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**
751	BACILLUS COAGULANS	A	Only permitted for use in medicines: (a) limited to oral routes of administration; and (b) when the strain of Bacillus coagulans is confirmed to be: (i) Microbial Type Culture Collection (MTCC) accession number 5260; and/or (ii) MTCC accession number 5856. The strain of Bacillus coagulans must be declared on the label. When the strain of Bacillus coagulans is MTCC accession number 5260: (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 (b) the following warning statements are required on the medicine label: - (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).'

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			When the strain of Bacillus coagulans is MTCC accession number 5856: (a) the maximum recommended daily dose of the medicine must not provide more than 2 billion cfu of Bacillus coagulans strain MTCC accession number 5856; and (b) the following warning statements are required on the medicine label: - (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).'
752	BACKHOUSIA CITRIODORA	A, E, H	The herbal substance must be derived from leaf oil only. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%. The medicine requires the following warning statements on the medicine label: - (IRRIT) 'If irritation develops - discontinue use' - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
753	BACOPA MONNIERI	A, H	

754	BALLOTA NIGRA	A, H	
755	BALM OF GILEAD BUD DRY	A, H	
756	BALM OF GILEAD BUD POWDER	A, H	
757	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%.
758	BAMBUSA BREVIFLORA	A, E, H	
759	BAMBUSA TEXTILIS	A, H	
760	BANANA	E	
761	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%.
762	BAPTISIA CONFUSA	A, H	
763	BAPTISIA TINCTORIA	A, H	
764	BARBAREA VULGARIS	A, H	
765	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
766	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
767	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
768	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other than topical and mucosal.
769	BARLEY LEAF	E	

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770	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
771	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
772	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%.
773	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%.
774	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).
775	BASIL OIL EUROPEAN	A, E, H	Methyl chavicol is a mandatory component of Basil oil European. When the concentration of Methyl chavicol in the medicine is more

			than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
776	BASSIA SCOPARIA	A, H	
777	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
778	BAY LEAF	E	
779	BAY OIL	A, E, H	When the total concentration of bay oil in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) the container must be fitted with a restricted flow insert; (c) the following warning statements are required on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect); - (NTAKEN) 'Not to be taken'; and (d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.
780	BEESWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a

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

			for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%. Residual levels of ethylene oxide are to be kept below the level of detection.
786	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
787	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
788	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%.
789	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
790	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%.
791	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are

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			mandatory components of Belladonna herb powder. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropinei n the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
792	BELLADONNA HERB PREPARED	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
793	BELLIS PERENNIS	A, H	
794	BEMOTRIZINOL	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and

			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
795	BENINCASA HISPIDA	A, E, H	
796	BENTONITE	E	
797	BENZALDEHYDE	E	
798	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%.
799	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).
800	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal

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			application.
801	BENZOIC ACID	E, H	
802	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%.
803	BENZOIN SIAM	A, E, H	
804	BENZOIN SUMATRA	A, E, H	
805	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%.
806	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.
807	BENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
808	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%.
809	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).
810	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application.
811	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%.
812	BENZYL CINNAMATE	E	Only for use in: (a) topical medicines for dermal

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

			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
817	BENZYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
818	BENZYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
819	BENZYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
820	BENZYL PROPIONATE	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%.
821	BENZYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
822	BENZYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
823	BENZYLIDENE ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

824	BENZYLIDENE CAMPHOR SULFONIC ACID	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 6% (as acid). When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged 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).
825	BERBERIS AQUIFOLIUM	A, H	
826	BERBERIS ARISTATA	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
827	BERBERIS VULGARIS	A, E, H	
828	BERGAMOT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour, the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The medicine requires the following warning statement on

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			the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
829	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%.
830	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.
831	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%.

832	BERTHOLLETIA EXCELSA	A, E, H	
833	BETA RAPA	A, E, H	
834	BETA VULGARIS	A, E, H	
835	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%.
836	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%.
837	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%.
838	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%.
839	BETA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
840	BETA-HOMO CYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
841	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
842	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%.
843	BETA-IONONE EPOXIDE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.

844	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%.
845	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%.
846	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%.
847	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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848	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%.
849	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%.
850	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%.
851	BETA-PINENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

			medicine must be no more than 1%.
852	BETA-TOCOPHEROL	E	
853	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.'
854	BETADEX	E	
855	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%.
856	BETAINE	E	Only for use in topical medicines for dermal application.
857	BETAINE HYDROCHLORIDE	E	
858	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

			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 NIGRA	A, H	Cresol, eugenol and methyl salicylate are mandatory components of Betula nigra. For external use only when the total concentration of cresols, xylenols and other phenol homologues in the medicine is greater than 3%. When for internal use, the concentration of eugenol in the medicine must not exceed 0.06%. When the concentration of eugenol in the medicine is more than 25%: a) the nominal capacity of the container must be no more than 25 mL; b) the medicine must be fitted with a restricted flow insert; c) when the nominal capacity of the container is more than 15 mL, the medicine must be fitted with a child resistant closure; and d) the medicine requires 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'. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.

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	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 greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
860	BETULA PENDULA	A, E, H	Methyl salicylate is a mandatory component of Betula pendula. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish.

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			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'.
861	BETULA PUBESCENS	A, E, H	
862	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%.
863	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-	E	Permitted for use only in combination with other permitted

	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%.
864	BIFIDOBACTERIUM ADOLESCENTIS	A	
865	BIFIDOBACTERIUM ANIMALIS	A	
866	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
867	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
868	BIFIDOBACTERIUM BIFIDUM	A	
869	BIFIDOBACTERIUM BREVE	A	
870	BIFIDOBACTERIUM INFANTIS	A	
871	BIFIDOBACTERIUM LACTIS	A	
872	BIFIDOBACTERIUM LONGUM	A	
873	BILBERRY	E	
874	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%.
875	BIOTA ORIENTALIS	A, H	
876	BIOTIN	A, E	
877	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

			greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
878	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%.
879	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%.
880	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
881	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
882	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%.
883	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%.
884	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%.
885	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%.
886	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%.
887	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
888	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.

889	BITTERN	A, E, H	Magnesium is a mandatory component of bittern. Only permitted for use in: (a) medicines limited to oral routes of administration; and (b) topical medicines for dermal administration. 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; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
890	BIXA ORELLANA	A, E, H	
891	BLACK BONED CHICKEN POWDER	A	
892	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.'
893	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.'
894	BLACK CURRANT	E	
895	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%.
896	BLACK CURRANT FRESH	A, E, H	
897	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted

			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
898	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
899	BLACK PEPPER OIL	A, E, H	
900	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%.
901	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
902	BLACKBERRY	E	
903	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%.
904	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%.
905	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%.
906	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%.
907	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, sucrose is a mandatory component of blackstrap molasses.
908	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.
909	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.
910	BLAINVILLEA ACMELLA	A, E, H	When used as an excipient, permitted for use only in combination with other permitted

			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
911	BLETILLA STRIATA	A, H	
912	BLUE FLAG RHIZOME DRY	A, H	
913	BLUE FLAG RHIZOME POWDER	A, H	
914	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%.
915	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%.
916	BLUMEA LACERA	A, H	
917	BOEHMERIA NIVEA	A, H	
918	BOERHAVIA DIFFUSA	A, H	
919	BOERHAVIA REPENS	A, H	
920	BOGBEAN LEAF DRY	A, H	
921	BOGBEAN LEAF POWDER	A, H	
922	BOIS DE ROSE OIL	A, E, H	
923	BOMBAX CEIBA	A, H	
924	BORAGO OFFICINALIS	A, E, H	Only for use when the preparation is 'fixed oil' and the fixed oil is derived from seeds of Borago officinalis.

