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

Note: See sections 5 and 6.

Permissible in	Permissible ingredients and requirements				
Column 1	Column 2	Column 3	Column 4		
Item	Ingredient name	Purpose	Specific requirements		
751	BACILLUS COAGULANS	A	Only permitted for use in medicines:		
			(a) limited to oral routes of administration; and		
			(b) when the strain of Bacillus coagulans is confirmed to be:		
			(i) Microbial Type Culture Collection (MTCC) accession number 5260; and/or		
			(ii) MTCC accession number 5856.		
			The strain of Bacillus coagulans must be declared on the label.		
			When the strain of Bacillus coagulans is MTCC accession number 5260:		
			(a) the maximum recommended daily dose of the medicine must not provide more than 6 billion cfu of Bacillus coagulans strain MTCC accession number 5260; and		
			(b) the following warning statements are required on the medicine label:		
			- (CHILD2) 'Not suitable for children'; and		
			- (BACCOAG) 'Bacillus coagulans may affect the way some medicines work,		
			including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'		

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			When the strain of Bacillus coagulans is MTCC accession number 5856: (a) the maximum recommended daily dose of the medicine must not provide more than 2 billion cfu of Bacillus coagulans strain MTCC accession number 5856; and (b) the following warning statements are required on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect); - (CHILD2) 'Not suitable for children'; and - (BACCOAG) 'Bacillus
			coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect).'
752	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

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

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			(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';
			- (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'

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			- (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	Е	
762	BANANA DISTILLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
763	BAPTISIA CONFUSA	A, H	
764	BAPTISIA TINCTORIA	A, H	
765	BARBAREA VULGARIS	A, H	
766	BARIUM CARBONATE	Н	Only for use as an active homoeopathic ingredient.
767	BARIUM CHLORIDE	Н	Only for use as an active homoeopathic ingredient.
768	BARIUM SULFATE	Е	Only for use in topical medicines for dermal application.

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769	BARLEY	Е	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	Е	Only for use in oral medicines.
772	BASIC FUCHSIN	Е	Only for use as a colour ingredient in topical medicines for dermal application.
773	BASIC RED 1	Е	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	Е	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 is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the

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

			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	Е	
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:

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			- (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. If used in a flavour the total flavour concentration in a 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	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
784	BEETROOT	E, H	

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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	Е	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
788	BEHENOXY DIMETHICONE	Е	Only for use in topical medicines for dermal application.
789	BEHENOYL STEARIC ACID	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%.
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.

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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. 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

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			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	Е	
800	BENZALDEHYDE GLYCERYL ACETAL	Е	Permitted for use only in combination with 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	Е	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

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			medicine must not be more than 0.03%.
			When benzalkonium chloride is used in a nasal spray dosage form which is either:
			(i) indicated for use in children; or
			(ii) not specifically indicated for adults only;
			the following warning statement is required on the medicine label:
			- (NTAKEN2) 'Not to be used by children under 2 years old' (or words to that effect).
802	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.
803	BENZOIC ACID	E, H	
804	BENZOIN	Е	Permitted for use only in combination with 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	Е	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

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			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. If used in a flavour the total flavour concentration in a 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	Е	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	Е	Only for use in topical medicines for dermal application.

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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	Е	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 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	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.

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

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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. The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
825	BENZYLIDENE ACETONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			If used in a flavour the total flavour concentration in 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%.

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			Volum
			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	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
841	BETA-DAMASCONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
842	BETA-HOMO CYCLOCITRAL	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a
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%.

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846	BETA-ISO-METHYL IONONE	Е	Permitted for use only in combination with 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. If used in a flavour the total flavour concentration in a 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

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
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%.
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

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v Orume 2			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	Е	Only for use in topical medicines for dermal 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	Е	Only for use in topical medicines for dermal application.
859	BETAINE HYDROCHLORIDE	Е	
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. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, and the dosage form is spray,

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 Volume
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:

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			- (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 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

Volume	2

	Volume
	requires child resistant packaging.
	When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if:
	- the delivery device is engaged into the container in such a way that prevents it from being readily removed;
	- direct suction through the delivery device results in delivery of no more than one dosage unit; and
	- actuation of the spray device is ergonomically difficult for young children to accomplish.
	The following warning statement is required on the medicine label:
	- (METSAL) 'Contains methyl salicylate' (or words to that effect).
	When for use in topical medicines for dermal application:
	i) the concentration of methyl salicylate in the medicine must not be more than 25%;
	ii) the following warning statements are required on the medicine label:
	- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
	- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
	- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);
	- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

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			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;
			- 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).

