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).' 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:

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			- (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	BACILLUS SUBTILIS	A	Only to be used in a medicine where ADM Australia Pty Ltd (Client ID 33326), 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 14 June 2026. The route of administration for medicines that contain Bacillus subtilis must be limited to oral. Only permitted for use in medicines when the strain of Bacillus subtilis is confirmed to be Agricultural Research Service Culture Collection (NRRL) accession number B-67989. The strain of Bacillus subtilis must be declared on the label. Bacillus subtilis is not permitted for use in children under the age of 2 years. The maximum recommended daily dose of the medicine must not provide more than: (a) 1 billion cfu Bacillus subtilis in individuals aged 2 to 17 years (inclusive); and (b) 5 billion cfu Bacillus subtilis in individuals aged 18 years and above. The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women';

Authorised Version F2024L01196 registered 23/09/2024

			- (ANTIBI1) ‘To be administered 2-3 hours before or after antibiotics’; and - (IMMUNO2) ‘May not be suitable for someone taking immunomodulators. Consult your health professional before taking with other medicines’.
753	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).
754	BACOPA MONNIERI	A, H	
755	BALLOTA NIGRA	A, H	
756	BALM OF GILEAD BUD DRY	A, H	
757	BALM OF GILEAD BUD POWDER	A, H	
758	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%.
759	BAMBUSA BREVIFLORA	A, E, H	
760	BAMBUSA TEXTILIS	A, H	
761	BANANA	E	
762	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

763	BAPTISIA CONFUSA	A, H	
764	BAPTISIA TINCTORIA	A, H	
765	BARBAREA VULGARIS	A, H	
766	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
767	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
768	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
769	BARLEY	E	Gluten is a mandatory component of Barley when the route of administration is other than topical and mucosal.
770	BARLEY LEAF	E	
771	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
772	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
773	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%.
774	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%.
775	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

Authorised Version F2024L01196 registered 23/09/2024

			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	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).
777	BASSIA SCOPARIA	A, H	
778	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
779	BAY LEAF	E	
780	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.
781	BEESWAX ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
782	BEESWAX ALCOHOLS	A	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: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (CHILD2) 'Not suitable for children'.
783	BEET RED	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
784	BEETROOT	E, H	
785	BEGONIA FIMBRISTIPULA	A, H	
786	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.
787	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
788	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
789	BEHENOYL STEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included

Authorised Version F2024L01196 registered 23/09/2024

			in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%.
790	BEHENTRIMONIUM METILSULFATE	E	Behentrimonium metilsulfate must: (a) Only be used in topical medicines for dermal application; and (b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must not be more than 1.06%.
791	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
792	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%.
793	BELLADONNA HERB POWDER	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb powder. The concentration of alkaloids calculated as hyoscyamine in the medicine must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropinei n the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
794	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.

Authorised Version F2024L01196 registered 23/09/2024

			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%.
795	BELLIS PERENNIS	A, H	
796	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).
797	BENINCASA HISPIDA	A, E, H	
798	BENTONITE	E	
799	BENZALDEHYDE	E	
800	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%.
801	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%.

Authorised Version F2024L01196 registered 23/09/2024

			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).
802	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.
803	BENZOIC ACID	E, H	
804	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%.
805	BENZOIN SIAM	A, E, H	
806	BENZOIN SUMATRA	A, E, H	
807	BENZOPHENONE	E	Permitted for topical use only in combination with other permitted ingredients as a fragrance. The total concentration of fragrance proprietary excipient formulations containing benzophenone must not be more than 1% of the total medicine.
808	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.
809	BENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
810	BENZYL 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%.
811	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).
812	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application.
813	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%.
814	BENZYL CINNAMATE	E	Only for use in: (a) topical medicines for dermal application when the concentration of benzyl cinnamate in the medicine is not greater than 0.15%; or (b) medicines in combination with other permitted ingredients as a constituent of a flavour proprietary excipient

Authorised Version F2024L01196 registered 23/09/2024

			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.
815	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%.
816	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%.
817	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%.
818	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%.
819	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
820	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%.
821	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%.
822	BENZYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
823	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%.
824	BENZYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.

Authorised Version F2024L01196 registered 23/09/2024

			The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
825	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%.
826	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).
827	BERBERIS AQUIFOLIUM	A, H	
828	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).
829	BERBERIS VULGARIS	A, E, H	
830	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The medicine requires the following warning statement on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
831	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%.
832	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.
833	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%.
834	BERTHOLLETIA EXCELSA	A, E, H	
835	BETA RAPA	A, E, H	
836	BETA VULGARIS	A, E, H	

Authorised Version F2024L01196 registered 23/09/2024

837	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%.
838	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%.
839	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%.
840	BETA-DAMASCENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
841	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

842	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%.
843	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
844	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%.
845	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%.
846	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%.
847	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%.
848	BETA-N-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a 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-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%.
850	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%.
851	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%.
852	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

853	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%.
854	BETA-TOCOPHEROL	E	
855	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.'
856	BETADEX	E	
857	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%.
858	BETAINE	E	Only for use in topical medicines for dermal application.
859	BETAINE HYDROCHLORIDE	E	
860	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 packaging.

Authorised Version F2024L01196 registered 23/09/2024

			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'.
861	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

Authorised Version F2024L01196 registered 23/09/2024

			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%. 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:

Authorised Version F2024L01196 registered 23/09/2024

			- (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'.
862	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;

Authorised Version F2024L01196 registered 23/09/2024

			- 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'.
863	BETULA PUBESCENS	A, E, H	
864	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%.
865	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
866	BIFIDOBACTERIUM ADOLESCENTIS	A	
867	BIFIDOBACTERIUM ANIMALIS	A	
868	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
869	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
870	BIFIDOBACTERIUM BIFIDUM	A	
871	BIFIDOBACTERIUM BREVE	A	
872	BIFIDOBACTERIUM INFANTIS	A	
873	BIFIDOBACTERIUM LACTIS	A	
874	BIFIDOBACTERIUM LONGUM	A	
875	BILBERRY	E	
876	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%.
877	BIOTA ORIENTALIS	A, H	
878	BIOTIN	A, E	
879	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;

Authorised Version F2024L01196 registered 23/09/2024

			- 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'.
880	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%.
881	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.

Authorised Version F2024L01196 registered 23/09/2024

			The concentration in the medicine must be no more than 1.5%.
882	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
883	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%.
884	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%.
885	BIS-PEG-12 DIMETHICONE BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
886	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%.
887	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%.
888	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

889	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
890	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.
891	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

Authorised Version F2024L01196 registered 23/09/2024

			in infants younger than 12 months of age.
892	BIXA ORELLANA	A, E, H	
893	BLACK BONED CHICKEN POWDER	A	
894	BLACK COHOSH DRY	A, H	The medicine requires the following warning statement on the medicine label: - (BCOHOSH) 'Warning: In very rare cases - black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes - dark urine - nausea - vomiting - unusual tiredness - weakness - stomach or abdominal pain - and/or loss of appetite - you should stop using this product and see your doctor.'
895	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.'
896	BLACK CURRANT	E	
897	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%.
898	BLACK CURRANT FRESH	A, E, H	
899	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

900	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
901	BLACK PEPPER OIL	A, E, H	
902	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%.
903	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
904	BLACKBERRY	E	
905	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%.
906	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%.
907	BLACKCURRANT ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
908	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%.