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925	BORAX	A, E, H	Boron is a mandatory component of borax. The percentage of boron from borax should be calculated based on the molecular weight of borax. The maximum recommended daily dose must not provide more than 6mg of boron. 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%. 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).
926	BORAX PENTAHYDRATE	A, E	Boron is a mandatory component of borax pentahydrate. The percentage of boron from borax pentahydrate should be calculated based on the molecular weight of borax pentahydrate. The maximum recommended daily dose must not provide more than 6mg of boron from borax pentahydrate. 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%. 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

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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).
927	BORIC ACID	A, H	Boron is a mandatory component of boric acid. The percentage of boron from boric acid should be calculated based on the molecular weight of boric acid. The maximum recommended daily dose must not provide more than 6mg of boron. 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%.

		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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928	BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
929	BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
930	BORON NITRIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
931	BORONIA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
932	BORONIA MEGASTIGMA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%.
933	BOSWELLIA CARTERII	A, E, H	
934	BOSWELLIA SERRATA	A, E, H	
935	BOSWELLIA THURIFERA	A, H	
936	BOVINE CALCIUM CHONDROITIN SULFATE	A	
937	BOVINE CHONDROITIN SULFATE	A	
938	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).
939	BOVINE LACTOFERRIN	A	
940	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
941	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%.
942	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).
943	BRANDY	E	
944	BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended

			for use in the eye. The concentration in the medicine must be no more than 1%.
945	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%.
946	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%.
947	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%.
948	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%.
949	BRASSICA OLERACEA VAR. BOTRYTIS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. botrytis when the

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

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			than 10 mg/kg or 10 mg/L or 0.001%.
954	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%.
955	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%.
956	BRILLIANT BLACK BN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
957	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
958	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
959	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
960	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
961	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.

962	BRIZA MEDIA	A, H	
963	BROCCOLI	E	
964	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (Ananas comosus).
965	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%.
966	BROMUS CATHARTICUS	A, H	
967	BROMUS INERMIS	A, H	
968	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
969	BRONOPOL	E	Only for use in topical medicines for dermal application.
970	BROUSSONETIA PAPYRIFERA	A, H	
971	BROWN FK	E	Permitted for use only as a colour for topical use.
972	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
973	BRUSSEL SPROUT	E	
974	BRYONIA ALBA	A, H	
975	BRYONIA DIOICA	A, H	
976	BUCHU LEAF DRY	A, H	
977	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%.
978	BUCHU LEAF POWDER	A, E, H	
979	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
980	BUDDLEJA OFFICINALIS	A, H	
981	BULNESIA SARMIENTI	A, E, H	
982	BUNIAS ORIENTALIS	A, H	
983	BUPLEURUM FALCATUM	A, H	
984	BURDOCK LEAF DRY	A, H	
985	BURDOCK LEAF POWDER	A, H	
986	BURDOCK ROOT DRY	A, H	
987	BURDOCK ROOT POWDER	A, H	
988	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
989	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%.
990	BUTANE	E	Only for use as an excipient propellant ingredient.
991	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%.
992	BUTTER	E	
993	BUTTER ACIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
994	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%.
995	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%.
996	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%.
997	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%.
998	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%.
999	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%.
1000	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%.
1001	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).
1002	BUTYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

			flavour concentration in a medicine must be no more than 5%.
1003	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
1004	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%.
1005	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%.
1006	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%.
1007	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%.
1008	BUTYL METHOXYDIBENZOYLMETHANE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for

			use in the eye. The concentration in preparation must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1009	BUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1010	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
1011	BUTYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1012	BUTYLATED HYDROXYANISOLE	E	
1013	BUTYLATED HYDROXYTOLUENE	E	
1014	BUTYLENE GLYCOL	E	Only for use in topical medicines

	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%.
1015	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%.
1016	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%.
1017	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%.
1018	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%.
1019	BUTYRIC ACID	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%.
1020	C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.012%.
1021	C10-12 ALKANE/CYCLOALKANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1022	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.
1023	C11-13 ALKANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%.
1024	C11-14-ISO-ALCOHOL C-13 RICH	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

1025	C12-13 PARETH-23	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
1026	C12-13 PARETH-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
1027	C12-15 ALKYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.2%.
1028	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1029	C12-20 ACID PEG-8 ESTER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1030	C12-20 ALKYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 0.75%.
1031	C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.
1032	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1033	C14-22 ALCOHOLS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2.55%.
1034	C15-16 ISOPARAFFIN	E	C15-16 isoparaffin must only be included in topical medicines: (a) for dermal application; and (b) where the dosage form of the medicine is not spray. The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%. When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation, the total concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%.
1035	C15-19 ALKANE	E	Only for use in topical medicines for dermal application and not to

			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
1036	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%.
1037	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1038	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1039	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%.
1040	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1041	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%.
1042	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%.
1043	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%.
1044	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%.
1045	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1046	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1047	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%
1048	CABBAGE	E	
1049	CABREUVA OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1050	CADE OIL	A, E, H	
1051	CAESALPINIA SAPPAN	A, H	
1052	CAFFEINE	A, E, H	When used as an excipient, only for use in topical medicines for dermal application. Only for use as an active ingredient for: (a) oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine); and (b) Topical medicines for dermal application that are directed for use in adults only. When for topical application: (a) the concentration of total caffeine in the medicine must not be more than 1%; and (b) the medicine must not be intended for use on broken skin. 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. When for internal use or oral application, the following warning statement is required on the medicine label: - (ADULT) 'Adults only' (or words to that effect). 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%. 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).
1053	CAJUPUT OIL	A, E, H	Cineole is a mandatory component of Cajuput oil. When the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. 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. When the concentration in the medicine is more than 25% and the nominal capacity of the container is less than 15 mL, a restricted flow insert must be fitted to the container. When the concentration in the medicine is more than 25%, the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container

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			and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is 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: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'.
1054	CALAMINE	A, E	Only for use as an active or excipient ingredient for dermal application. 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.
1055	CALANUS FINMARCHICUS OIL	A	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. The route of administration for medicines that contain Calanus

			finmarchicus oil must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2.3 g of Calanus finmarchicus oil. The following warning statements (or words to that effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) ‘Adults only'.
1056	CALCIFEDIOL MONOHYDRATE	A	The maximum recommended daily dose of the medicine must not provide more than 10 micrograms of calcifediol. Only for use in oral medicines. Calcifediol must not be used in medicines with other Vitamin D analogues; such as ergocalciferol or colecalciferol. The medicine requires the following warning statements on the label: - (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).
1057	CALCIFIED LITHOTHAMNION	A	Only for use in oral medicines.

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

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	SPECIES		
1058	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1059	CALCIUM ALGINATE	E	
1060	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.
1061	CALCIUM ASCORBATE	A, E, H	
1062	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1063	CALCIUM ASPARTATE	A	
1064	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1065	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.
1066	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1067	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1068	CALCIUM CARBONATE	A, E, H	
1069	CALCIUM CASEINATE	E	
1070	CALCIUM CHLORIDE DIHYDRATE	E	
1071	CALCIUM CITRATE	A, E, H	
1072	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1073	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1074	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular

			weight of Calcium fluoride. The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.
1075	CALCIUM FOLINATE	A	Folinic acid is a mandatory component of calcium folinate. The maximum recommended daily dose must not provide more than 500 micrograms of folinic acid. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
1076	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1077	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1078	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1079	CALCIUM GLYCINATE DIHYDRATE	A	
1080	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1081	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1082	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1083	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1084	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.
1085	CALCIUM HYDROXYCITRATE	A, H	
1086	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1087	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1088	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%
1089	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1090	CALCIUM LACTATE	A, E, H	
1091	CALCIUM LACTATE GLUCONATE	A, E, H	
1092	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1093	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1094	CALCIUM LYSINATE	A	Only for use in oral medicines.
1095	CALCIUM METHIONINATE	A	Only for use in oral medicines.
1096	CALCIUM OROTATE	A, E, H	
1097	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1098	CALCIUM PANTOTHENATE	A, E, H	
1099	CALCIUM PHOSPHATE	A, E, H	
1100	CALCIUM PYRUVATE	A	