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			Volume
			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-	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than
0.65	Provide of a constant to the		1%.
865	BICYCLO(2.2.2)OCT-5-ENE-2- CARBOXALDEHYDE, 6- METHYL-8-(1-METHYLETHYL)-	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
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	Е	
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.

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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);

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			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	Е	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.5%.
882	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
883	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	Е	Only for use in topical medicines for dermal 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	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

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			The concentration in the medicine must be no more than 2.5%.
885	BIS-PEG-12 DIMETHICONE BEESWAX	Е	Only for use in topical medicines for dermal 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	Е	Only for use in 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/NEOPENTY L 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
889	BISABOLOL	Е	If used as an excipient, the medicine is only for use in topical medicines for dermal application.

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890	BITTER ALMOND OIL	Е	Permitted for use only in combination with 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).

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			When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
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

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

			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	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
900	BLACK OF CURACAO SPIDER	Н	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	Н	Only for use as an active homoeopathic ingredient.
904	BLACKBERRY	Е	
905	BLACKBERRY OILS	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than
906	BLACKBERRY WINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

			Volum
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
907	BLACKCURRANT ESTERS	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
909	BLACKSTRAP MOLASSES	Е	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

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

			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	Е	Permitted for use only in combination with 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	Е	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%.
918	BLUMEA LACERA	A, H	
919	BOEHMERIA NIVEA	A, H	
920	BOERHAVIA DIFFUSA	A, H	
921	BOERHAVIA REPENS	A, H	

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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 internal use and/or oral application, one of the following warning

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			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

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

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			is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN12) 'Not to be taken by children under 12 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). When the maximum recommended daily dose of the medicine provides more than 1 mg boron and up to, and including, 3 mg of boron, and the medicine is for internal use and/or oral application, one of the following warning statements is required on the label: - (NTAKEN2) 'Not to be taken by children under 2 years old' (or words to that effect); or - (ADULT) 'Adults only' (or words to that effect). When for excipient use and the maximum recommended daily dose of the medicine provides
			more than 1 mg of boron and the medicine is for internal use and/or oral application, the following warning statement is required on the label: - (BORON) 'Contains boron'
			(or words to that effect). When the medicine is for topical use for dermal application, the following warning statement is required on the label:
			- (BROKEN) 'Use on unbroken skin only' (or words to that effect).
929	BORIC ACID	A, H	Boron is a mandatory component of boric acid. The percentage of boron from boric acid should be calculated

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based on the molecular weight of boric acid.

The maximum recommended daily dose must not provide more than 6mg of boron.

In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 mg/L or 0.35%.

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

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

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

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

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

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			VOIUII
			- (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	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			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	Е	Permitted for use only in combination with 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; - 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.

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			VOIUIIIE
			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	Е	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	А, Н	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%.

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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

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			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%.
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	Е	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	Е	Permitted for use only as a colour for oral and topical use.

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961	BRILLIANT BLUE FCF BARIUM LAKE	Е	Permitted for use only as a colour for oral and topical use.
962	BRILLIANT SCARLET 4R	Е	Permitted for use only as a colour in medicines for topical and oral routes of administration.
963	BRILLIANT SCARLET 4R ALUMINIUM LAKE	Е	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	Е	Not for use in infants
			Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
968	BROMUS CATHARTICUS	A, H	
969	BROMUS INERMIS	A, H	
970	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
971	BRONOPOL	Е	Only for use in topical medicines for dermal application.
972	BROUSSONETIA PAPYRIFERA	A, H	
973	BROWN FK	Е	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.

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975	BRUSSEL SPROUT	Е	
976	BRYONIA ALBA	A, H	
977	BRYONIA DIOICA	A, H	
978	BUCHU LEAF DRY	A, H	
979	BUCHU LEAF OIL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	
989	BURDOCK ROOT POWDER	A, H	
990	BUSHMASTER SNAKE	Н	Only for use as an active homoeopathic ingredient.
991	BUTAN-1-OL	Е	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	Е	Only for use as an excipient propellant ingredient.