Authorised Version F2024L01196 registered 23/09/2024

909	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, sucrose is a mandatory component of blackstrap molasses.
910	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.
911	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.
912	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%.
913	BLETILLA STRIATA	A, H	
914	BLUE FLAG RHIZOME DRY	A, H	
915	BLUE FLAG RHIZOME POWDER	A, H	
916	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%.
917	BLUEBERRY JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour or fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a flavour the total flavour concentration in 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%.
918	BLUMEA LACERA	A, H	
919	BOEHMERIA NIVEA	A, H	
920	BOERHAVIA DIFFUSA	A, H	
921	BOERHAVIA REPENS	A, H	
922	BOGBEAN LEAF DRY	A, H	
923	BOGBEAN LEAF POWDER	A, H	
924	BOIS DE ROSE OIL	A, E, H	
925	BOMBAX CEIBA	A, H	
926	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.
927	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

Authorised Version F2024L01196 registered 23/09/2024

			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).
928	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

Authorised Version F2024L01196 registered 23/09/2024

			- (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).
929	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:

Authorised Version F2024L01196 registered 23/09/2024

			- (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).
930	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%.
931	BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
932	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%.
933	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%.
934	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%.
935	BOSWELLIA CARTERII	A, E, H	
936	BOSWELLIA SERRATA	A, E, H	
937	BOSWELLIA THURIFERA	A, H	
938	BOVINE CALCIUM CHONDROITIN SULFATE	A	
939	BOVINE CHONDROITIN SULFATE	A	
940	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).
941	BOVINE LACTOFERRIN	A	
942	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
943	BOVINE SODIUM CHONDROITIN SULFATE	A, E	When used as an excipient: - only for use in topical medicines for dermal application;

Authorised Version F2024L01196 registered 23/09/2024

			- 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%.
944	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).
945	BRANDY	E	
946	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%.
947	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%.
948	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%.
949	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

950	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%.
951	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%.
952	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%.
953	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%.
954	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%.
955	BRASSICA OLERACEA VAR. VIRIDIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. viridis when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.

Authorised Version F2024L01196 registered 23/09/2024

956	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%.
957	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%.
958	BRILLIANT BLACK BN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
959	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
960	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
961	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
962	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
963	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
964	BRIZA MEDIA	A, H	
965	BROCCOLI	E	
966	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (Ananas comosus).
967	BROMOSTYROL	E	Not for use in infants Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
968	BROMUS CATHARTICUS	A, H	
969	BROMUS INERMIS	A, H	
970	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
971	BRONOPOL	E	Only for use in topical medicines for dermal application.
972	BROUSSONETIA PAPYRIFERA	A, H	
973	BROWN FK	E	Permitted for use only as a colour for topical use.
974	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
975	BRUSSEL SPROUT	E	
976	BRYONIA ALBA	A, H	
977	BRYONIA DIOICA	A, H	
978	BUCHU LEAF DRY	A, H	
979	BUCHU LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
980	BUCHU LEAF POWDER	A, E, H	
981	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
982	BUDDLEJA OFFICINALIS	A, H	
983	BULNESIA SARMIENTI	A, E, H	
984	BUNIAS ORIENTALIS	A, H	
985	BUPLEURUM FALCATUM	A, H	
986	BURDOCK LEAF DRY	A, H	
987	BURDOCK LEAF POWDER	A, H	
988	BURDOCK ROOT DRY	A, H	

Authorised Version F2024L01196 registered 23/09/2024

989	BURDOCK ROOT POWDER	A, H	
990	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
991	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%.
992	BUTANE	E	Only for use as an excipient propellant ingredient.
993	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%.
994	BUTTER	E	
995	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%.
996	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%.
997	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%.
998	BUTYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
999	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%.
1000	BUTYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1001	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%.
1002	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%.
1003	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)

Authorised Version F2024L01196 registered 23/09/2024

			- (EYE2) 'May be irritant to the eyes' (or words to that effect).
1004	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%.
1005	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application.
1006	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%.
1007	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%.
1008	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%.
1009	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%.
1010	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.

Authorised Version F2024L01196 registered 23/09/2024

			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).
1011	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%.
1012	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
1013	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%.
1014	BUTYLATED HYDROXYANISOLE	E	
1015	BUTYLATED HYDROXYTOLUENE	E	
1016	BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1017	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%.

Authorised Version F2024L01196 registered 23/09/2024

1018	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%.
1019	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%.
1020	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%.
1021	BUTYRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1022	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%.
1023	C10-12 ALKANE/CYCLOALKANE	E	Only permitted for use in solid or semi-solid medicines or in medicines: (a) containing 25% or less of hydrocarbons, liquid; or (b) when packed in pressurised spray packs; or (c) when packed in containers with a capacity of 2 millilitres or less.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must not be more than 1%.
1024	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.
1025	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%.
1026	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%.
1027	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.
1028	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.
1029	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.

Authorised Version F2024L01196 registered 23/09/2024

			The concentration in the medicine must be no more than 1.2%.
1030	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1031	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%.
1032	C12-20 ALKYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.75%.
1033	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%.
1034	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1035	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%.
1036	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

Authorised Version F2024L01196 registered 23/09/2024

			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%.
1037	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%.
1038	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%.
1039	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1040	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1041	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%.
1042	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1043	C20-40 ALKYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Authorised Version F2024L01196 registered 23/09/2024

			The concentration in the medicine must be no more than 2%.
1044	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%.
1045	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%.
1046	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%.
1047	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1048	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1049	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%
1050	CABBAGE	E	
1051	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%.
1052	CADE OIL	A, E, H	
1053	CAESALPINIA SAPPAN	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1054	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

Authorised Version F2024L01196 registered 23/09/2024

			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).
1055	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)

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			- (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 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'.
1056	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.
1057	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.

Authorised Version F2024L01196 registered 23/09/2024

			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'.
1058	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).
1059	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1060	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1061	CALCIUM ALGINATE	E	
1062	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.

Authorised Version F2024L01196 registered 23/09/2024

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

Volume 2

1063	CALCIUM ASCORBATE	A, E, H	
1064	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1065	CALCIUM ASPARTATE	A	
1066	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1067	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.
1068	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1069	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1070	CALCIUM CARBONATE	A, E, H	
1071	CALCIUM CASEINATE	E	
1072	CALCIUM CHLORIDE DIHYDRATE	E	
1073	CALCIUM CITRATE	A, E, H	
1074	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1075	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1076	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%.
1077	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.