1101	CALCIUM SACCHARATE	E	
1102	CALCIUM SILICATE	E	
1103	CALCIUM SODIUM CASEINATE	A, H	
1104	CALCIUM SODIUM LACTATE	A, E, H	
1105	CALCIUM STEARATE	E	
1106	CALCIUM SUCCINATE	A, E, H	
1107	CALCIUM SULFATE	A, E, H	
1108	CALCIUM SULFATE DIHYDRATE	A, E, H	
1109	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1110	CALCIUM THREONINATE	A	
1111	CALENDULA FLOWER DRY	A, E, H	
1112	CALENDULA FLOWER POWDER	A, H	
1113	CALENDULA OFFICINALIS	A, E, H	
1114	CALLERYA RETICULATA	A, H	
1115	CALLICARPA PEDUNCULATA	A, H	
1116	CALLISTEPHUS CHINENSIS	A, H	
1117	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%.
1118	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%.
1119	CALLITRIS RHOMBOIDEA	A, H	
1120	CALLUNA VULGARIS	A, E, H	
1121	CALOCHORTUS TOLMIEI	A, H	
1122	CALTHA PALUSTRIS	A, H	
1123	CALUMBA ROOT DRY	A, H	

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1124	CALUMBA ROOT POWDER	A, H	
1125	CALVATIA GIGANTEA	A, E, H	
1126	CALYCANTHUS FLORIDUS	A, H	
1127	CALYCANTHUS PRAECOX	A, H	
1128	CAMELLIA JAPONICA	A, H	
1129	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or sunscreen preparations for dermal application only.
1130	CAMELLIA SINENSIS	A, E, H	Caffeine is a mandatory component of Camellia sinensis. 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%. 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 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).
1131	CAMPHENE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1132	CAMPHOLENIC ALDEHYDE	E	Permitted for use only in combination with other permitted

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			ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
1133	CAMPHOR	A, E, H	In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the concentration of camphor must be no more than 2.5%.
1134	CAMPHOR BENZALKONIUM METHOSULFATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the preparation must not be more than 6%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1135	CAMPHOR OIL BROWN	A, H	camphor, cineole and safrole are mandatory components of camphor oil brown. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of

	camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole

		in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the 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: - (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% 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: - (CHILD) 'Keep out of reach of children' (or words to that effect); 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	CAMPHOR OIL WHITE	A, E, H	Camphor and safrole are mandatory components of camphor oil white. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted

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			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 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.
1137	CAMPSIS GRANDIFLORA	A, H	
1138	CANADA BALSAM	A, H	
1139	CANANGA ODORATA	A, E, H	
1140	CANANGA OIL	A, E, H	
1141	CANARIUM INDICUM	A, H	Only for use when the plant part is seed and the plant preparation is oil.
1142	CANARIUM LUZONICUM	A, H	
1143	CANDELILLA WAX	A, E, H	
1144	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1145	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%.

1146	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1147	CANOLA OIL	A, E, H	Allyl isothiocyanate is a mandatory component of canola oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
1148	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1149	CANTHAXANTHIN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1150	CAPRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1151	CAPROIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1152	CAPRYLIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1153	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1154	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC 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%
1155	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1156	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%.
1157	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%
1158	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%.
1159	CAPRYLYL GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%
1160	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%.
1161	CAPSELLA BURSA-PASTORIS	A, H	
1162	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1163	CAPSICUM ANNUUM	A, E, H	
1164	CAPSICUM DRY	A, E, H	
1165	CAPSICUM FRUIT OLEORESIN	A, E	
1166	CAPSICUM FRUTESCENS	A, E, H	
1167	CAPSICUM POWDER	A, E, H	
1168	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1169	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1170	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%.

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1171	CARAWAY DRY	A, H	
1172	CARAWAY OIL	A, E, H	
1173	CARAWAY POWDER	A, H	
1174	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1175	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.
1176	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1177	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1178	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1179	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1180	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1181	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1182	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal

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

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			oral routes of administration.
1200	CARMOISINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1201	CARNAUBA WAX	A, E, H	
1202	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%.
1203	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%.
1204	CAROB GUM	E	
1205	CAROB POD	E	
1206	CAROTENES	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1207	CARPINUS BETULUS	A, H	
1208	CARPINUS CORDATA	A, H	
1209	CARRAGEENAN	E	
1210	CARROT	E	
1211	CARROT SEED OIL	A, E, H	
1212	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).
1213	CARUM CARVI	A, H	
1214	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%.
1215	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%.
1216	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%.
1217	CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1218	CARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1219	CARYA ILLINOINENSIS	A, H	
1220	CARYA OVATA	A, H	
1221	CARYOPHYLLENE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1222	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) ‘Use in children 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 - (LAX2) ‘Prolonged use may cause serious bowel problems’.
1223	CASCARA POWDER	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara powder when the route of

		administration is oral administration. 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 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 - (LAX2) ‘Prolonged use may cause serious bowel problems’.
1224	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.
1225	CASEIN	E	
1226	CASHEW NUT	E	
1227	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%.
1228	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%.

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1229	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.
1230	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 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 - (LAX2) 'Prolonged use may cause serious bowel problems'. When Cassia fistula is for use as an excipient: (a) the plant part must be fruit; and (b) must only be included in medicines when in combination with other permitted ingredients as a: (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. The total concentration of flavour proprietary excipient formulations containing Cassia fistula must not be more than 5% of the total medicine. The total concentration of fragrance proprietary excipient formulations containing Cassia fistula must not be more than 1% of the total medicine.
1231	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%.
1232	CASSIE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1233	CASTANEA MOLLISSIMA	A, H	
1234	CASTANEA SATIVA	A, H	
1235	CASTOR OIL	A, E	
1236	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1237	CASUARINA EQUISITIFOLIA	A, H	
1238	CATALPA BIGNONIOIDES	A, H	
1239	CATALPA OVATA	A, H	
1240	CATECHU	A, H	
1241	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%.
1242	CAULIFLOWER	E	
1243	CAULOPHYLLUM THALICTROIDES	A, E, H	
1244	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.

1245	CEANOTHUS AMERICANUS	A, H	
1246	CEDAR LEAF OIL	A, E, H	
1247	CEDARWOOD OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1248	CEDARWOOD OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1249	CEDARWOOD OIL VIRGINIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1250	CEDRENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1251	CEDRENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1252	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%.
1253	CEDRUS ATLANTICA	A, E, H	
1254	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%.
1255	CEDRUS DEODARA	A, H	
1256	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1257	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%.
1258	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%.
1259	CELERY SEED DRY	A, E, H	
1260	CELERY SEED OIL	A, E, H	
1261	CELERY SEED POWDER	A, H	
1262	CELLACEFATE	E	
1263	CELLULASE	A	Must be derived from Trichoderma longibrachiatum only.
1264	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%.
1265	CELOSIA ARGENTEA	A, H	
1266	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1267	CENTAUREA CYANUS	A, E, H	
1268	CENTAURIUM ERYTHRAEA	A, H	
1269	CENTELLA ASIATICA	A, E, H	
1270	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%.
1271	CENTIPEDA CUNNINGHAMII	A, E, H	
1272	CENTIPEDA MINIMA	A, H	
1273	CEPHALANOPSIS SEGETUM	A, H	
1274	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1275	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%.
1276	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1277	CERATONIA SILIQUA	A, E, H	
1278	CERATOSTIGMA WILLMOTTIANUM	A, H	
1279	CERESIN	E	Only for use in topical medicines for dermal application.
1280	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%.
1281	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1282	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1283	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1284	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1285	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1286	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.
1287	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1288	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1289	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%.
1290	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1291	CETETH-10	E	Only for use in topical medicines for dermal application.
1292	CETETH-2	E	Only for use in topical medicines for dermal application.
1293	CETETH-24	E	Only for use in topical medicines for dermal application.
1294	CETETH-5	E	Only for use in topical medicines for dermal application.
1295	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1296	CETOMACROGOL 1000 PHOSPHATE	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 or on damaged skin. The concentration in the medicine must be no more than 2%.
1297	CETOMACROGOL 500 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1298	CETOSTEARYL ALCOHOL	E	
1299	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 %
1300	CETRARIA ISLANDICA	A, H	
1301	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1302	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1303	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1304	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1305	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1306	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1307	CETYL DIMETICONE/BIS-	E	Only for use in topical medicines

