a medicine where Ajinomoto Co Inc (Client ID 15631), 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 25 October 2023.</p> <p>The route of administration for medicines that contain dihydrocapsiate must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 9 mg dihydrocapsiate.</p> <p>The following warning statements (or words to the same effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (ADULT) 'Adults only'; and - (PREGNT) 'Not recommended for use by pregnant and lactating women'.
1820	DIHYDROCARVYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
1821	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1822	DIHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1823	DIHYDROEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1824	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1825	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%.
1826	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%.

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1827	DIHYDROMYRCENOL	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>
1828	DIHYDROMYRCENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
1829	DIHYDROXYACETONE	E	<p>Only for use in topical medicines for dermal application.</p>
1830	DIISOPROPYL ADIPATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 15%.</p>
1831	DIISOPROPYL SEBACATE	E	<p>Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p>
1832	DIISOSTEARYL DIMER DILINOLEATE	E	<p>Only for use in topical medicines for dermal application.</p>
1833	DILAURYL THIODIPROPIONATE	E	<p>Only for use in topical medicines for dermal application.</p>

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1834	DILL HERB OIL	A, E, H	
1835	DILL SEED OIL	A, E, H	
1836	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%.
1837	DIMETHICONE 12500	E	
1838	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%.
1839	DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1840	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%.
1841	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%.
1842	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1843	DIMETHYL 3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1844	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%.
1845	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%.
1846	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%.

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1847	DIMETHYL BENZYL CARBINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1848	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%.
1849	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%.
1850	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%.
1851	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%.

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1852	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%.
1853	DIMETHYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1854	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1855	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%.
1856	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%.
1857	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	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%.
1858	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1859	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1860	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%.
1861	DIMETICONE 10	E	
1862	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1863	DIMETICONE 1000	E	
1864	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%
1865	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%.
1866	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1867	DIMETICONE 200	E	Only for use in topical medicines for dermal application.

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1868	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%.
1869	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.
1870	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1871	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1872	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1873	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1874	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1875	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%.
1876	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.

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1877	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1878	DIMETICONE CROSSPOLYMER- 3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1879	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%.
1880	DIMETICONOL	E	Only for use in topical medicines for dermal application.
1881	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%.
1882	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%.
1883	DIMOCARPUS LONGAN	A, H	
1884	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1885	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.

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1886	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1887	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%.
1888	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%
1889	DIOLAMINE CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye.
1890	DIOSCOREA COLLETTII	A, H	
1891	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1892	DIOSCOREA JAPONICA	A, H	
1893	DIOSCOREA OPPOSITIFOLIA	A, H	
1894	DIOSCOREA POLYSTACHYA	A, H	
1895	DIOSCOREA SEPTEMLOBA	A, H	
1896	DIOSCOREA VILLOSA	A, E, H	
1897	DIOSPYROS KAKI	A, E, H	
1898	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 3%.

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			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).
1899	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin. The concentration in the medicine must be no more than 0.5%.
1900	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%.
1901	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%.
1902	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1903	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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1904	DIPHENYL OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
1905	DIPOTASSIUM GLYCYRRHIZATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
1906	DIPROPIONYL	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>
1907	DIPROPYLENE GLYCOL	E	<p>Only for use in topical medicines for dermal application.</p>
1908	DIPROPYLENE GLYCOL DIBENZOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 4.2%.</p>
1909	DIPROPYLENE GLYCOL SALICYLATE	E	<p>Only for use in topical medicines for dermal application.</p>
1910	DIPSACUS ASPER	A, H	

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1911	DIPSACUS JAPONICUS	A, H	
1912	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%.
1913	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1914	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1915	DISODIUM COCOAMPHODIPROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1916	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%.
1917	DISODIUM EDETATE	E	Edetic acid is a mandatory component of disodium edetate. The total concentration of edetic acid in the medicine must not be more than 0.25%.
1918	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%.
1919	DISODIUM GUANYLATE	E	Permitted for use only in

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			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1920	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%.
1921	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%.
1922	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%.
1923	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1924	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%.
1925	DISODIUM PHENYL DIBENZIMIDAZOLE	A	Only for use as an active ingredient in sunscreens for