Authorised Version F2024L01196 registered 23/09/2024

1078	CALCIUM FRUCTOBORATE TETRAHYDRATE	A	Only to be used in a medicine where VDF FutureCeuticals Inc (Client ID 62256), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 25 October 2025. Boron is a mandatory component of calcium fructoborate tetrahydrate. The percentage of boron from calcium fructoborate tetrahydrate should be calculated based on the molecular weight of calcium fructoborate tetrahydrate. The route of administration for medicines that contain calcium fructoborate tetrahydrate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 220 mg of calcium fructoborate tetrahydrate; and (b) 6 mg of boron. The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) ‘Adults only'.
1079	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1080	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1081	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1082	CALCIUM GLYCINATE DIHYDRATE	A	
1083	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1084	CALCIUM HYDROGEN PHOSPHATE	A, E, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

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

Authorised Version F2024L01196 registered 23/09/2024

1104	CALCIUM SACCHARATE	E	
1105	CALCIUM SILICATE	E	
1106	CALCIUM SODIUM CASEINATE	A, H	
1107	CALCIUM SODIUM LACTATE	A, E, H	
1108	CALCIUM STEARATE	E	
1109	CALCIUM SUCCINATE	A, E, H	
1110	CALCIUM SULFATE	A, E, H	
1111	CALCIUM SULFATE DIHYDRATE	A, E, H	
1112	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1113	CALCIUM THREONINATE	A	
1114	CALENDULA FLOWER DRY	A, E, H	
1115	CALENDULA FLOWER POWDER	A, H	
1116	CALENDULA OFFICINALIS	A, E, H	
1117	CALLERYA RETICULATA	A, H	
1118	CALLICARPA PEDUNCULATA	A, H	
1119	CALLISTEPHUS CHINENSIS	A, H	
1120	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%.
1121	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%.
1122	CALLITRIS RHOMBOIDEA	A, H	
1123	CALLUNA VULGARIS	A, E, H	
1124	CALOCHORTUS TOLMIEI	A, H	
1125	CALTHA PALUSTRIS	A, H	
1126	CALUMBA ROOT DRY	A, H	
1127	CALUMBA ROOT POWDER	A, H	
1128	CALVATIA GIGANTEA	A, E, H	
1129	CALYCANTHUS FLORIDUS	A, H	
1130	CALYCANTHUS PRAECOX	A, H	
1131	CAMELLIA JAPONICA	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1132	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.
1133	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 medicine is for internal use or oral

Authorised Version F2024L01196 registered 23/09/2024

			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). The requirements specified in paragraphs (a) to (b) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines, the following warning statements are required on the medicine label: (i) 'In rare cases, Camellia sinensis may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes, or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'; and (ii) (FOOD) ‘To be taken with food.’ unless when: (A) the preparation of Camellia sinensis is derived from an aqueous extract and contains 300 mg or less epigallocatechin-3-gallate per maximum recommended daily dose; or (B) Camellia sinensis is used in combination with other permitted ingredients as a flavour proprietary excipient formulation. (b) The total concentration of flavour proprietary excipient formulations containing Camellia sinensis must not be more than 5% of the total medicine.
1134	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1135	CAMPHOLENIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
1136	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%.
1137	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).
1138	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 not be more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must not be 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

Authorised Version F2024L01196 registered 23/09/2024

			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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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

Authorised Version F2024L01196 registered 23/09/2024

			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 not 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 the concentration of safrole in a medicine must not be more than 0.1%. When for topical use the concentration of safrole in a medicine must not be more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must not be more than 25 millilitres.
1139	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 not be more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must not be 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:

Authorised Version F2024L01196 registered 23/09/2024

			- (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). 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); - (NTAKEN) 'Not to be taken'; and - (BABY4) ‘Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist’ (or words to that effect). When for internal use the concentration of safrole in a medicine must not be more than 0.1%. When for topical use the concentration of safrole in a medicine must not be more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the

Authorised Version F2024L01196 registered 23/09/2024

			container must not be more than 25 millilitres.
1140	CAMPSIS GRANDIFLORA	A, H	
1141	CANADA BALSAM	A, H	
1142	CANANGA ODORATA	A, E, H	
1143	CANANGA OIL	A, E, H	
1144	CANARIUM INDICUM	A, H	Only for use when the plant part is seed and the plant preparation is oil.
1145	CANARIUM LUZONICUM	A, H	
1146	CANDELILLA WAX	A, E, H	
1147	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1148	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%.
1149	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1150	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%.
1151	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1152	CANTHAXANTHIN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1153	CAPRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1154	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%.
1155	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%.
1156	CAPRYLIC/CAPRIC/ISOSTEARIC/ADIPIC TRIGLYCERIDE	E	
1157	CAPRYLIC/CAPRIC/MYRISTIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3%
1158	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1159	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1160	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%
1161	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%.
1162	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%
1163	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%.
1164	CAPSELLA BURSA-PASTORIS	A, H	
1165	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1166	CAPSICUM ANNUUM	A, E, H	
1167	CAPSICUM DRY	A, E, H	
1168	CAPSICUM FRUIT OLEORESIN	A, E	
1169	CAPSICUM FRUTESCENS	A, E, H	
1170	CAPSICUM POWDER	A, E, H	
1171	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1172	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1173	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha.

Authorised Version F2024L01196 registered 23/09/2024

			The concentration of emetine in the medicine must not be more than 0.2%.
1174	CARAWAY DRY	A, H	
1175	CARAWAY OIL	A, E, H	
1176	CARAWAY POWDER	A, H	
1177	CARBOMER 1342	E	Only for use as an excipient in topical medicines for dermal application.
1178	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.
1179	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1180	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1181	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1182	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1183	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1184	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal application.
1185	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1186	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1187	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1188	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%.
1189	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1190	CARBON BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1191	CARBON DIOXIDE	E	
1192	CARDAMOM FRUIT DRY	A, H	
1193	CARDAMOM FRUIT POWDER	A, E, H	
1194	CARDAMOM OIL	A, E, H	
1195	CARDIOSPERMUM HALICACABUM	A, H	
1196	CARICA PAPAYA	A, E, H	
1197	CARLINA ACAULIS	A, H	
1198	CARMELLOSE	E	
1199	CARMELLOSE CALCIUM	E	
1200	CARMELLOSE SODIUM	E	
1201	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1202	CARMOISINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1203	CARMOISINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1204	CARNAUBA WAX	A, E, H	
1205	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%.

Authorised Version F2024L01196 registered 23/09/2024

1206	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%.
1207	CAROB GUM	E	
1208	CAROB POD	E	
1209	CAROTENES	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1210	CARPINUS BETULUS	A, H	
1211	CARPINUS CORDATA	A, H	
1212	CARRAGEENAN	E	
1213	CARROT	E	
1214	CARROT SEED OIL	A, E, H	
1215	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).
1216	CARUM CARVI	A, H	
1217	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%.
1218	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1219	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%.
1220	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%.
1221	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%.
1222	CARYA ILLINOINENSIS	A, H	
1223	CARYA OVATA	A, H	
1224	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%.
1225	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral.

Authorised Version F2024L01196 registered 23/09/2024

			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’.
1226	CASCARA POWDER	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a

Authorised Version F2024L01196 registered 23/09/2024

			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’.

Authorised Version F2024L01196 registered 23/09/2024

1227	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.
1228	CASEIN	E	
1229	CASHEW NUT	E	
1230	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%.
1231	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%.
1232	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.
1233	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’;

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			- (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

Authorised Version F2024L01196 registered 23/09/2024

			(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.
1234	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%.
1235	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%.
1236	CASTANEA MOLLISSIMA	A, H	
1237	CASTANEA SATIVA	A, H	
1238	CASTOR OIL	A, E	
1239	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1240	CASUARINA EQUISITIFOLIA	A, H	
1241	CATALPA BIGNONIOIDES	A, H	
1242	CATALPA OVATA	A, H	
1243	CATECHU	A, H	
1244	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

Authorised Version F2024L01196 registered 23/09/2024

			medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1245	CAULIFLOWER	E	
1246	CAULOPHYLLUM THALICTROIDES	A, E, H	
1247	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1248	CEANOTHUS AMERICANUS	A, H	
1249	CEDAR LEAF OIL	A, E, H	
1250	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%.
1251	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%.
1252	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%.
1253	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%.