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

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	Е	
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	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
999	BUTYL ACETATE	Е	The residual solvent limit for Butyl acetate is 50 mg per

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

			Volum
			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	Е	Permitted for use only in combination with 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%.

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

		The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
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%.
BUTYL HYDROXYBENZOATE	Е	Only for use in topical medicines for dermal application.
BUTYL ISOBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
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%.
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%.
	BUTYL HYDROXYBENZOATE BUTYL ISOBUTYRATE BUTYL ISOVALERATE	BUTYL HYDROXYBENZOATE E BUTYL ISOBUTYRATE E BUTYL ISOVALERATE E

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

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1009	BUTYL LEVULINATE	Е	Permitted for use only in combination with 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 METHOXYDIBENZOYLMETHAN E	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in preparation must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1011	BUTYL PROPIONATE	Е	Permitted for use only in combination with 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	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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

volume 2			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	Е	
1015	BUTYLATED HYDROXYTOLUENE	Е	
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%.
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%.

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

1020	BUTYRALDEHYDE	Е	Permitted for use only in combination with 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 TETRAHYDROXYCYCLOHEXAN OATE	Е	Only for use in topical medicines for dermal 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. Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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

			medicine must not be more than 1%.
1024	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	Е	Only for use in topical medicines for dermal application.
1025	C11-13 ALKANE	Е	Only for use in 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	Е	Permitted for use only in combination with 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

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

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			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. The concentration in the medicine must be no more than 1.2%.
1030	C12-15 ALKYL OCTANOATE	Е	Only for use in topical medicines for dermal application.
1031	C12-20 ACID PEG-8 ESTER	Е	Only for use in topical medicines for dermal 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	Е	Only for use in topical medicines for dermal 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/HYDROXYETHYLA CRYLATE 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%.

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

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	Е	C15-16 isoparaffin must only be included in topical medicines:
			(a) for dermal application; and
			(b) where the dosage form of the medicine is not spray.
			The total concentration of C15-16 isoparaffin and C17-18 isoparaffin in the medicine must not be more than 50%.
			When the nominal capacity of the container is more than 2 mL and the medicine is not a solid or semi-solid preparation,
			the total concentration of designated solvents (including C15-16 isoparaffin) in the medicine must not be more than 25%.
1037	C15-19 ALKANE	Е	Only for use in topical medicines for dermal 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.

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

			Volume
			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	Е	Only for use topical medicines for dermal application.
1040	C18-36 ACID TRIGLYCERIDE	Е	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	Е	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. The concentration in the medicine must be no more than 2%.
1044	C20-40 PARETH-24	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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

			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	GADDA GE		
1050 1051	CABBAGE 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

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

			medicine must be no more than 1%.
1052	CADE OIL	A, E, H	
1053	CAESALPINIA SAPPAN	A, H	
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%.

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

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When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 1%. When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.

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

- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.'
- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'

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

- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'
- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before

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

			Volume
			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)
			- (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

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

			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.

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			Volume
			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).

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1059	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1060	CALCIFIED LITHOTHAMNION TOPHIFORME	A	Only for oral use.
1061	CALCIUM ALGINATE	Е	
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.
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	Е	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	Е	
1072	CALCIUM CHLORIDE DIHYDRATE	Е	
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	Н	The percentage of fluoride from Calcium fluoride should be calculated based on the

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			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.
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

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

			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	Н	Only for use as an active homoeopathic ingredient.
1084	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
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.

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

			Volume
1088	CALCIUM HYDROXYCITRATE	A, H	The requirements specified below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2025; or - released for supply on or after 1 March 2026. When for oral use, the following warning statement is required on the medicine label: 'In very rare cases, calcium hydroxycitrate 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.' Medicines containing calcium hydroxycitrate must not be directed for use in children, or in pregnant or lactating women.
1089	CALCIUM HYPOPHOSPHITE	Н	Only for use as an active homoeopathic ingredient.
1090	CALCIUM IODIDE	Н	Only for use as an active homoeopathic ingredient.
1091	CALCIUM KETOGLUCONATE	Е	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	