	VINYLDIMETICONE CROSSPOLYMER		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%.
1308	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1309	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%.
1310	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1311	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1312	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1313	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1314	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%.
1315	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;

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			b) the medicine must not contain more than 2 mg of cetylpyridinium chloride per lozenge; c) the maximum recommended daily dose of the medicine must not provide more than 24 mg of cetylpyridinium chloride; and d) the medicine label must specify that the medicine is only to be used for 7 days (or less).
1316	CHAENOMELES LAGENARIA	A, H	
1317	CHAENOMELES SPECIOSA	A, H	
1318	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.
1319	CHAMAECYPARIS LAWSONIANA	A, H	
1320	CHAMAELIRIUM LUTEUM	A, H	
1321	CHAMAEMELUM NOBILE	A, E, H	
1322	CHAMOMILE FLOWER DRY	A, E, H	
1323	CHAMOMILE OIL ENGLISH	A, E, H	
1324	CHAMOMILE OIL GERMAN	A, E, H	
1325	CHANGIUM SMYRNIOIDES	A, H	
1326	CHEIRANTHUS CHEIRI	A, H	
1327	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 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.'
1328	CHELONE GLABRA	A, H	
1329	CHENOPODIUM ALBUM	A, H	
1330	CHENOPODIUM VULVARIA	A, H	
1331	CHERRY	E	
1332	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

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			medicine must be no more than 5%.
1333	CHESTNUT SWEET	E, H	
1334	CHICKEN COMB EXTRACT	A	
1335	CHICKEN STERNUM CARTILAGE POWDER	A	Only to be used in a medicine 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. The route of administration for medicines that contain chicken sternum cartilage powder must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 40 mg of chicken sternum cartilage powder. The following warning statement (or words to that effect) is required on the medicine label: - (ADULT) ‘Adults only'.
1336	CHIMAPHILA UMBELLATA	A, H	Beta-arbutin is a mandatory component of Chimaphila umbellata. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and

			c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
1337	CHIONANTHUS VIRGINICA	A, H	
1338	CHLORELLA	E	Iodine is a mandatory component of Chlorella. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1339	CHLORELLA PYRENOIDOSA	E	
1340	CHLORELLA VULGARIS	A, E	Iodine is a mandatory component of Chlorella vulgaris. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1341	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1342	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines

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

			ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1354	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1355	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1356	CHOLESTERYL/BEHENYL/OCTYLDODECYL 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%.
1357	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1358	CHOLINE BITARTRATE	A, E	
1359	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1360	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%.
1361	CHONDRUS CRISPUS	A, E, H	Iodine is a mandatory component of Chondrus crispus. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.

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1362	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. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1363	CHONDRUS EXTRACT	A, E, H	Iodine is a mandatory component of Chondrus extract. 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.
1364	CHROMIC CHLORIDE HEXAHYDRATE	A, H	When used as an active ingredient in a preparation for mineral supplementation, chromium is a mandatory component of chromic chloride hexahydrate. The amount of chromium in the active ingredient should be calculated based on the molecular weight of chromic chloride hexahydrate. 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).

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

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			quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1377	CINCHONA BARK POWDER	A, H	Quinidine and quinine are mandatory components of Cinchona bark powder. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1378	CINCHONA OFFICINALIS	A, H	Quinidine and quinine are mandatory components of Cinchona officinalis. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1379	CINCHONA PUBESCENS	A, H	Quinidine and quinine are mandatory components of Cinchona pubescens. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1380	CINEOLE	E	In liquid preparations when the concentration of cineole in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect);

			and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole 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.
1381	CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1382	CINNAMIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1383	CINNAMOMUM CAMPHORA	A, E, H	Camphor, cineole and safrole are mandatory components of Cinnamomum camphora. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the

		concentration of camphor must be no more than 2.5%. In essential oil preparations or distillates and the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label: - (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: - (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%.
1384	CINNAMOMUM CASSIA	A, E	Cassia oil is a mandatory component of Cinnamomum

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			cassia if the plant preparation is an essential oil, distillate, fixed oil or infused oil. The concentration of Cassia oil in the medicine must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1385	CINNAMOMUM VERUM	A, E, H	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%. 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. The concentration of cinnamon bark oil in the medicine must be no more than 2%. Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the plant part is leaf. When the concentration of cinnamon leaf oil in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.

			When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but no more than 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. 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.
1386	CINNAMON BARK OIL	A, E, H	The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1387	CINNAMON DRY	A, H	Cinnamon bark oil is a mandatory component of cinnamon dry. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1388	CINNAMON LEAF OIL	A, E, H	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. When the concentration of cinnamon leaf oil in the preparation is more than 25% and

			the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. 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: - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1389	CINNAMON POWDER	A, E, H	Cinnamon bark oil is a mandatory component of cinnamon powder. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1390	CINNAMYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1391	CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1392	CINNAMYL BUTYRATE	E	If used in a flavour the total flavour concentration in a medicine must be no more than 5%. Permitted for use only in combination with other permitted ingredients as a flavour.
1393	CINNAMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1394	CINNAMYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1395	CINNAMYL ISOBUTYRATE	E	Permitted for use only in

			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1396	CINNAMYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
1397	CINNAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1398	CINOXATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 6%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1399	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	E	Permitted for use only in combination with other permitted

			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1400	CIS-3-HEXEN-1-OL	E	cis-3-Hexen-1-ol must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 5% of the total medicine. The total concentration of fragrance proprietary excipient formulations containing cis-3-hexen-1-ol must not be more than 1% of the total medicine.
1401	CIS-3-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1402	CIS-3-HEXENYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1403	CIS-3-HEXENYL ACETATE	E	Permitted for use only in

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

			fragrance concentration in a medicine must be no more than 1%.
1413	CIS-3-HEXENYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1414	CIS-4-HEPTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1415	CIS-6-NONEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1416	CIS-6-NONENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1417	CIS-BETA-OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1418	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%.
1419	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%.
1420	CISTANCHE DESERTICOLA	A, H	
1421	CISTANCHE SALSA	A, H	
1422	CISTUS LADANIFER	A, E, H	
1423	CITRAL	E	
1424	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

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			medicine must be no more than 1%.
1425	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%.
1426	CITRIC ACID	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label: - (SENS) 'Application to skin 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 DIHYDRATE	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'
1428	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.'

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			- (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.'
1429	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%.
1430	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%.
1431	CITRON	E	
1432	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'.
1433	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%.
1434	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%.
1435	CITRONELLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1436	CITRONELLOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
1437	CITRONELLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1443	CITRONELLYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1444	CITRONELLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1445	CITRULLINE	A	Only permitted for use in medicines: (a) limited to oral routes of administration; and (b) when the maximum recommended daily dose does not provide more than 6 g of citrulline.
1446	CITRULLUS COLOCYNTHIS	H	Citrullus colocynthis can only be included in medicines for oral use when the dilution of the mother tincture is 10,000 fold (4X) or more.
1447	CITRULLUS VULGARIS	A, H	
1448	CITRUS AURANTIFOLIA	A, E, H	When the plant preparation is oil or distillate, the warning statement

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			(SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1449	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.
1450	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1451	CITRUS CHACHIENSIS	A, H	
1452	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%.