Authorised Version F2024L01196 registered 23/09/2024

1254	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%.
1255	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%.
1256	CEDRUS ATLANTICA	A, E, H	
1257	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%.
1258	CEDRUS DEODARA	A, H	
1259	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1260	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%.
1261	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%.
1262	CELERY SEED DRY	A, E, H	
1263	CELERY SEED OIL	A, E, H	
1264	CELERY SEED POWDER	A, H	
1265	CELLACEFATE	E	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1266	CELLULASE	A	Must be derived from Trichoderma longibrachiatum only.
1267	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%.
1268	CELOSIA ARGENTEA	A, H	
1269	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1270	CENTAUREA CYANUS	A, E, H	
1271	CENTAURIUM ERYTHRAEA	A, H	
1272	CENTELLA ASIATICA	A, E, H	
1273	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%.
1274	CENTIPEDA CUNNINGHAMII	A, E, H	
1275	CENTIPEDA MINIMA	A, H	
1276	CEPHALANOPSIS SEGETUM	A, H	
1277	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1278	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%.
1279	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1280	CERAMIDE 6 II	E	Ceramide 6 II must: (a) Only be used in topical medicines for dermal application; and

Authorised Version F2024L01196 registered 23/09/2024

			(b) Not be included in medicines intended for use on broken skin or in the eye. The concentration in the medicine must be no more than 0.011%.
1281	CERATONIA SILIQUA	A, E, H	
1282	CERATOSTIGMA WILLMOTTIANUM	A, H	
1283	CERESIN	E	Only for use in topical medicines for dermal application.
1284	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%.
1285	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1286	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1287	CETEARETH-20	E	Only for use in topical medicines for dermal application.
1288	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1289	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1290	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1291	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1292	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1293	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%.
1294	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1295	CETETH-10	E	Only for use in topical medicines for dermal application.
1296	CETETH-2	E	Only for use in topical medicines for dermal application.
1297	CETETH-24	E	Only for use in topical medicines for dermal application.
1298	CETETH-5	E	Only for use in topical medicines for dermal application.
1299	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1300	CETOMACROGOL 1000 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1301	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%.

Authorised Version F2024L01196 registered 23/09/2024

1302	CETOSTEARYL ALCOHOL	E	
1303	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 %
1304	CETRARIA ISLANDICA	A, H	
1305	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1306	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1307	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1308	CETYL ALCOHOL	E	Only for use in topical medicines for dermal application.
1309	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1310	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1311	CETYL DIMETICONE/BIS-VINYLDIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
1312	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1313	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%.
1314	CETYL LACTATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1315	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1316	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1317	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1318	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%.
1319	CETYLPYRIDINIUM CHLORIDE	A, E	Only permitted for use in medicines containing 5% or less of quaternary ammonium compounds. When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient: (a) permitted for use only in medicated throat lozenges; (b) the medicine must not contain more than 2 milligrams of cetylpyridinium chloride per lozenge; (c) the maximum recommended daily dose of the medicine must not provide more than 24 milligrams of cetylpyridinium chloride; and (d) the medicine label must specify that the medicine is only to be used for 7 days (or less).
1320	CHAENOMELES LAGENARIA	A, H	
1321	CHAENOMELES SPECIOSA	A, H	
1322	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.

Authorised Version F2024L01196 registered 23/09/2024

1323	CHAMAECYPARIS LAWSONIANA	A, H	
1324	CHAMAELIRIUM LUTEUM	A, H	
1325	CHAMAEMELUM NOBILE	A, E, H	
1326	CHAMOMILE FLOWER DRY	A, E, H	
1327	CHAMOMILE OIL ENGLISH	A, E, H	
1328	CHAMOMILE OIL GERMAN	A, E, H	
1329	CHANGIUM SMYRNIOIDES	A, H	
1330	CHEIRANTHUS CHEIRI	A, H	
1331	CHELIDONIUM MAJUS	A, E, H	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.'
1332	CHELONE GLABRA	A, H	
1333	CHENOPODIUM ALBUM	A, H	
1334	CHENOPODIUM VULVARIA	A, H	
1335	CHERRY	E	
1336	CHERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1337	CHESTNUT SWEET	E, H	
1338	CHICKEN COMB EXTRACT	A	
1339	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.

Authorised Version F2024L01196 registered 23/09/2024

			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'.
1340	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%.
1341	CHIONANTHUS VIRGINICA	A, H	
1342	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.
1343	CHLORELLA PYRENOIDOSA	E	
1344	CHLORELLA VULGARIS	A, E	Iodine is a mandatory component of Chlorella vulgaris. Only for external use when the concentration of iodine in the medicine

Authorised Version F2024L01196 registered 23/09/2024

			(excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1345	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1346	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1347	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1348	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1349	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%.
1350	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1351	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1352	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.
1353	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1354	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1355	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1356	CHOCOLATE BROWN HT	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1357	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1358	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1359	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1360	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%.
1361	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1362	CHOLINE BITARTRATE	A, E	
1363	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1364	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%.
1365	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.
1366	CHONDRUS DRY	A, E, H	Iodine is a mandatory component of Chondrus dry.

Authorised Version F2024L01196 registered 23/09/2024

			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.
1367	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.
1368	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).
1369	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.
1370	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate. The maximum recommended daily dose must not provide more than 50

Authorised Version F2024L01196 registered 23/09/2024

			micrograms of chromium from organic sources. Chromium picolinate is considered to be an organic form of chromium.
1371	CHRYSANTHEMUM BALSAMITA	A, H	
1372	CHRYSANTHEMUM INDICUM	A, H	
1373	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1374	CHRYSANTHEMUM SINENSE	A, H	
1375	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1376	CHRYSOSPORIUM PRUINOSUM	A, H	
1377	CIBOTIUM BAROMETZ	A, H	
1378	CICHORIUM INTYBUS	A, E, H	
1379	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1380	CINCHONA BARK DRY	A, H	Quinidine and quinine are mandatory components of Cinchona bark dry. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1381	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.
1382	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.
1383	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.

Authorised Version F2024L01196 registered 23/09/2024

1384	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.
1385	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%.
1386	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%.
1387	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			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'.

Authorised Version F2024L01196 registered 23/09/2024

			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%.
1388	CINNAMOMUM CASSIA	A, E	Cassia oil is a mandatory component of Cinnamomum 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%.
1389	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 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.
1390	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%.
1391	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%.
1392	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.

Authorised Version F2024L01196 registered 23/09/2024

			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%.
1393	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%.
1394	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%.
1395	CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1396	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.
1397	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%.
1398	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%.
1399	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%.
1400	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%.
1401	CINNAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1402	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).
1403	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%.
1404	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.
1405	CIS-3-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1406	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%.
1407	CIS-3-HEXENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1408	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%.
1409	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%.
1410	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%.