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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	Е	Only for use in topical medicines for dermal application.
1101	CALCIUM PANTOTHENATE	A, E, H	
1102	CALCIUM PHOSPHATE	A, E, H	
1103	CALCIUM PROPIONATE	E	Only to be used in a medicine where Procter & Gamble Australia Pty Ltd (Client ID 11364), 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 2027. The route of administration for medicines that contain calcium propionate must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 1 milligram of calcium propionate.
1104	CALCIUM PYRUVATE	A	
1105	CALCIUM SACCHARATE	Е	
1106	CALCIUM SILICATE	Е	
1107	CALCIUM SODIUM CASEINATE	A, H	
1108	CALCIUM SODIUM LACTATE	A, E, H	
1109	CALCIUM STEARATE	Е	
1110	CALCIUM SUCCINATE	A, E, H	
1111	CALCIUM SULFATE	A, E, H	

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1112	CALCIUM SULFATE	A, E, H	
1113	DIHYDRATE CALCIUM SULFIDE	Н	Only for use as an active homoeopathic ingredient.
1114	CALCIUM THREONINATE	A	
1115	CALENDULA FLOWER DRY	A, E, H	
1116	CALENDULA FLOWER POWDER	A, H	
1117	CALENDULA OFFICINALIS	A, E, H	
1118	CALLERYA RETICULATA	A, H	
1119	CALLICARPA PEDUNCULATA	A, H	
1120	CALLISTEPHUS CHINENSIS	A, H	
1121	CALLITRIS COLUMELLARIS	Е	Permitted for use only in combination with 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 COLUMELLARIS SUBSP. INTRATROPICA	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1123	CALLITRIS RHOMBOIDEA	A, H	
1124	CALLUNA VULGARIS	A, E, H	
1125	CALOCHORTUS TOLMIEI	A, H	
1126	CALTHA PALUSTRIS	A, H	
1127	CALUMBA ROOT DRY	A, H	
1128	CALUMBA ROOT POWDER	A, H	
1129	CALVATIA GIGANTEA	A, E, H	
1130	CALYCANTHUS FLORIDUS	A, H	
1131	CALYCANTHUS PRAECOX	A, H	
1132	CAMELLIA JAPONICA	A, H	
1133	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is restricted to topical or

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			sunscreen preparations for dermal application only.
1134	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

Volume	2

volume
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).
When used in oral medicines,
the following warning
statements are required on the
medicine label:
- '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
- (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
 permisses ingressents as a

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

			flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing Camellia sinensis must not be more than 5% of the total medicine.
1135	CAMPHENE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1136	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%.
1137	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%.
1138	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%.

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

			Volume
			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).
1139	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 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

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

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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 than 15 millilitres but less than or equal

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

			Volume
			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.
1140	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

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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:

- (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

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

			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 container must not be more than 25 millilitres.
1141	CAMPSIS GRANDIFLORA	A, H	
1142	CANADA BALSAM	A, H	
1143	CANANGA ODORATA	A, E, H	
1144	CANANGA OIL	A, E, H	
1145	CANARIUM INDICUM	A, H	Only for use when the plant part is seed and the plant preparation is oil.
1146	CANARIUM LUZONICUM	A, H	
1147	CANDELILLA WAX	A, E, H	
1148	CANDIDA ALBICANS	Н	Only for use as an active homoeopathic ingredient.
1149	CANDIDA UTILIS	A, E, H	When used as an excipient, only for use in medicines in combination with other permitted ingredients as a

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			flavour proprietary excipient formulation.
			The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
1150	CANINE MILK	Н	Only for use as an active homoeopathic ingredient.
1151	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%.
1152	CANTHARIDES	Н	Only available as an active homoeopathic ingredient.
1153	CANTHAXANTHIN	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1154	CAPRIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	CAPROIC ALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1156	CAPRYLIC ALDEHYDE	Е	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%.
1157	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	Е	
1158	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC TRIGLYCERIDE	Е	Only for use 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%
1159	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	Е	Only for use in topical medicines for dermal application.
1160	CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER	Е	Only for use in 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%.
1161	CAPRYLOYL GLYCINE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must not be more than 2%
1162	CAPRYLOYL SALICYLIC ACID	Е	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%.
1163	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%
1164	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%.
1165	CARCELLA DURGA RACTORIO	A 11	
1165 1166	CAPSICUM CAPSICUM	A, H E, H	Only for use as an active homoeopathic or excipient ingredient.
1167	CAPSICUM ANNUUM	A, E, H	
1168	CAPSICUM DRY	A, E, H	
1169	CAPSICUM FRUIT OLEORESIN	A, E	
1170	CAPSICUM FRUTESCENS	A, E, H	
1171	CAPSICUM POWDER	A, E, H	
1172	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.