1453	CITRUS FIBRE	E	
1454	CITRUS LIMETTA	A, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus limetta oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1455	CITRUS LIMON	A, E, H	Oxedrine is a mandatory component of Citrus limon when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus limon oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1456	CITRUS MAXIMA	A, H	
1457	CITRUS MEDICA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may

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			increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus medica oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1458	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%.
1459	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.
1460	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.
1461	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.
1462	CITRUS SINENSIS PEEL MOLASSES EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1463	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.
1464	CITRUS X PARADISI	A, E, H	
1465	CITRUS X WILSONII	A, H	
1466	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%.
1467	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%.
1468	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%.

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1469	CIVETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1470	CLARY OIL	A, E, H	
1471	CLEMATIS ARMANDII	A, H	
1472	CLEMATIS CHINENSIS	A, E, H	
1473	CLEMATIS RECTA	A, H	
1474	CLEMATIS VITALBA	A, H	
1475	CLERODENDRUM TRICHOTOMUM	A, H	
1476	CLINOPODION POLYCEPHALUM	A, H	
1477	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1478	CLIVER HERB DRY	A, H	
1479	CLIVER HERB POWDER	A, H	
1480	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.

1481	CLOVE DRY	A, E, H	
1482	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 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.
1483	CLOVE OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1484	CLOVE POWDER	A, E, H	
1485	CLOVE STEM 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.
1486	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.
1487	CNICUS BENEDICTUS	A, H	
1488	CNICUS JAPONICUS	A, H	
1489	CNIDIUM MONNIERI	A, H	
1490	CNIDIUM OFFICINALE	A, H	
1491	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1492	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1493	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1494	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.
1495	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 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.
1496	COCCOLOBIA UVIFERA	A, H	
1497	COCCULUS ORBICULATUS	A, H	
1498	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1499	COCHLEARIA OFFICINALIS	A, H	
1500	COCILLANA DRY	A, H	
1501	COCILLANA POWDER	A, H	
1502	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1503	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.
1504	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%

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1505	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.
1506	COCOA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1507	COCOA POWDER	A, E, H	
1508	COCOGLYCERIDES	E	
1509	COCONUT	E	
1510	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1511	COCONUT OIL	A, E, H	
1512	COCOS NUCIFERA	A, E, H	
1513	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. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of vitamin D.
1514	CODONOPSIS LANCEOLATA	A, H	
1515	CODONOPSIS PILOSULA	A, H	
1516	CODONOPSIS TANGSHEN	A, H	
1517	COFFEA ARABICA	A, E, H	Caffeine is a mandatory component of Coffea arabica. 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%. 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 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).
1518	COFFEA CANEPHORA	A, E, H	Caffeine is a mandatory component of Coffea canephora. 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%. 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 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).
1519	COFFEE	E, H	Caffeine is a mandatory component of coffee. 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%. 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 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).
1520	COFFEE OIL	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%.
1521	COFFEE SOLID EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1522	COGNAC OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1523	COGNAC OIL GREEN	A, E, H	
1524	COGNAC OIL WHITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1525	COIX LACHRYMA-JOBI	A, H	
1526	COLA ACUMINATA	A, E, H	Caffeine is a mandatory component of Cola acuminata. 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%. 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 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).
1527	COLA NITIDA	A, E, H	Caffeine is a mandatory component of Cola nitida. 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%. 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 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).
1528	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%.
1529	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1530	COLLAGEN	E	
1531	COLLINSONIA CANADENSIS	A, H	
1532	COLLOIDAL ANHYDROUS	A, E, H	Only for use when the route of

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	SILICA		administration is other than inhalation.
1533	COLOPHONY	A, E, H	
1534	COMMIPHORA HABESSINICA	A, H	
1535	COMMIPHORA KATAF	A, H	
1536	COMMIPHORA MYRRHA	A, E, H	
1537	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1538	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1539	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’.
1540	CONIFER GREEN NEEDLE COMPLEX	A	Only for topical and oral use. Must be made by petroleum ether extraction of needles of the conifer species Pinus sylvestris (Scotch Pine) and Picea abies (Norwegian Spruce).
1541	CONIFER PHYTOSTEROL COMPLEX	A	
1542	CONIOSELINUM TATARICUM	A, H	
1543	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The homoeopathic potency of Conium maculatum in the final medicine must be 12X or greater.

1544	CONVALLARIA MAJALIS	A, H	The concentration of equivalent dry Convallaria majalis in the product must be no more than 10mg/Kg or 10mg/L or 0.001%.
1545	CONYZA CANADENSIS	A, H	
1546	COPAIBA OIL	A, E, H	
1547	COPAIFERA LANGSDORFFII	A, E, H	
1548	COPERNICIA CERIFERA	A, E, H	
1549	COPOVIDONE	E	
1550	COPPER	H	Only for use as an active homoeopathic ingredient. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1551	COPPER (II) ASPARTATE	A, H	Copper is a mandatory component of copper (II) aspartate. The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1552	COPPER (II) GLYCINATE	A, H	Copper is a mandatory component of copper (II) glycinate. The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not

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

			for dermal application. The concentration in the medicine must be no more than 3%.
1559	COPTIS CHINENSIS	A, H	
1560	COPTIS JAPONICA	A, H	
1561	CORALLINA OFFICINALIS	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is to be no more than 1%.
1562	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1563	CORIANDER DRY	A, H	
1564	CORIANDER OIL	A, E, H	
1565	CORIANDER POWDER	A, H	
1566	CORIANDRUM SATIVUM	A, E, H	
1567	CORMUS DOMESTICA	A, H	
1568	CORN GLYCERIDES	E	
1569	CORN SILK DRY	A, H	
1570	CORN SILK POWDER	A, H	
1571	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%.
1572	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%.

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1573	CORNUS FLORIDA	A, H	
1574	CORNUS OFFICINALIS	A, H	
1575	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1576	CORYDALIS AMBIGUA	A, E, H	
1577	CORYDALIS BUNGEANA	A, H	
1578	CORYDALIS CAVA	A, H	
1579	CORYDALIS FABACEA	A, H	
1580	CORYDALIS FORMOSA	A, H	
1581	CORYDALIS TURTSCHANINOVII	A, H	
1582	CORYLUS AMERICANA	A, H	
1583	CORYLUS AVELLANA	A, H	
1584	CORYMBIA CITRIODORA	A, E, H	Cineole is a mandatory component of Corymbia citriodora. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1585	CORYMBIA FICIFOLIA	A, H	Cineole is a mandatory component

			of Corymbia ficifolia. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1586	COSMOS BIPINNATUS	A, H	
1587	COSTUS ROOT OIL	A, H	
1588	COSTUS SPICATUS	A, H	
1589	COTTONSEED OIL	A, E, H	
1590	COUCH GRASS RHIZOME DRY	A, H	
1591	COUCH GRASS RHIZOME POWDER	A, H	
1592	COUMARIN	E, H	Only for use as an active homoeopathic ingredient or excipient ingredient. The concentration of coumarin in the medicine must not be more than 0.001%. When used as an excipient: (a) must only be used in topical medicines for dermal application;

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			and (b) the label of the medicine must specify that the product should only be used by adults.
1593	CRANBERRY	E	
1594	CRATAEGUS CUNEATA	A, E, H	
1595	CRATAEGUS GERMANICA	A, H	
1596	CRATAEGUS LAEVIGATA	A, E, H	
1597	CRATAEGUS MONOGYNA	A, E, H	
1598	CRATAEGUS PINNATIFIDA	A, E, H	
1599	CRATEVA MAGNA	A, E, H	
1600	CREATINE	A, E	
1601	CREATINE MONOHYDRATE	A, E	
1602	CREATINE PHOSPHATE	A, E	
1603	CREATININE	E	Only for use in topical medicines for dermal application and not for use in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1604	CREOSOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1605	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1606	CRESOL	E	Only for use as a preservative in topical medicines. The concentration of phenols (including cresols and xylenols and any other homologue of

			phenol) boiling below 220 degrees centigrade must be no more than 3%.
1607	CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1608	CRITHMUM MARITIMUM WHOLE PLANT EXTRACT	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.00341%.
1609	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.
1610	CROSCARMELLOSE SODIUM	E	
1611	CROSPOVIDONE	E	
1612	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.