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	TETRASULFONATE		<p>dermal application.</p> <p>The concentration in the medicine must be no more than 10%.</p> <p>When used in primary sunscreen products, the medicine requires the following warning statements on the label:</p> <ul style="list-style-type: none"> - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1926	DISODIUM PYROPHOSPHATE	E	<p>Disodium pyrophosphate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing disodium pyrophosphate must not be more than 5% of the total medicine.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2.4 g of phosphorus.</p> <p>The following statement (or words to the same effect) is required on the medicine label:</p> <ul style="list-style-type: none"> - (PHOS) 'Contains phosphorus'.
1927	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
1928	DISODIUM RUTINYL DISULFATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended</p>

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			for use in the eye. The concentration in the medicine must be no more than 0.05%.
1929	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%.
1930	DISPERSIBLE CELLULOSE	E	
1931	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%.
1932	DISTEARDIMONIUM HECTORITE	E	Only for use in topical medicines for dermal application and not to be included for medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1933	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1934	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%.
1935	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%.

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1936	DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1937	DL-ALPHA-TOCOPHEROL	A, E	
1938	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1939	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1940	DL-BORNEOL	E	
1941	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1942	DL-THREONINE	A, E	
1943	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.
1944	DOCUSATE SODIUM	E	
1945	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%.
1946	DODECANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1947	DODECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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			for use in the eye. The concentration in the medicine must be no more than 0.2%.
1948	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%.
1949	DODECYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1950	DOLICHOS LABLAB	A, H	
1951	DOLOMITE	A, E, H	
1952	DRACAENA DRACO	A, H	
1953	DRIED BUTTERMILK	E	
1954	DRIED CALCIUM SULFATE	A, E, H	
1955	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g. Magnesium is a mandatory component of dried magnesium sulfate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;

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			<p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
1956	DRIMIA INDICA	A, H	
1957	DRIMIA MARITIMA	A, H	
1958	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> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
1959	DROSERANGLICA	A, H	
1960	DROSERABURMANNI	A, H	
1961	DROSERAINTERMEDIA	A, H	
1962	DROSERARAMENTACIA	A, H	
1963	DROSERAROTUNDIFOLIA	A, E, H	

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1964	DROSER A ROTUNDIFOLIA MIS	A, H	
1965	DRYNARIA FORTUNEI	A, H	
1966	DRYOBALANOPS AROMATICA	A, H	
1967	DRYOPTERIS FILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1968	DULACIA INOPIFLORA	A, H	
1969	DUNALIELLA SALINA	A, E, H	
1970	DURVILLAEA ANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1971	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%.
1972	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of <i>Dysphania ambrosioides</i>) are mandatory components of <i>Dysphania ambrosioides</i> .
1973	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

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1974	ECHINACEA ANGUSTIFOLIA	A, E, H	
1975	ECHINACEA PALLIDA	A, E, H	
1976	ECHINACEA PURPUREA	A, E, H	
1977	ECHINOPA SPINOSISSIMUS	A, H	
1978	ECLIPTA PROSTRATA	A, H	
1979	ECTOINE	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%.
1980	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%.
1981	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1982	EGG LECITHIN	A, E	
1983	EGGSHELL MEMBRANE HYDROLYSATE	A	
1984	EGGSHELL MEMBRANE POWDER	A	
1985	ELAEAGNUS ANGUSTIFOLIA	A, H	
1986	ELAEIS GUINEENSIS	A, E, H	
1987	ELASTIN	E	Only for use in topical medicines for dermal application.
1988	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
1989	ELDER FLOWER BLACK DRY	A, E, H	
1990	ELDER FLOWER BLACK POWDER	A, H	
1991	ELECAMPANE RHIZOME DRY	A, H	
1992	ELECAMPANE RHIZOME POWDER	A, H	
1993	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%.
1994	ELEMI RESINOID	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1995	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%.
1996	ELEOCHARIS DULCIS	A, H	
1997	ELETTARIA CARDAMOMUM	A, E, H	
1998	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1999	ELEUTHEROCOCCUS ROOT DRY	A, H	
2000	ELEUTHEROCOCCUS ROOT POWDER	A, H	