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1173	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1174	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must not be more than 0.2%.
1175	CARAWAY DRY	A, H	
1176	CARAWAY OIL	A, E, H	
1177	CARAWAY POWDER	A, H	
1178	CARBOMER 1342	Е	Only for use as an excipient in topical medicines for dermal application.
1179	CARBOMER 2001	Е	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.
1180	CARBOMER 934	Е	Only for use in topical medicines for dermal application.
1181	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1182	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1183	CARBOMER 941	Е	Only for use as an excipient in topical medicines for dermal application.

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1184	CARBOMER 954	Е	Only for use as an excipient in topical medicines for dermal application.
1185	CARBOMER 980	Е	Only for use as an excipient in topical medicines for dermal application.
1186	CARBOMER 981	Е	Only for use as an excipient in topical medicines for dermal application.
1187	CARBOMER COPOLYMER (TYPE B)	Е	Only for use as an excipient in topical medicines for dermal application.
1188	CARBOMER HOMOPOLYMER (TYPE B)	Е	Only for use as an excipient in topical medicines for dermal application.
1189	CARBOMER U-10	Е	Only for use in topical medicines for dermal 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%.
1190	CARBON	Е, Н	Only for use as an active homoeopathic or excipient ingredient.
1191	CARBON BLACK	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1192	CARBON DIOXIDE	Е	
1193	CARDAMOM FRUIT DRY	A, H	
1194	CARDAMOM FRUIT POWDER	A, E, H	
1195	CARDAMOM OIL	A, E, H	
1196	CARDIOSPERMUM HALICACABUM	A, H	
1197	CARICA PAPAYA	A, E, H	
1198	CARLINA ACAULIS	A, H	

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1199	CARMELLOSE	Е	
1200	CARMELLOSE CALCIUM	Е	
1201	CARMELLOSE SODIUM	Е	
1202	CARMINE	Е	Permitted for use only as a colour for oral and topical use.
1203	CARMOISINE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1204	CARMOISINE ALUMINIUM LAKE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1205	CARNAUBA WAX	A, E, H	
1206	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%.
1207	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%.
1208	CAROB GUM	Е	
1209	CAROB POD	Е	
1210	CAROTENES	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1211	CARPINUS BETULUS	A, H	
1212	CARPINUS CORDATA	A, H	
1213	CARRAGEENAN	Е	

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1214	CARROT	Е	
1215	CARROT SEED OIL	A, E, H	
1216	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).
1217	CARUM CARVI	A, H	
1218	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%.
1219	CARVACRYL METHYL ETHER	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1220	CARVEOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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			Volume
1221	CARVONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	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%.
1223	CARYA ILLINOINENSIS	A, H	
1224	CARYA OVATA	A, H	
1225	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%.
1226	CASCARA DRY	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara dry when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine

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requires the following warning statements on the medicine label:
- (CHILD3) 'Use in children under 12 years is not

- (LAX2) 'Prolonged use may cause serious bowel problems'; and

recommended';

- (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';

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			(LAVI) (D. L. L. L. C.
			- (LAX1) 'Drink plenty of water' [or words to that effect]; and
			- (LAX2) 'Prolonged use may cause serious bowel problems'.
1227	CASCARA POWDER	A, H	Hydroxyanthracene derivatives calculated as cascaroside A is a mandatory component of cascara powder when the route of administration is oral administration. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are
			pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect).
			When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:
			- (LAX1) 'Drink plenty of water' (or words to that effect).
			When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:
			- (LAX5) 'This product contains [name of the herb(s)

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

Volume 2			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'.
1228	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.
1229	CASEIN	Е	
1230	CASHEW NUT	E	
1231	CASSIA ALATA LEAF EXTRACT	Е	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.