Authorised Version F2024L01196 registered 23/09/2024

1411	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%.
1412	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%.
1413	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.
1414	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%.
1415	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%.
1416	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%.
1417	CIS-3-HEXENYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part

Authorised Version F2024L01196 registered 23/09/2024

			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%.
1418	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%.
1419	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%.
1420	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%.
1421	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%.
1422	CIS-HEXAHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1423	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%.
1424	CISTANCHE DESERTICOLA	A, H	
1425	CISTANCHE SALSA	A, H	
1426	CISTUS LADANIFER	A, E, H	
1427	CITRAL	E	
1428	CITRAL DIETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1429	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%.
1430	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)

Authorised Version F2024L01196 registered 23/09/2024

			- (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'
1431	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'
1432	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.'

Authorised Version F2024L01196 registered 23/09/2024

			- (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.'
1433	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%.
1434	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%.
1435	CITRON	E	
1436	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'.
1437	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%.
1438	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%.
1439	CITRONELLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a 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	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%.
1441	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%.
1442	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%.
1443	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%.

Authorised Version F2024L01196 registered 23/09/2024

1444	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%.
1445	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%.
1446	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%.
1447	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%.
1448	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%.
1449	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1450	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.
1451	CITRULLUS VULGARIS	A, H	
1452	CITRUS AURANTIFOLIA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.5% or less of citrus aurantifolia oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1453	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.
1454	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1455	CITRUS CHACHIENSIS	A, H	
1456	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%.

Authorised Version F2024L01196 registered 23/09/2024

1457	CITRUS FIBRE	E	
1458	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.
1459	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.
1460	CITRUS MAXIMA	A, H	
1461	CITRUS MEDICA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus medica oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1462	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%.
1463	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.
1464	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.
1465	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.
1466	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%.
1467	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.
1468	CITRUS X PARADISI	A, E, H	

Authorised Version F2024L01196 registered 23/09/2024

1469	CITRUS X WILSONII	A, H	
1470	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%.
1471	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%.
1472	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%.
1473	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%.
1474	CLARY OIL	A, E, H	
1475	CLEMATIS ARMANDII	A, H	
1476	CLEMATIS CHINENSIS	A, E, H	
1477	CLEMATIS RECTA	A, H	
1478	CLEMATIS VITALBA	A, H	
1479	CLERODENDRUM TRICHOTOMUM	A, H	
1480	CLINOPODION POLYCEPHALUM	A, H	
1481	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1482	CLIVER HERB DRY	A, H	
1483	CLIVER HERB POWDER	A, H	
1484	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%:

Authorised Version F2024L01196 registered 23/09/2024

			(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.
1485	CLOVE DRY	A, E, H	
1486	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.
1487	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%.
1488	CLOVE POWDER	A, E, H	
1489	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%:

Authorised Version F2024L01196 registered 23/09/2024

			(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.
1490	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.
1491	CNICUS BENEDICTUS	A, H	
1492	CNICUS JAPONICUS	A, H	
1493	CNIDIUM MONNIERI	A, H	
1494	CNIDIUM OFFICINALE	A, H	
1495	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1496	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.
1497	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1498	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%.
1499	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.

Authorised Version F2024L01196 registered 23/09/2024

			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.
1500	COCCOLOBIA UVIFERA	A, H	
1501	COCCULUS ORBICULATUS	A, H	
1502	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1503	COCHLEARIA OFFICINALIS	A, H	
1504	COCILLANA DRY	A, H	
1505	COCILLANA POWDER	A, H	
1506	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1507	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.
1508	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%
1509	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.
1510	COCOA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1511	COCOA POWDER	A, E, H	
1512	COCOGLYCERIDES	E	
1513	COCONUT	E	
1514	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1515	COCONUT OIL	A, E, H	
1516	COCOS NUCIFERA	A, E, H	
1517	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1518	CODONOPSIS LANCEOLATA	A, H	
1519	CODONOPSIS PILOSULA	A, H	
1520	CODONOPSIS TANGSHEN	A, H	
1521	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

Authorised Version F2024L01196 registered 23/09/2024

			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).
1522	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.'

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			- (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).
1523	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).

Authorised Version F2024L01196 registered 23/09/2024

			- (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).
1524	COFFEE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1525	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%.
1526	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%.
1527	COGNAC OIL GREEN	A, E, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1528	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%.
1529	COIX LACHRYMA-JOBI	A, H	
1530	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.’

Authorised Version F2024L01196 registered 23/09/2024

			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).
1531	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

Authorised Version F2024L01196 registered 23/09/2024

			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).
1532	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%.
1533	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1534	COLLAGEN	E	
1535	COLLINSONIA CANADENSIS	A, H	
1536	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1537	COLOPHONY	A, E, H	
1538	COMMIPHORA HABESSINICA	A, H	
1539	COMMIPHORA KATAF	A, H	
1540	COMMIPHORA MYRRHA	A, E, H	
1541	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1542	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.

Authorised Version F2024L01196 registered 23/09/2024

1543	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’.
1544	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).
1545	CONIFER PHYTOSTEROL COMPLEX	A	
1546	CONIOSELINUM TATARICUM	A, H	
1547	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.
1548	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%.
1549	CONYZA CANADENSIS	A, H	
1550	COPAIBA OIL	A, E, H	
1551	COPAIFERA LANGSDORFFII	A, E, H	
1552	COPERNICIA CERIFERA	A, E, H	
1553	COPOVIDONE	E	
1554	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1555	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.
1556	COPPER (II) GLYCINATE	A, H	Copper is a mandatory component of copper (II) glycinate. The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1557	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.
1558	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1559	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%.
1560	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.

Authorised Version F2024L01196 registered 23/09/2024

1561	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%.
1562	COPPER TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1563	COPTIS CHINENSIS	A, H	
1564	COPTIS JAPONICA	A, H	
1565	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%.
1566	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1567	CORIANDER DRY	A, H	
1568	CORIANDER OIL	A, E, H	
1569	CORIANDER POWDER	A, H	
1570	CORIANDRUM SATIVUM	A, E, H	
1571	CORMUS DOMESTICA	A, H	
1572	CORN GLYCERIDES	E	
1573	CORN SILK DRY	A, H	
1574	CORN SILK POWDER	A, H	
1575	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1576	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%.
1577	CORNUS FLORIDA	A, H	
1578	CORNUS OFFICINALIS	A, H	
1579	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1580	CORYDALIS AMBIGUA	A, E, H	
1581	CORYDALIS BUNGEANA	A, H	
1582	CORYDALIS CAVA	A, H	
1583	CORYDALIS FABACEA	A, H	
1584	CORYDALIS FORMOSA	A, H	
1585	CORYDALIS TURTSCHANINOVII	A, H	
1586	CORYLUS AMERICANA	A, H	
1587	CORYLUS AVELLANA	A, H	
1588	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.