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2001	ELEUTHEROCOCCUS SENTICOSUS	A, H	
2002	ELSHOLTZIA SPLENDENS	A, H	
2003	ELYMUS REPENS	A, E, H	
2004	EMU OIL	A, E	Emu oil ingredients must meet the following two requirements: 1) the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and 2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption.
2005	EMULSIFYING WAX	E	
2006	ENOXOLONE	E	Only for use in topical medicines for dermal application.
2007	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%.
2008	EPA-RICH NANNOCHLOROPSIS OCULATA OIL	A, E	Only to be used in a medicine where Lipa Pharmaceuticals Ltd (Client ID 23299), 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

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			<p>after 15 August 2024.</p> <p>The route of administration for medicines that contain EPA-rich <i>Nannochloropsis oculata</i> oil must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 2000 mg of EPA-rich <i>Nannochloropsis oculata</i> oil.</p> <p>The following warning statements (or words to the same effect) must be included on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) 'Adults only'.
2009	EPHEDRA DISTACHYA	A, H	<p>Ephedrine and Pseudoephedrine (of <i>Ephedra distachya</i>) are mandatory components of <i>Ephedra distachya</i> and must be declared in the application.</p> <p>The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
2010	EPHEDRA SINICA	A, H	<p>Ephedrine and Pseudoephedrine (of <i>Ephedra sinica</i>) are mandatory components of <i>Ephedra sinica</i>.</p> <p>The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.</p>
2011	EPIGAEA REPENS	A, H	
2012	EPILOBIUM ANGUSTIFOLIUM	E	<p>Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The extract must be processed from the flower, leaf and stem (herb top flowering) of the plant.</p>

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			<p>The extracts used must be: 1:20 in 100% water or 1:2 in 100% water.</p> <p>The concentrations of <i>Epilobium angustifolium</i> must be no more than 0.75% for a 1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.</p>
2013	EPILOBIUM PALUSTRE	A, H	
2014	EPILOBIUM PARVIFLORUM	A, H	
2015	EPIMEDIUM BREVICORNU	A, H	
2016	EPIMEDIUM GRANDIFLORUM	A, H	
2017	EPIMEDIUM SAGITTATUM	A, H	
2018	EQUISETUM ARVENSE	A, E, H	
2019	EQUISETUM HIEMALE	A, H	
2020	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2021	ERGOTHIONEINE	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 0.0005%.</p>
2022	ERIGERON BREVISCAPUS	A, H	
2023	ERIOBOTRYA JAPONICA	A, H	<p>Amygdalin and hydrocyanic acid are mandatory components.</p> <p>The concentration of amygdalin in the medicine must be 0%.</p> <p>The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.</p>
2024	ERIOCAULON BUERGERIANUM	A, H	
2025	ERIODICTYON CRASSIFOLIUM	A, H	
2026	ERIODICTYON GLUTINOSUM	A, H	
2027	ERODIUM CICUTARIUM	A, H	

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2028	ERUCA SATIVA	A, H	
2029	ERYTHORBIC ACID	E	
2030	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%.
2031	ERYTHROSINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2032	ERYTHROSINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2033	ERYTHRULOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
2034	ESCHSCHOLZIA CALIFORNICA	A, H	
2035	ESTRONE	H	Only for use as an active homoeopathic ingredient. The total concentration of estrone in the medicine must not be more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
2036	ETHANOL	A, E	When used as an active ingredient, can only be supplied as an un compounded medicine substance packed for retail sale and must comply with an un compounded substance monograph of the British

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			Pharmacopoeia, as in force or existing from time to time.
2037	ETHANOL ABSOLUTE	A, E	When ethanol absolute is used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2038	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2039	ETHOHEXADIOL	E	Only for use in topical medicines for dermal application. The total concentration of ethohexadiol in the medicine must not be more than 5%.
2040	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2041	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%.
2042	ETHOXYMETHOXY CYCLODODECANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2043	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%.
2044	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%.
2045	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2046	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%.
2047	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%.
2048	ETHYL 2-ETHYL-6,6-DIMETHYL-2-	E	Permitted for use only in combination with other permitted