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			The concentration in the medicine must be no more than 0.0275%.
1232	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%.
1233	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.
1234	CASSIA FISTULA	A, E, H	Hydroxyanthracene glycosides calculated as sennoside B is a mandatory component of Cassia fistula when the route of administration is oral. When used in oral medicines, if the maximum recommended daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label:

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	- (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label:
	- (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'.
	When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children
	under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and
	- (LAX2) 'Prolonged use may cause serious bowel problems'. When Cassia fistula is for use as an excipient:
	(a) the plant part must be fruit; and (b) must only be included in medicines when in combination with other permitted ingredients as a:
	(i) flavour proprietary excipient formulation when the plant preparation is an extract; and/or
	(ii) fragrance proprietary excipient formulation when the plant preparation is an essential oil.
	The total concentration of flavour proprietary excipient formulations containing Cassia

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			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.
1235	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%.
1236	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%.
1237	CASTANEA MOLLISSIMA	A, H	
1238	CASTANEA SATIVA	A, H	
1239	CASTOR OIL	A, E	
1240	CASTOREUM	Н	Only permitted for use as an active homoeopathic ingredient.
1241	CASUARINA EQUISITIFOLIA	A, H	
1242	CATALPA BIGNONIOIDES	A, H	
1243	CATALPA OVATA	A, H	
1244	CATECHU	A, H	
1245	CATHARANTHUS ROSEUS	A, H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus. The concentration of vinblastine, vincamine, vincristine, vindesine,

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			vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1246	CAULIFLOWER	Е	
1247	CAULOPHYLLUM THALICTROIDES	A, E, H	
1248	CAUSTICUM	Н	Only for use as an active homoeopathic ingredient.
1249	CEANOTHUS AMERICANUS	A, H	
1250	CEDAR LEAF OIL	A, E, H	
1251	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%.
1252	CEDARWOOD OIL TERPENES	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1253	CEDARWOOD OIL VIRGINIA	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

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1254	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%.
1255	CEDRENYLACETATE	Е	Permitted for use only in combination with 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	CEDROL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1257	CEDRUS ATLANTICA	A, E, H	
1258	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%.
1259	CEDRUS DEODARA	A, H	
1260	CEDRUS LIBANI	Н	Only for use as an active homoeopathic ingredient.
1261	CEDRYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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

			medicine must be no more than 1%.
1262	CEDRYL METHYL ETHER	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1263	CELERY SEED DRY	A, E, H	
1264	CELERY SEED OIL	A, E, H	
1265	CELERY SEED POWDER	A, H	
1266	CELLACEFATE	E	
1267	CELLULASE	A	Must be derived from Trichoderma longibrachiatum only.
1268	CELLULOSE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1269	CELOSIA ARGENTEA	A, H	
1270	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1271	CENTAUREA CYANUS	A, E, H	
1272	CENTAURIUM ERYTHRAEA	A, H	
1273	CENTELLA ASIATICA	A, E, H	
1274	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%.
1275	CENTIPEDA CUNNINGHAMII	A, E, H	

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1276	CENTIPEDA MINIMA	A, H	
1277	CEPHALANOPSIS SEGETUM	A, H	
1278	CERAMIDE 1	Е	Only for use in topical medicines for dermal application.
1279	CERAMIDE 2	Е	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%.
1280	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1281	CERAMIDE 6 II	E	Ceramide 6 II 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 be no more than 0.011%.
1282	CERATONIA SILIQUA	A, E, H	
1283	CERATOSTIGMA WILLMOTTIANUM	A, H	
1284	CERESIN	Е	Only for use in topical medicines for dermal application.
1285	CESTRUM LATIFOLIUM	Е	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.

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			The concentration must be no more than 0.5%.
1286	CETEARETH-12	Е	Only for use in topical medicines for dermal application.
1287	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1288	CETEARETH-20	Е	Only for use in topical medicines for dermal application.
1289	CETEARETH-25	Е	Only for use in topical medicines for dermal application.
1290	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1291	CETEARETH-33	Е	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.
1292	CETEARYL GLUCOSIDE	Е	Only for use in topical medicines for dermal application.
1293	CETEARYL ISONONANOATE	Е	Only for use in topical medicines for dermal application.
1294	CETEARYL NONANOATE	Е	Only for use in topical medicines for dermal application and not to be

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

			Volum
			included in topical medicines intended for use in the eye. The concentration in the medicine must not be more than 5%.
1295	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1296	СЕТЕТН-10	Е	Only for use in topical medicines for dermal application.
1297	СЕТЕТН-2	Е	Only for use in topical medicines for dermal application.
1298	СЕТЕТН-24	Е	Only for use in topical medicines for dermal application.
1299	СЕТЕТН-5	Е	Only for use in topical medicines for dermal application.
1300	CETOMACROGOL 1000	Е	Only for use in topical medicines for dermal application.
1301	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%.
1302	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.