Authorised Version F2024L01196 registered 23/09/2024

1589	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.
1590	COSMOS BIPINNATUS	A, H	
1591	COSTUS ROOT OIL	A, H	
1592	COSTUS SPICATUS	A, H	
1593	COTTONSEED OIL	A, E, H	
1594	COUCH GRASS RHIZOME DRY	A, H	
1595	COUCH GRASS RHIZOME POWDER	A, H	
1596	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; and (b) the label of the medicine must specify that the product should only be used by adults.
1597	CRANBERRY	E	
1598	CRATAEGUS CUNEATA	A, E, H	
1599	CRATAEGUS GERMANICA	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1600	CRATAEGUS LAEVIGATA	A, E, H	
1601	CRATAEGUS MONOGYNA	A, E, H	
1602	CRATAEGUS PINNATIFIDA	A, E, H	
1603	CRATEVA MAGNA	A, E, H	
1604	CREATINE	A, E	
1605	CREATINE MONOHYDRATE	A, E	
1606	CREATINE PHOSPHATE	A, E	
1607	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%.
1608	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%.
1609	CREOSOTE	H	Only for use as an active homoeopathic ingredient. Creosote must not be derived from coal or beechwood.
1610	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%.
1611	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%.
1612	CROCUS SATIVUS	A, E, H	When Crocus sativus is used as an excipient:

Authorised Version F2024L01196 registered 23/09/2024

			(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.
1613	CROSCARMELLOSE SODIUM	E	
1614	CROSPOVIDONE	E	
1615	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1616	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1617	CRYPTOMERIA JAPONICA	A, H	
1618	CUBEB OIL	A, H	
1619	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%.
1620	CUCUMBER	E	
1621	CUCUMIS MELO	A, H	
1622	CUCUMIS SATIVUS	A, E, H	
1623	CUCURBITA MAXIMA	A, E, H	
1624	CUCURBITA MOSCHATA	A, H	
1625	CUCURBITA PEPO	A, E, H	
1626	CULLEN CORYLIFOLIUM	A, H	
1627	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1628	CUMIN OIL	A, E, H	
1629	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%.
1630	CUMINUM CYMINUM	A, H	
1631	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%.
1632	CUPRESSUS ARIZONICA	A, H	
1633	CUPRESSUS FUNEBRIS	A, E, H	
1634	CUPRESSUS SEMPERVIRENS	A, E, H	
1635	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1636	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1637	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.
1638	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate.

Authorised Version F2024L01196 registered 23/09/2024

			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.
1639	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%.
1640	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%.
1641	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			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.
1642	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.
1643	CURCULIGO ORCHIOIDES	A, H	
1644	CURCUMA AROMATICA	A, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.'

Authorised Version F2024L01196 registered 23/09/2024

			(b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than: (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years.
1645	CURCUMA LONGA	A, E, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' (b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than: (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years.
1646	CURCUMA ZANTHORRHIZA	A, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is:

Authorised Version F2024L01196 registered 23/09/2024

			- listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' (b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than: (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years.
1647	CURCUMA ZEDOARIA	A, H	The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' (b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than:

Authorised Version F2024L01196 registered 23/09/2024

			(i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years.
1648	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines. The requirements specified in paragraphs (a) to (c) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2024; or - released for supply on or after 1 March 2025. (a) When used in oral medicines as an active ingredient, the following warning statement is required on the medicine label: 'In very rare cases, curcumin may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' (b) When used in oral medicines the maximum daily dose of (1E,6E)-1,7-bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione in the medicine must not provide more than: (i) 36 mg for children from 2-3 years (inclusive); (ii) 48 mg for children from 4-11 years (inclusive); and (iii) 123 mg for children from 12-17 years (inclusive). (c) Not permitted for use in children aged below 2 years.
1649	CUSCUTA EPITHYMUM	A, H	
1650	CUSCUTA EUROPAEA	A, H	
1651	CUSCUTA HYGROPHILAE	A, H	
1652	CUSCUTA RACEMOSA	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1653	CUSPARIA FEBRIFUGA	A, H	
1654	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1655	CYANOCOBALAMIN	A, E, H	
1656	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%.
1657	CYATHULA OFFICINALIS	A, H	
1658	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1659	CYCLAMEN PURPURASCENS	A, H	
1660	CYCLOCARYA PALIURUS LEAF EXTRACT DRY	A	Only to be used in a medicine where Infinitus (China) Company Ltd (Client ID 81208), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 25 October 2025. The route of administration for medicines that contain Cyclocarya paliurus leaf extract dry must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2 g of Cyclocarya paliurus leaf extract dry. The recommend duration of use for a medicine containing Cyclocarya paliurus leaf extract dry must be limited to 12 weeks or less. The following warning statements (or words to the same effect) are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women'; and - (ADULT) ‘Adults only'.

Authorised Version F2024L01196 registered 23/09/2024

1661	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%.
1662	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%.
1663	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%.
1664	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%.
1665	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%.
1666	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1667	CYCLOHEXYL PHENETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1668	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%.
1669	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%.
1670	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1671	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%.
1672	CYDONIA OBLONGA	A, H	
1673	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%.
1674	CYMBOPOGON MARTINI	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon martini and

Authorised Version F2024L01196 registered 23/09/2024

			the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1675	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%.
1676	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%.
1677	CYNANCHUM ATRATUM	A, H	
1678	CYNANCHUM STAUNTONII	A, E, H	
1679	CYNARA SCOLYMUS	A, E, H	
1680	CYNODON DACTYLON	A, E, H	
1681	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1682	CYPERUS LONGUS	A, H	
1683	CYPERUS ROTUNDUS	A, H	
1684	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%.
1685	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1686	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1687	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.
1688	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.
1689	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.
1690	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%.
1691	D-ALPHA-TOCOPHEROL	A, E	
1692	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1693	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1694	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.

Authorised Version F2024L01196 registered 23/09/2024

			The concentration in the medicine must be no more than 3%.
1695	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%.
1696	D-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1697	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%.
1698	D-GLUCOSE, POLYMER WITH XYLITOL	E	The route of administration for medicines that contain D-glucose, polymer with xylitol must be limited to topical for dermal use. The total concentration of D-glucose, polymer with xylitol in the medicine must not be more than 5%. The following warning statements (or words to the same effect) are required on the medicine label: - (EYE) ‘Avoid contact with eyes'; and - (BROKEN) ‘Use on unbroken skin only’.
1699	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%.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1700	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%.
1701	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.
1702	DACTYLIS GLOMERATA	A, H	
1703	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1704	DAEMONOROPS DRACO	A, E, H	
1705	DAHLIA PINNATA	A, H	
1706	DALBERGIA ODORIFERA	A, H	
1707	DAMIANA LEAF POWDER	A	
1708	DANDELION LEAF DRY	A, H	
1709	DANDELION LEAF POWDER	A, H	
1710	DANDELION ROOT DRY	A, H	
1711	DANDELION ROOT POWDER	A, H	
1712	DAPHNE GENKWA	A, H	
1713	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1714	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%.

Authorised Version F2024L01196 registered 23/09/2024

1715	DAUCUS CAROTA	A, E, H	
1716	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%.
1717	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).
1718	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.
1719	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1720	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%.
1721	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%.
1722	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%.
1723	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%.
1724	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%.
1725	DECANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Authorised Version F2024L01196 registered 23/09/2024

1726	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.
1727	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%.
1728	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%.
1729	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%.
1730	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1731	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1732	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1733	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1734	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.
1735	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.

Authorised Version F2024L01196 registered 23/09/2024

1736	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%.
1737	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1738	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%.
1739	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%.
1740	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1741	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%.
1742	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1743	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%.
1744	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%.
1745	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%.
1746	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%.
1747	DELTA-TOCOPHEROL	E	
1748	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%.