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1613	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1614	CRYPTOMERIA JAPONICA	A, H	
1615	CUBEB OIL	A, H	
1616	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%.
1617	CUCUMBER	E	
1618	CUCUMIS MELO	A, H	
1619	CUCUMIS SATIVUS	A, E, H	
1620	CUCURBITA MAXIMA	A, E, H	
1621	CUCURBITA MOSCHATA	A, H	
1622	CUCURBITA PEPO	A, E, H	
1623	CULLEN CORYLIFOLIUM	A, H	
1624	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%.
1625	CUMIN OIL	A, E, H	
1626	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%.

1627	CUMINUM CYMINUM	A, H	
1628	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%.
1629	CUPRESSUS ARIZONICA	A, H	
1630	CUPRESSUS FUNEBRIS	A, E, H	
1631	CUPRESSUS SEMPERVIRENS	A, E, H	
1632	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1633	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1634	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.
1635	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate. The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate

			hemipenthydrate. The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.
1636	CUPRIC OXIDE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric oxide. The percentage of copper from cupric oxide should be calculated based on the molecular weight of cupric oxide. 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%.
1637	CUPRIC SULFATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate. The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1638	CUPRIC SULFATE MONOHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate.

			The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.
1639	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.
1640	CURCULIGO ORCHIOIDES	A, H	
1641	CURCUMA AROMATICA	A, H	
1642	CURCUMA LONGA	A, E, H	

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1643	CURCUMA ZANTHORRHIZA	A, H	
1644	CURCUMA ZEDOARIA	A, H	
1645	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1646	CUSCUTA EPITHYMUM	A, H	
1647	CUSCUTA EUROPAEA	A, H	
1648	CUSCUTA HYGROPHILAE	A, H	
1649	CUSCUTA RACEMOSA	A, H	
1650	CUSPARIA FEBRIFUGA	A, H	
1651	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1652	CYANOCOBALAMIN	A, E, H	
1653	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1654	CYATHULA OFFICINALIS	A, H	
1655	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1656	CYCLAMEN PURPURASCENS	A, H	
1657	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%.
1658	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%.
1659	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%.
1660	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%.
1661	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%.
1662	CYCLOHEXYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1663	CYCLOHEXYL PHENETHYL ETHER	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%.
1664	CYCLOHEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1665	CYCLOHEXYLETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1666	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1667	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%.
1668	CYDONIA OBLONGA	A, H	
1669	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%.
1670	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%.
1671	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%.
1672	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%.
1673	CYNANCHUM ATRATUM	A, H	
1674	CYNANCHUM STAUNTONII	A, E, H	
1675	CYNARA SCOLYMUS	A, E, H	
1676	CYNODON DACTYLON	A, E, H	
1677	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1678	CYPERUS LONGUS	A, H	
1679	CYPERUS ROTUNDUS	A, H	
1680	CYPRESS OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1681	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1682	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.
1683	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.
1684	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient and the total flavour proprietary excipient formulation concentration in a medicine must not be more than 5%. The maximum recommended daily dose must contain no more than 652 mg of cysteine hydrochloride monohydrate. When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.
1685	CYSTINE	A	The maximum recommended

			daily dose must contain no more than 450 mg of cystine. When cysteine, cystine and/or their salts are used in combination, the medicine must not provide more than a total of 450 mg cysteine per maximum recommended daily dose.
1686	CYTISUS SCOPARIUS	A, H	Sparteine is a mandatory component of Cytisus scoparius. The concentration of Sparteine in the medicine must be no more than 0.001%.
1687	D-ALPHA-TOCOPHEROL	A, E	
1688	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1689	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1690	D-ALPHA-TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1691	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%.
1692	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1693	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%.
1694	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%.
1695	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%.
1696	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.

1697	DACTYLIS GLOMERATA	A, H	
1698	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1699	DAEMONOROPS DRACO	A, E, H	
1700	DAHLIA PINNATA	A, H	
1701	DALBERGIA ODORIFERA	A, H	
1702	DAMIANA LEAF POWDER	A	
1703	DANDELION LEAF DRY	A, H	
1704	DANDELION LEAF POWDER	A, H	
1705	DANDELION ROOT DRY	A, H	
1706	DANDELION ROOT POWDER	A, H	
1707	DAPHNE GENKWA	A, H	
1708	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1709	DATURA STRAMONIUM	A, H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1710	DAUCUS CAROTA	A, E, H	
1711	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%.

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1712	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).
1713	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-cyclopentacyclooct-3-yl formate must not be more than 1% of the total medicine.
1714	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%.
1715	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%.

1716	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%.
1717	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%.
1718	DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1719	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%.
1720	DECANAL DIMETHYL ACETAL	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%.
1721	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.
1722	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%.
1723	DECYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1724	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%.

1725	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1726	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1727	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%.
1728	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1729	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or

			existing from time to time.
1730	DEER VELVET ANTLER SLICE	A	Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1731	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%.
1732	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1733	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%.
1734	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%.
1735	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1736	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%.
1737	DELTA-DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1738	DELTA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1739	DELTA-NONALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1740	DELTA-OCTALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1741	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%.
1742	DELTA-TOCOPHEROL	E	
1743	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%.
1744	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1745	DENATONIUM BENZOATE	E	
1746	DENDROBIUM NOBILE	A, H	
1747	DESCURAINIA SOPHIA	A, H	
1748	DESMODIUM STYRACIFOLIUM	A, H	
1749	DEVIL'S CLAW TUBER DRY	A, H	
1750	DEVIL'S CLAW TUBER POWDER	A, H	
1751	DEXPANTHENOL	A, E	
1752	DEXTRAN 20	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.3%.
1753	DEXTRAN 40	A, E	
1754	DEXTRATES	E	
1755	DEXTRIN	E	
1756	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%.
1757	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.
1758	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%.
1759	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%.
1760	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%.
1761	DI-PPG-3 MYRISTYL ETHER ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1762	DIACETIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1763	DIACETYL	E	Permitted for use only in

			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1764	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1765	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.
1766	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1767	DIANTHUS SUPERBUS	A, H	
1768	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1769	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1770	DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE	A, E, H	Magnesium is a mandatory component of dibasic magnesium phosphate trihydrate. The percentage of magnesium from dibasic magnesium phosphate trihydrate should be calculated based on the molecular weight of dibasic magnesium phosphate trihydrate. 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; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
1771	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1772	DIBASIC POTASSIUM PHOSPHATE TRIHYDRATE	A, E, H	When used as an active ingredient and the medicine is intended as a

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

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			dodecahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1776	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1777	DIBASIC SODIUM PHOSPHATE MONOHYDRATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate monohydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1778	DIBENZYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1779	DIBUTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1780	DIBUTYL SEBACATE	E	
1781	DIBUTYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1782	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1783	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1784	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%.
1785	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%.
1786	DICHLOROBENZYL ALCOHOL	E	
1787	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.
1788	DICTAMNUS ALBUS	A, H	
1789	DICTAMNUS DASYCARPUS	A, H	
1790	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%.
1791	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1792	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1793	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%.
1794	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.
1795	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%.
1796	DIETHYL PHTHALATE	E	
1797	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%.
1798	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

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1799	DIETHYLAMINOMETHYLCOUMARIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1800	DIETHYLDIMETHYL-2-CYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1801	DIETHYLENE GLYCOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1802	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1803	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%.
1804	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1805	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%.
1806	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).
1807	DIETHYLTOLUAMIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 20%. The medicine requires the following warning statement on the medicine label: - (DEET) 'WARNING: May be dangerous; particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.'
1808	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%.
1809	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%.
1810	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%.
1811	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.