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			The concentration in the medicine must be no more than 2%.
1303	CETOSTEARYL ALCOHOL	E	
1304	CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE COMPLEX	Е	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 %
1305	CETRARIA ISLANDICA	A, H	
1306	CETRIMONIUM BROMIDE	Е	Only for use in topical medicines for dermal application.
1307	CETRIMONIUM CHLORIDE	Е	Only for use in topical medicines for dermal application.
1308	CETYL ACETATE	Е	Only for use in topical medicines for dermal application.
1309	CETYL ALCOHOL	Е	Only for use in topical medicines for dermal application.
1310	CETYL DIMETHICONE COPOLYOL	Е	Only for use in topical medicines for dermal application.
1311	CETYL DIMETICONE	Е	Only for use in topical medicines for dermal application.
1312	CETYL DIMETICONE/BIS- VINYLDIMETICONE CROSSPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

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			The concentration in the medicine must be no more than 0.1%.
1313	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1314	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%.
1315	CETYL LACTATE	E	Only for use in topical medicines for dermal application.
1316	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1317	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1318	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1319	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%.
1320	CETYLPYRIDINIUM CHLORIDE	A, E	Only permitted for use in medicines containing 5% or less of quaternary ammonium compounds.

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			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).
1321	CHAENOMELES LAGENARIA	A, H	
1322	CHAENOMELES SPECIOSA	A, H	
1323	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.
1324	CHAMAECYPARIS LAWSONIANA	A, H	
1325	CHAMAELIRIUM LUTEUM	A, H	
1326	CHAMAEMELUM NOBILE	A, E, H	
1327	CHAMOMILE FLOWER DRY	A, E, H	
1328	CHAMOMILE OIL ENGLISH	A, E, H	
1329	CHAMOMILE OIL GERMAN	A, E, H	
1330	CHANGIUM SMYRNIOIDES	A, H	
1331	CHEIRANTHUS CHEIRI	A, H	
1332	CHELIDONIUM MAJUS	A, E, H	When the medicine is for oral or sublingual use, the following

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			Volun
			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.'
1333	CHELONE GLABRA	A, H	
1334	CHENOPODIUM ALBUM	A, H	
1335	CHENOPODIUM VULVARIA	A, H	
1336	CHERRY	E	
1337	CHERRY DISTILLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1338	CHESTNUT SWEET	E, H	
1339	CHICKEN COMB EXTRACT	A	
1340	CHICKEN STERNUM CARTILAGE POWDER	A	Only to be used in a medicine where Capsugel Australia Pty Ltd (Client ID 43174), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 3 July 2025. The route of administration for medicines that contain chicken sternum cartilage powder must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 40

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			The following warning statement (or words to that effect) is required on the medicine label: - (ADULT) 'Adults only'.
1341	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%.
1342	CHIONANTHUS VIRGINICA	A, H	
1343	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.
1344	CHLORELLA PYRENOIDOSA	Е	

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1345	CHLORELLA VULGARIS	A, E	Iodine is a mandatory component of Chlorella vulgaris.
			Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.
			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1346	CHLORHEXIDINE ACETATE	Е	Only for use in topical medicines for dermal application.
1347	CHLORHEXIDINE GLUCONATE	Е	Only for use in topical medicines for dermal application.
1348	CHLOROBUTANOL HEMIHYDRATE	Е	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1349	CHLOROCRESOL	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1350	CHLOROFORM	Е	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%.
1351	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.

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1352	CHLOROPHYLL-COPPER COMPLEXES	Е	Only for use as a colour in oral and topical medicines.
1353	CHLOROPHYLLIN-COPPER COMPLEX	Е	Only for use as a colour in oral and topical medicines.
1354	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	Е	Only for as a colour in oral and topical medicines.
1355	CHLOROXYLENOL	Е	Only for use in topical medicines for dermal application.
1356	CHLORPHENESIN	Е	Only for use in topical medicines for dermal application.
1357	CHOCOLATE BROWN HT	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1358	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1359	CHOLESTERYL HYDROXYSTEARATE	Е	Only for use in topical medicines for dermal application.
1360	CHOLESTERYL MACADAMIATE	Е	Only for use in topical medicines for dermal application.
1361	CHOLESTERYL/BEHENYL/OCTY LDODECYL LAUROYL GLUTAMATE	Е	Only for use in topical medicines for dermal 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%.