Authorised Version F2024L01196 registered 23/09/2024

1749	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1750	DENATONIUM BENZOATE	E	
1751	DENDROBIUM NOBILE	A, H	
1752	DESCURAINIA SOPHIA	A, H	
1753	DESMODIUM STYRACIFOLIUM	A, H	
1754	DEVIL'S CLAW TUBER DRY	A, H	
1755	DEVIL'S CLAW TUBER POWDER	A, H	
1756	DEXPANTHENOL	A, E	
1757	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%.
1758	DEXTRAN 40	A, E	
1759	DEXTRATES	E	
1760	DEXTRIN	E	
1761	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%.
1762	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.
1763	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%.
1764	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			The concentration in the medicine must be no more than 5%.
1765	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%.
1766	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%.
1767	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%.
1768	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%.
1769	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%.
1770	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.

Authorised Version F2024L01196 registered 23/09/2024

1771	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1772	DIANTHUS SUPERBUS	A, H	
1773	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1774	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1775	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.
1776	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral

Authorised Version F2024L01196 registered 23/09/2024

			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.
1777	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.
1778	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.
1779	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.
1780	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

Authorised Version F2024L01196 registered 23/09/2024

			component of dibasic sodium phosphate dodecahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1781	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.
1782	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.
1783	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%.
1784	DIBUTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1785	DIBUTYL SEBACATE	E	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1786	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%.
1787	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1788	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1789	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%.
1790	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%.
1791	DICHLOROBENZYL ALCOHOL	E	
1792	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.
1793	DICTAMNUS ALBUS	A, H	
1794	DICTAMNUS DASYCARPUS	A, H	
1795	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%.
1796	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.

Authorised Version F2024L01196 registered 23/09/2024

1797	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1798	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%.
1799	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.
1800	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%.
1801	DIETHYL PHTHALATE	E	
1802	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%.
1803	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and

Authorised Version F2024L01196 registered 23/09/2024

			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).
1804	DIETHYLAMINOMETHYLCOUMARIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1805	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%.
1806	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%.
1807	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1808	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%.
1809	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

1810	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%.
1811	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).
1812	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.'
1813	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%.
1814	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%.
1815	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%.
1816	DIGLYCOL/CHDM/ISOPHTHALATES/ SIP COPOLYMER	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1817	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%.
1818	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%.
1819	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%.
1820	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%.
1821	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%.
1822	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%.

Authorised Version F2024L01196 registered 23/09/2024

1823	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%.
1824	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%.
1825	DIHYDROCAPSIATE	A	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 (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'.
1826	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%.
1827	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%.
1828	DIHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as part

Authorised Version F2024L01196 registered 23/09/2024

			of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1829	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%.
1830	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%.
1831	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%.
1832	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%.
1833	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%.
1834	DIHYDROMYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1835	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1836	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%.
1837	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%.
1838	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1839	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1840	DILL HERB OIL	A, E, H	
1841	DILL SEED OIL	A, E, H	
1842	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%.
1843	DIMETHICONE 12500	E	
1844	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%.
1845	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			The concentration in the medicine must be no more than 15%.
1846	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%.
1847	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%.
1848	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%.
1849	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%.
1850	DIMETHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1851	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%.

Authorised Version F2024L01196 registered 23/09/2024

1852	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%.
1853	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%.
1854	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%.
1855	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%.
1856	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%.
1857	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1858	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%.
1859	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%.
1860	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1861	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%.
1862	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%.
1863	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%.
1864	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1865	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

1866	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%.
1867	DIMETICONE 10	E	
1868	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1869	DIMETICONE 1000	E	
1870	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%
1871	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%.
1872	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1873	DIMETICONE 200	E	Only for use in topical medicines for dermal application.
1874	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%.
1875	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1876	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1877	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1878	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1879	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1880	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1881	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%.
1882	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1883	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1884	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%.
1885	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%.
1886	DIMETICONOL	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

1887	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%.
1888	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%.
1889	DIMOCARPUS LONGAN	A, H	
1890	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1891	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1892	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1893	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%.
1894	DIOLAMINE C8-18 PERFLUOROALKYLETHYL PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 0.7%
1895	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.
1896	DIOSCOREA COLLETTII	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1897	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1898	DIOSCOREA JAPONICA	A, H	
1899	DIOSCOREA OPPOSITIFOLIA	A, H	
1900	DIOSCOREA POLYSTACHYA	A, H	
1901	DIOSCOREA SEPTEMLOBA	A, H	
1902	DIOSCOREA VILLOSA	A, E, H	
1903	DIOSPYROS KAKI	A, E, H	
1904	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).
1905	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%.
1906	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TETRA ISOSTEARATE	E	Only for use in topical medicines for dermal 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%.
1907	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%.
1908	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

1909	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%.
1910	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%.
1911	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%.
1912	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%.
1913	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1914	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%.
1915	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1916	DIPSACUS ASPER	A, H	
1917	DIPSACUS JAPONICUS	A, H	
1918	DIPTERYX ODORATA	A, E, H	When used as an active ingredient coumarin is a mandatory component of

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			Dipteryx odorata and the concentration of coumarin in the medicine must be no more than 0.001%.
1919	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1920	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1921	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%.
1922	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%.
1923	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%.
1924	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%.
1925	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%.
1926	DISODIUM INOSINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1927	DISODIUM LAURIL SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 0.35%.
1928	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%.
1929	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1930	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%.
1931	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).
1932	DISODIUM PYROPHOSPHATE	E	Disodium pyrophosphate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.

Authorised Version F2024L01196 registered 23/09/2024

			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'.
1933	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%.
1934	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%.
1935	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%.
1936	DISPERSIBLE CELLULOSE	E	
1937	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%.
1938	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%.
1939	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

1940	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%.
1941	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%.
1942	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%.
1943	DL-ALPHA-TOCOPHEROL	A, E	
1944	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1945	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1946	DL-BORNEOL	E	
1947	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1948	DL-THREONINE	A, E	
1949	DOCOSAHEXAENOIC ACID (DHA)-RICH OIL DERIVED FROM MICROALGAE SCHIZOCHYTRIUM SP.	A	Only for use in oral medicines and must be present in combination with other ingredients.
1950	DOCUSATE SODIUM	E	
1951	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%.
1952	DODECANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1953	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%.
1954	DODECYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1955	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%.
1956	DOLICHOS LABLAB	A, H	
1957	DOLOMITE	A, E, H	
1958	DRACAENA DRACO	A, H	
1959	DRIED BUTTERMILK	E	
1960	DRIED CALCIUM SULFATE	A, E, H	
1961	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

Authorised Version F2024L01196 registered 23/09/2024

			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.
1962	DRIMIA INDICA	A, H	
1963	DRIMIA MARITIMA	A, H	
1964	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).
1965	DROSERA ANGLICA	A, H	
1966	DROSERA BURMANNI	A, H	
1967	DROSERA INTERMEDIA	A, H	
1968	DROSERA RAMENTACIA	A, H	
1969	DROSERA ROTUNDIFOLIA	A, E, H	
1970	DROSERA ROTUNDIFOLIA MIS	A, H	
1971	DRYNARIA FORTUNEI	A, H	
1972	DRYOBALANOPS AROMATICA	A, H	
1973	DRYOPTERIS FILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1974	DULACIA INOPIFLORA	A, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

1975	DUNALIELLA SALINA	A, E, H	
1976	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%.
1977	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%.
1978	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1979	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).
1980	ECHINACEA ANGUSTIFOLIA	A, E, H	
1981	ECHINACEA PALLIDA	A, E, H	
1982	ECHINACEA PURPUREA	A, E, H	
1983	ECHINOPA SPINOSISSIMUS	A, H	
1984	ECLIPTA PROSTRATA	A, H	
1985	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%.