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	CYCLOHEXENECARBOXYLATE		<p>ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2049	ETHYL 2-HEXYL ACETOACETATE	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>
2050	ETHYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2051	ETHYL 2-METHYLPENTANOATE	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>
2052	ETHYL 3-HEXENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%.
2053	ETHYL 3-HYDROXYBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2054	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%.
2055	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%.
2056	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%.
2057	ETHYL 4,7-OCTADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2058	ETHYL ACETATE	E	The residual solvent limit for ethyl

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			acetate is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
2059	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%.
2060	ETHYL ACRYLATE	E	
2061	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%.
2062	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%.
2063	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

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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>
2064	ETHYL BENZOYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2065	ETHYL BUTYLACETYLAMINOPROPIONATE	E	<p>Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%.</p> <p>The medicine requires the following warning statement on the medicine label:</p> <p>- (EYE2) 'May be irritant to the eyes (or words to that effect)'.</p>
2066	ETHYL BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2067	ETHYL CAPRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2068	ETHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2069	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%.
2070	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%.
2071	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%.
2072	ETHYL ENANTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2073	ETHYL 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>
2074	ETHYL HYDROXYBENZOATE	E	
2075	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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2076	ETHYL ISOVALERATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2077	ETHYL LACTATE	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2078	ETHYL LAURATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2079	ETHYL LEVULATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2080	ETHYL LEVULINATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2081	ETHYL LINALOOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total</p>

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2082	ETHYL LINALYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2083	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2084	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2085	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%.
2086	ETHYL MALTOL	E	
2087	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%.
2088	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2089	ETHYL METHYLPHENYLGLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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			<p>fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2090	ETHYL METICONE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 3%.</p>
2091	ETHYL MYRISTATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2092	ETHYL OLEATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2093	ETHYL ORTHO-METHOXYBENZYL ETHER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
2094	ETHYL OXYHYDRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2095	ETHYL PALMITATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2096	ETHYL PARA-ANISATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2097	ETHYL PELARGONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2098	ETHYL PHENYLACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2099	ETHYL PHENYLGLYCIDATE	E	<p>Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).</p>
2100	ETHYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2101	ETHYL PYRUVATE	E	<p>Ethyl pyruvate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p>

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			The total concentration of the flavour proprietary excipient formulation containing ethyl pyruvate must not be more than 5% of the total medicine.
2102	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%.
2103	ETHYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2104	ETHYL SEBACATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2105	ETHYL STEARATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2106	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%.
2107	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%.
2108	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2109	ETHYL TRANS-2-HEXENOATE	E	Ethyl trans-2-hexenoate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing ethyl trans-2-hexenoate must not be more than 5% of the total medicine.
2110	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%.
2111	ETHYL UNDECYLENATE	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%.
2112	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%.
2113	ETHYL VANILLIN	E	
2114	ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2115	ETHYL-2-METHYL-4-PENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2116	ETHYL-2-METHYLPENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2117	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.002%.
2118	ETHYLCELLULOSE	E	
2119	ETHYLENE BRASSYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2120	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%.
2121	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2122	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%.
2123	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%.
2124	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.

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2125	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL 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 medicine must be no more than 4%.</p>
2126	ETHYLENEDIAMINE/STEARYL 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 or on damaged skin.</p> <p>The concentration in the medicine must be no more than 6%.</p>
2127	ETHYLHEXYL BENZOATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.</p> <p>The concentration in the medicine must be no more than 3.5%.</p>
2128	ETHYLHEXYL METHOXYCRYLENE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p>
2129	ETHYLHEXYL TRIAZONE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must not be more than 5%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to</p>