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1812	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%.
1813	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%.
1814	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%.
1815	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%.
1816	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%.

1817	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%.
1818	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%.
1819	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%.
1820	DIHYDROCAPSIATE	A	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. The route of administration for medicines that contain dihydrocapsiate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 9 mg dihydrocapsiate. The following warning statements

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			(or words to the same effect) are required on the medicine label: - (ADULT) 'Adults only'; and - (PREGNT) 'Not recommended for use by pregnant and lactating women'.
1821	DIHYDROCARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1822	DIHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1823	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%.
1824	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%.

1825	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%.
1826	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%.
1827	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%.
1828	DIHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1829	DIHYDROMYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1830	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1831	DIISOPROPYL ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1832	DIISOPROPYL SEBACATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1833	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1834	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1835	DILL HERB OIL	A, E, H	
1836	DILL SEED OIL	A, E, H	
1837	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%.
1838	DIMETHICONE 12500	E	
1839	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%.
1840	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%.
1841	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%.
1842	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%.
1843	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1844	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%.
1845	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1846	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%.
1847	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%.
1848	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%.
1849	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%.

1850	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%.
1851	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%.
1852	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%.
1853	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%.
1854	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%.

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

			for dermal application.
1864	DIMETICONE 1000	E	
1865	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%
1866	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%.
1867	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1868	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1869	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%.
1870	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.
1871	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1872	DIMETICONE 450	E	Only for use in topical medicines for dermal application.

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1873	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1874	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1875	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1876	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%.
1877	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1878	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1879	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%.
1880	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%.
1881	DIMETICONOL	E	Only for use in topical medicines for dermal application.

1882	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%.
1883	DIMETICONOL/PROPYLSILSESQUIOXANE/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%.
1884	DIMOCARPUS LONGAN	A, H	
1885	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1886	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1887	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1888	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%.
1889	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.

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			The concentration in the medicine must be no more than 0.7%
1890	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.
1891	DIOSCOREA COLLETTII	A, H	
1892	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1893	DIOSCOREA JAPONICA	A, H	
1894	DIOSCOREA OPPOSITIFOLIA	A, H	
1895	DIOSCOREA POLYSTACHYA	A, H	
1896	DIOSCOREA SEPTEMLOBA	A, H	
1897	DIOSCOREA VILLOSA	A, E, H	
1898	DIOSPYROS KAKI	A, E, H	
1899	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 3%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1900	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE	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%.
1901	DIPENTAERYTHRITYL	E	Only for use in topical medicines

	TETRAHYDROXYSTEARATE/TETRAISOSTEARATE		for dermal 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%.
1902	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%.
1903	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1904	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%.
1905	DIPHENYL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1906	DIPOTASSIUM GLYCYRRHIZATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.

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1907	DIPROPIONYL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1908	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1909	DIPROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.2%.
1910	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1911	DIPSACUS ASPER	A, H	
1912	DIPSACUS JAPONICUS	A, H	
1913	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%.
1914	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1915	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1916	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%.

1917	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%.
1918	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%.
1919	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%.
1920	DISODIUM GUANYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1921	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%.
1922	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

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			must not be more than 0.35%.
1923	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%.
1924	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1925	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%.
1926	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1927	DISODIUM PYROPHOSPHATE	E	Disodium pyrophosphate 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 disodium pyrophosphate must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 2.4 g of phosphorus. The following statement (or words to the same effect) is required on the medicine label: - (PHOS) 'Contains phosphorus'.
1928	DISODIUM RICINOLEAMIDO MEA-SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1929	DISODIUM RUTINYL DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.05%.
1930	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%.
1931	DISPERSIBLE CELLULOSE	E	
1932	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%.

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1933	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%.
1934	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1935	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%.
1936	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%.
1937	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%.
1938	DL-ALPHA-TOCOPHEROL	A, E	
1939	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1940	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1941	DL-BORNEOL	E	
1942	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1943	DL-THREONINE	A, E	
1944	DOCOSAHEXAENOIC ACID	A	Only for use in oral medicines and

	(DHA)-RICH OIL DERIVED FROM MICROALGAE SCHIZOCHYTRIUM SP.		must be present in combination with other ingredients.
1945	DOCUSATE SODIUM	E	
1946	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%.
1947	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%.
1948	DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1949	DODECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1950	DODECYL ACETATE	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%.
1951	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%.
1952	DOLICHOS LABLAB	A, H	
1953	DOLOMITE	A, E, H	
1954	DRACAENA DRACO	A, H	
1955	DRIED BUTTERMILK	E	
1956	DRIED CALCIUM SULFATE	A, E, H	
1957	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; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is

			required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
1958	DRIMIA INDICA	A, H	
1959	DRIMIA MARITIMA	A, H	
1960	DROMETRIZOLE TRISILOXANE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in a medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1961	DROSERA ANGLICA	A, H	
1962	DROSERA BURMANNI	A, H	
1963	DROSERA INTERMEDIA	A, H	
1964	DROSERA RAMENTACIA	A, H	
1965	DROSERA ROTUNDIFOLIA	A, E, H	
1966	DROSERA ROTUNDIFOLIA MIS	A, H	
1967	DRYNARIA FORTUNEI	A, H	
1968	DRYOBALANOPS AROMATICA	A, H	
1969	DRYOPTERIS FILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1970	DULACIA INOPIFLORA	A, H	

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1971	DUNALIELLA SALINA	A, E, H	
1972	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%.
1973	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%.
1974	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1975	ECAMSULE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1976	ECHINACEA ANGUSTIFOLIA	A, E, H	
1977	ECHINACEA PALLIDA	A, E, H	
1978	ECHINACEA PURPUREA	A, E, H	

1979	ECHINOPA SPINOSISSIMUS	A, H	
1980	ECLIPTA PROSTRATA	A, H	
1981	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%.
1982	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%.
1983	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1984	EGG LECITHIN	A, E	
1985	EGGSHELL MEMBRANE HYDROLYSATE	A	
1986	EGGSHELL MEMBRANE POWDER	A	
1987	ELAEAGNUS ANGUSTIFOLIA	A, H	
1988	ELAEIS GUINEENSIS	A, E, H	
1989	ELASTIN	E	Only for use in topical medicines for dermal application.
1990	ELDER FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1991	ELDER FLOWER BLACK DRY	A, E, H	
1992	ELDER FLOWER BLACK POWDER	A, H	
1993	ELECAMPANE RHIZOME DRY	A, H	

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1994	ELECAMPANE RHIZOME POWDER	A, H	
1995	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%.
1996	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%.
1997	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%.
1998	ELEOCHARIS DULCIS	A, H	
1999	ELETTARIA CARDAMOMUM	A, E, H	
2000	ELEUTHEROCOCCUS NODIFLORUS	A, H	
2001	ELEUTHEROCOCCUS ROOT DRY	A, H	
2002	ELEUTHEROCOCCUS ROOT POWDER	A, H	
2003	ELEUTHEROCOCCUS SENTICOSUS	A, H	
2004	ELSHOLTZIA SPLENDENS	A, H	
2005	ELYMUS REPENS	A, E, H	
2006	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.
2007	EMULSIFYING WAX	E	
2008	ENOXOLONE	E	Only for use in topical medicines for dermal application.
2009	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%.
2010	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 after 15 August 2024. The route of administration for medicines that contain EPA-rich Nannochloropsis oculata oil must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2000 mg of

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			EPA-rich Nannochloropsis oculata oil. The following warning statements (or words to the same effect) must be included on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) ‘Adults only'.
2011	EPHEDRA DISTACHYA	A, H	Ephedrine and Pseudoephedrine (of Ephedra distachya) are mandatory components of Ephedra distachya and must be declared in the application. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2012	EPHEDRA SINICA	A, H	Ephedrine and Pseudoephedrine (of Ephedra sinica) are mandatory components of Ephedra sinica. The concentration of ephedrine from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2013	EPIGAEA REPENS	A, H	
2014	EPILOBIUM ANGUSTIFOLIUM	E	Only for use in topical sunscreens for dermal application and not to be included in medicines intended for use in the eye. The extract must be processed from the flower, leaf and stem (herb top flowering) of the plant. The extracts used must be: 1:20 in 100% water or 1:2 in 100% water. The concentrations of Epilobium angustifolium must be no more than 0.75% for a 1:2 extract in 100% water, and 5% for a 1:20 extract in 100% water.