Authorised Version F2024L01196 registered 23/09/2024

1986	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%.
1987	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.
1988	EGG LECITHIN	A, E	
1989	EGGSHELL MEMBRANE HYDROLYSATE	A	
1990	EGGSHELL MEMBRANE POWDER	A	
1991	ELAEAGNUS ANGUSTIFOLIA	A, H	
1992	ELAEIS GUINEENSIS	A, E, H	
1993	ELASTIN	E	Only for use in topical medicines for dermal application.
1994	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%.
1995	ELDER FLOWER BLACK DRY	A, E, H	
1996	ELDER FLOWER BLACK POWDER	A, H	
1997	ELECAMPANE RHIZOME DRY	A, H	
1998	ELECAMPANE RHIZOME POWDER	A, H	
1999	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%.
2000	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%.
2001	ELEMOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2002	ELEOCHARIS DULCIS	A, H	
2003	ELETTARIA CARDAMOMUM	A, E, H	
2004	ELEUTHEROCOCCUS NODIFLORUS	A, H	
2005	ELEUTHEROCOCCUS ROOT DRY	A, H	
2006	ELEUTHEROCOCCUS ROOT POWDER	A, H	
2007	ELEUTHEROCOCCUS SENTICOSUS	A, H	
2008	ELSHOLTZIA SPLENDENS	A, H	
2009	ELYMUS REPENS	A, E, H	
2010	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.
2011	EMULSIFYING WAX	E	
2012	ENOXOLONE	E	Only for use in topical medicines for dermal application.
2013	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%.
2014	EPA-RICH NANNOCHLOROPSIS OCULATA OIL	A, E	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

Authorised Version F2024L01196 registered 23/09/2024

			than 2000 mg of 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'.
2015	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%.
2016	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%.
2017	EPIGAEA REPENS	A, H	
2018	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.
2019	EPILOBIUM PALUSTRE	A, H	
2020	EPILOBIUM PARVIFLORUM	A, H	
2021	EPIMEDIUM BREVICORNU	A, H	
2022	EPIMEDIUM GRANDIFLORUM	A, H	
2023	EPIMEDIUM SAGITTATUM	A, H	
2024	EQUISETUM ARVENSE	A, E, H	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2025	EQUISETUM HIEMALE	A, H	
2026	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2027	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%.
2028	ERIGERON BREVISCAPUS	A, H	
2029	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%.
2030	ERIOCAULON BUERGERIANUM	A, H	
2031	ERIODICTYON CRASSIFOLIUM	A, H	
2032	ERIODICTYON GLUTINOSUM	A, H	
2033	ERODIUM CICUTARIUM	A, H	
2034	ERUCA SATIVA	A, H	
2035	ERYTHORBIC ACID	E	
2036	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%.
2037	ERYTHROSINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2038	ERYTHROSINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2039	ERYTHRULOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

Authorised Version F2024L01196 registered 23/09/2024

			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'.
2040	ESCHSCHOLZIA CALIFORNICA	A, H	
2041	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%.
2042	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.
2043	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.
2044	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2045	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%.
2046	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2047	ETHOXYLATED NONYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2048	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%.
2049	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2050	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%.
2051	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%.
2052	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%.
2053	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2054	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%.
2055	ETHYL 2-HEXYL ACETOACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2056	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%.
2057	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%.
2058	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2059	ETHYL 3-HYDROXYBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2060	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%.
2061	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%.
2062	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%.
2063	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%.
2064	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%.
2065	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%.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2066	ETHYL ACRYLATE	E	
2067	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%.
2068	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%.
2069	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%.
2070	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%.
2071	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)'.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2072	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%.
2073	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%.
2074	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%.
2075	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%.
2076	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%.

Authorised Version F2024L01196 registered 23/09/2024

2077	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%.
2078	ETHYL ENANTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2079	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%.
2080	ETHYL HYDROXYBENZOATE	E	
2081	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%.
2082	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2083	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%.
2084	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%.
2085	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%.
2086	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%.
2087	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%.
2088	ETHYL LINALYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Authorised Version F2024L01196 registered 23/09/2024

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2089	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.
2090	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2091	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%.
2092	ETHYL MALTOL	E	
2093	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%.
2094	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application. Only permitted in medicines containing 1% or less of ethyl methacrylate as residual monomer in a polymer.
2095	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%.
2096	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2097	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%.
2098	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%.
2099	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%.
2100	ETHYL OXYHYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2101	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%.

Authorised Version F2024L01196 registered 23/09/2024

2102	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%.
2103	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%.
2104	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%.
2105	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).
2106	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%.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2107	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.
2108	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%.
2109	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%.
2110	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%.
2111	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%.
2112	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%.

Authorised Version F2024L01196 registered 23/09/2024

2113	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%.
2114	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%.
2115	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.
2116	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%.
2117	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%.
2118	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%.
2119	ETHYL VANILLIN	E	

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

2120	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%.
2121	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%.
2122	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%.
2123	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%.
2124	ETHYLCELLULOSE	E	
2125	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%.
2126	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%.
2127	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.

Authorised Version F2024L01196 registered 23/09/2024

2128	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%.
2129	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%.
2130	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2131	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%.
2132	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%.
2133	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%.
2134	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%.
2135	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.

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			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).
2136	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%.
2137	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2138	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.

Authorised Version F2024L01196 registered 23/09/2024

2139	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.
2140	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

Authorised Version F2024L01196 registered 23/09/2024

Volume 2

			to 25 millilitres the medicine must also have a child resistant closure.
2141	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.
2142	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’

Authorised Version F2024L01196 registered 23/09/2024

			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’
2143	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.
2144	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

Authorised Version F2024L01196 registered 23/09/2024

			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.
2145	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.
2146	EUCOMMIA ULMOIDES	A, H	
2147	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

Authorised Version F2024L01196 registered 23/09/2024

			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'
2148	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%.
2149	EUGLENA GRACILIS WHOLE CELL DRY	A	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);

Authorised Version F2024L01196 registered 23/09/2024

			(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'.
2150	EUONYMUS ATROPURPUREUS	A, H	
2151	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2152	EUPATORIUM FORTUNEI	A, H	
2153	EUPATORIUM JAPONICUM	A, H	
2154	EUPATORIUM PERFOLIATUM	A, H	
2155	EUPATORIUM PURPUREUM	A, H	
2156	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.
2157	EUPHORBIA CYPARISSIAS	A, H	
2158	EUPHORBIA DRY	A, H	
2159	EUPHORBIA HETERODOXA	A, H	
2160	EUPHORBIA HIRTA	A, H	
2161	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%.
2162	EUPHORBIA PEKINENSIS	A, H	
2163	EUPHORBIA PEPLUS	H	Only for use as an active homoeopathic ingredient.
2164	EUPHORBIA POWDER	A, H	
2165	EUPHORBIA RESINIFERA	A, H	
2166	EUPHORBIA SIEBOLDIANA	A, H	
2167	EUPHRASIA OFFICINALIS	A, H	
2168	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.

Authorised Version F2024L01196 registered 23/09/2024

2169	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2170	EURYALE FEROX	A, H	
2171	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'.
2172	EVENING PRIMROSE OIL	A, E, H	
2173	EVERNIA PRUNASTRI EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Authorised Version F2024L01196 registered 23/09/2024