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			<p>this effect); and</p> <p>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).</p>
2130	ETHYLHEXYLGLYCERIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
2131	ETIDRONIC ACID	E	<p>Only for use in topical medicines for dermal application only.</p> <p>The concentration in the medicine must be no more than 1%.</p>
2132	EUCALYPTUS DIVES	A, E, H	<p>Cineole is a mandatory component of Eucalyptus dives.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in 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</p>

			also have a child resistant closure.
2133	EUCALYPTUS FRUTICETORUM	A, E, H	<p>Cineole is a mandatory component of <i>Eucalyptus fruticetorum</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
2134	EUCALYPTUS GLOBULUS	A, E, H	<p>Cineole is a mandatory component of <i>Eucalyptus globulus</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p>

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			<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>
2135	EUCALYPTUS MACRORHYNCHA	A, E, H	<p>Cineole is a mandatory component of Eucalyptus macrorhyncha.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
2136	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 of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
2137	EUCALYPTUS RADIATA	A, E, H	<p>Cineole is a mandatory component of <i>Eucalyptus radiata</i>.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <ol 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

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c) the container must include the following warning statements on the medicine label:

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

- (NTAKEN) 'Not to be taken'.

In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.

2138	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>
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2139	EUCALYPTUS TERETICORNIS	A, E, H	<p>Cineole is a mandatory component of Eucalyptus tereticornis.</p> <p>In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
2140	EUCOMMIA ULMOIDES	A, H	
2141	EUGENOL	E	<p>When for oral ingestion, eugenol must not comprise more than 0.06% of the formulation.</p> <p>When used in topical medicines for dermal application, the following apply:</p> <p>a) When the concentration of Eugenol in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL.</p> <p>b) When the concentration of Eugenol in the preparation is more than 25% and the nominal</p>

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			<p>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’
2142	EUGENYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2143	EUGLENA GRACILIS WHOLE CELL DRY	A	<p>Only to be used in a medicine where Kemin Foods LC (Client ID 29988), 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</p>

			<p>ceases to be a requirement for this ingredient after 1 March 2024.</p> <p>The route of administration for medicines that contain <i>Euglena gracilis</i> whole cell dry must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 100 mg of <i>Euglena gracilis</i> whole cell dry for children aged between 1 and 3 years (inclusive);</p> <p>(b) 150 mg of <i>Euglena gracilis</i> whole cell dry for children aged between 4 and 8 years (inclusive);</p> <p>(c) 225 mg of <i>Euglena gracilis</i> whole cell dry for individuals aged between 9 and 18 years (inclusive); and</p> <p>(d) 375 mg of <i>Euglena gracilis</i> whole cell dry for adults aged 19 years or older.</p> <p>The following warning statement (or words to the same effect) must be included on the medicine label:</p> <p>- (BABY2) 'Not suitable for infants under the age of twelve months'.</p>
2144	EUONYMUS ATROPURPUREUS	A, H	
2145	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2146	EUPATORIUM FORTUNEI	A, H	
2147	EUPATORIUM JAPONICUM	A, H	
2148	EUPATORIUM PERFOLIATUM	A, H	
2149	EUPATORIUM PURPUREUM	A, H	
2150	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.
2151	EUPHORBIA CYPARISSIAS	A, H	

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2152	EUPHORBIA DRY	A, H	
2153	EUPHORBIA HETERODOXA	A, H	
2154	EUPHORBIA HIRTA	A, H	
2155	EUPHORBIA LATHYRIS	A	Levodopa is a mandatory component of Euphorbia lathyris. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
2156	EUPHORBIA PEKINENSIS	A, H	
2157	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2158	EUPHORBIA POWDER	A, H	
2159	EUPHORBIA RESINIFERA	A, H	
2160	EUPHORBIA SIEBOLDIANA	A, H	
2161	EUPHRASIA OFFICINALIS	A, H	
2162	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2163	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2164	EURYALE FEROX	A, H	
2165	EUTERPE OLERACEA	A, E	The plant part must be derived from the fruit. When used as an excipient: - permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation; - the total flavour proprietary excipient formulation in a medicine must not be more than 5%; and - the following warning statement is required on the medicine label: - (ACAI) 'Contains acai'.
2166	EVENING PRIMROSE OIL	A, E, H	

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2167	EVERNIA PRUNASTRI 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%.
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