2015	EPILOBIUM PALUSTRE	A, H	
2016	EPILOBIUM PARVIFLORUM	A, H	
2017	EPIMEDIUM BREVICORNU	A, H	
2018	EPIMEDIUM GRANDIFLORUM	A, H	
2019	EPIMEDIUM SAGITTATUM	A, H	
2020	EQUISETUM ARVENSE	A, E, H	
2021	EQUISETUM HIEMALE	A, H	
2022	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2023	ERGOTHIONEINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
2024	ERIGERON BREVISCAPUS	A, H	
2025	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components. The concentration of amygdalin in the medicine must be 0%. The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
2026	ERIOCAULON BUERGERIANUM	A, H	
2027	ERIODICTYON CRASSIFOLIUM	A, H	
2028	ERIODICTYON GLUTINOSUM	A, H	
2029	ERODIUM CICUTARIUM	A, H	
2030	ERUCA SATIVA	A, H	
2031	ERYTHORBIC ACID	E	
2032	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%.

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2033	ERYTHROSINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2034	ERYTHROSINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2035	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'.
2036	ESCHSCHOLZIA CALIFORNICA	A, H	
2037	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%.
2038	ETHANOL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
2039	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.
2040	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2041	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%.
2042	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2043	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%.
2044	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%.
2045	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

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			1%.
2046	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%.
2047	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%.
2048	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%.
2049	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%.
2050	ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2051	ETHYL 2-HEXYL	E	Permitted for use only in

	ACETOACETATE		combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2052	ETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2053	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2054	ETHYL 3-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2055	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

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			medicine must be no more than 5%.
2056	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%.
2057	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%.
2058	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%.
2059	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%.
2060	ETHYL ACETATE	E	The residual solvent limit for ethyl acetate is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
2061	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%.
2062	ETHYL ACRYLATE	E	
2063	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%.
2064	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%.
2065	ETHYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2066	ETHYL BENZOYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2067	ETHYL BUTYLACETYLAMINOPROPIONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes (or words to that effect)'.
2068	ETHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2069	ETHYL CAPRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2070	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%.
2071	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%.
2072	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%.
2073	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%.
2074	ETHYL ENANTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
2075	ETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2076	ETHYL HYDROXYBENZOATE	E	
2077	ETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2078	ETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2079	ETHYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2080	ETHYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2081	ETHYL LEVULATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2082	ETHYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2083	ETHYL LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2084	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%.
2085	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2086	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2087	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%.
2088	ETHYL MALTOL	E	
2089	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%.
2090	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2091	ETHYL METHYLPHENYLGLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

			fragrance concentration in a medicine must be no more 1%.
2092	ETHYL METICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
2093	ETHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2094	ETHYL OLEATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2095	ETHYL ORTHO-METHOXYBENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2096	ETHYL OXYHYDRATE	E	Permitted for use only in

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			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2097	ETHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2098	ETHYL PARA-ANISATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2099	ETHYL PELARGONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2100	ETHYL PHENYLACETATE	E	Permitted for use only in

			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2101	ETHYL PHENYLGLYCIDATE	E	Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).
2102	ETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2103	ETHYL PYRUVATE	E	Ethyl pyruvate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing ethyl pyruvate must not be more than 5% of the total medicine.

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2104	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%.
2105	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%.
2106	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%.
2107	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%.
2108	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%.
2109	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%.
2110	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%.
2111	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.
2112	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%.
2113	ETHYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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2114	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%.
2115	ETHYL VANILLIN	E	
2116	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%.
2117	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%.
2118	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%.
2119	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%.

2120	ETHYLCELLULOSE	E	
2121	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%.
2122	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%.
2123	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.
2124	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%.
2125	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%.
2126	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2127	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.

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2128	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 6%.
2129	ETHYLHEXYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
2130	ETHYLHEXYL METHOXYCRYLENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
2131	ETHYLHEXYL TRIAZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

2132	ETHYLHEXYLGLYCERIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2133	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2134	EUCALYPTUS DIVES	A, E, H	Cineole is a mandatory component of Eucalyptus dives. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2135	EUCALYPTUS FRUTICETORUM	A, E, H	Cineole is a mandatory component of Eucalyptus fruticetorum. In liquid preparations when the

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

			concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2137	EUCALYPTUS MACRORHYNCHA	A, E, H	Cineole is a mandatory component of Eucalyptus macrorhyncha. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2138	EUCALYPTUS OIL	A, E, H	Cineole is a mandatory component of Eucalyptus oil. 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. 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: - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’ 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: - (CHILD) ‘Keep out of reach of children’ (or words to that effect) - (NTAKEN) ‘Not to be taken’
2139	EUCALYPTUS RADIATA	A, E, H	Cineole is a mandatory component of Eucalyptus radiata. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect);

			and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2140	EUCALYPTUS ROSTRATA	A, E, H	Cineole is a mandatory component of Eucalyptus rostrata. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2141	EUCALYPTUS TERETICORNIS	A, E, H	Cineole is a mandatory component of Eucalyptus tereticornis. In liquid preparations when the concentration of cineole OR the

			concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2142	EUCOMMIA ULMOIDES	A, H	
2143	EUGENOL	E	When for oral ingestion, eugenol must not comprise more than 0.06% of the formulation. When used in topical medicines for dermal application, the following apply: 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. b) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following

			warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' 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: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2144	EUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2145	EUGLENA GRACILIS WHOLE CELL DRY	A	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 ceases to be a requirement for this ingredient after 1 March 2024. The route of administration for medicines that contain Euglena gracilis whole cell dry must be

			limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 100 mg of Euglena gracilis whole cell dry for children aged between 1 and 3 years (inclusive); (b) 150 mg of Euglena gracilis whole cell dry for children aged between 4 and 8 years (inclusive); (c) 225 mg of Euglena gracilis whole cell dry for individuals aged between 9 and 18 years (inclusive); and (d) 375 mg of Euglena gracilis whole cell dry for adults aged 19 years or older. The following warning statement (or words to the same effect) must be included on the medicine label: - (BABY2) 'Not suitable for infants under the age of twelve months'.
2146	EUONYMUS ATROPURPUREUS	A, H	
2147	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2148	EUPATORIUM FORTUNEI	A, H	
2149	EUPATORIUM JAPONICUM	A, H	
2150	EUPATORIUM PERFOLIATUM	A, H	
2151	EUPATORIUM PURPUREUM	A, H	
2152	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.
2153	EUPHORBIA CYPARISSIAS	A, H	
2154	EUPHORBIA DRY	A, H	
2155	EUPHORBIA HETERODOXA	A, H	
2156	EUPHORBIA HIRTA	A, H	
2157	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%.
2158	EUPHORBIA PEKINENSIS	A, H	
2159	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2160	EUPHORBIA POWDER	A, H	
2161	EUPHORBIA RESINIFERA	A, H	
2162	EUPHORBIA SIEBOLDIANA	A, H	
2163	EUPHRASIA OFFICINALIS	A, H	
2164	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2165	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2166	EURYALE FEROX	A, H	
2167	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’.
2168	EVENING PRIMROSE OIL	A, E, H	
2169	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

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	medicine must be no more than 1%.