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1362	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1363	CHOLINE BITARTRATE	A, E	
1364	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1365	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%.
1366	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.
1367	CHONDRUS DRY	A, E, H	Iodine is a mandatory component of Chondrus dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1368	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

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			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.
1369	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
1370	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.
1371	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources.

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			Chromium picolinate is considered to be an organic form of chromium.
1372	CHRYSANTHEMUM BALSAMITA	A, H	
1373	CHRYSANTHEMUM INDICUM	A, H	
1374	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1375	CHRYSANTHEMUM SINENSE	A, H	
1376	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1377	CHRYSOSPORIUM PRUINOSUM	A, H	
1378	CIBOTIUM BAROMETZ	A, H	
1379	CICHORIUM INTYBUS	A, E, H	
1380	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1381	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.
1382	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.
1383	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.

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1384	CINCHONA PUBESCENS	А, Н	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.
1385	CINEOLE	Е	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 than25 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.
1386	CINNAMALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1387	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%.
1388	CINNAMOMUM CAMPHORA	A, E, H	Camphor, cineole and safrole are mandatory components of Cinnamomum camphora. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil preparations or distillates and the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - Do not apply to infants under 12 months of age except on the advice of a doctor or
			pharmacist'. In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container.

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Volume 2

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

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

In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label:

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

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

cineole in the preparation is more than 25% and the

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			Volume
			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%.
1389	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%.
1390	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%.

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			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 than25 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.
1391	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%.

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			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%.
1393	CINNAMON LEAF OIL	A, E, H	When the concentration of cinnamon leaf oil in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 mL. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, the medicine must have a child resistant closure and restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
			- (NTAKEN) 'Not to be taken'. When used as an active

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			coumarin in the medicine must be no more than 0.001%.
1394	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%.
1395	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%.
1396	CINNAMYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1397	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.

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1398	CINNAMYL CINNAMATE	Е	Permitted for use only in combination with 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 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%.
1400	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%.
1401	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%.
1402	CINNAMYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1403	CINOXATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to

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			be included in medicines intended for use in the eye. The concentration in the medicine must 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).
1404	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1405	CIS-3-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.
1406	CIS-3-HEXENAL	Е	Permitted for use only in combination with other

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			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 2- METHYLBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1408	CIS-3-HEXENYL 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%.
1409	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%.
1410	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%.

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1411	CIS-3-HEXENYL FORMATE	Е	Permitted for use only in combination with 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 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%.
1413	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%.
1414	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.
1415	CIS-3-HEXENYL LACTATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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1416	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%.
417	CIS-3-HEXENYL SALICYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
418	CIS-3-HEXENYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1419	CIS-4-HEPTENAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1420	CIS-6-NONEN-1-AL	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1421	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%.
1422	CIS-BETA-OCIMENE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1423	CIS-HEXAHYDROCUMINYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1424	CIS-JASMONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total
			fragrance concentration in a medicine must be no more 1%.
1425	CISTANCHE DESERTICOLA	A, H	
1426	CISTANCHE SALSA	A, H	
1427	CISTUS LADANIFER	A, E, H	
1428	CITRAL	Е	
1429	CITRAL DIETHYL ACETAL	Е	Permitted for use only in combination with 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	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%.
1431	CITRIC ACID	A, E	Where intended for topical uses 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

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			- (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 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'
1433	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.

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			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.'
1434	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
1435	CITROL	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1436	CITRON	Е	
1437	CITRONELLA OIL	A, E, H	Medicines for topical use containing citronella oil require the following warning statement on the medicine label:

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			- (CITRON) 'Contains citronella oil'.
1438	CITRONELLA TERPENES	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1439	CITRONELLAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	CITRONELLIC ACID	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1441	CITRONELLOL	Е	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

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			medicine must be no more than 5%.
1442	CITRONELLYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1443	CITRONELLYL BUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1444	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%.
1445	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%.

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1446	CITRONELLYL NITRILE	Е	Permitted for use only in combination with 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 OXYACETALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total
			fragrance concentration in a medicine must be no more than 1%.
1448	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%.
1449	CITRONELLYL TIGLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1450	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.

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CITRULLUS COLOCYNTHIS CITRULLUS VULGARIS	Н	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.
CITRULLUS VIII GARIS		
CITICELES VELGINUS	A, E, H	When used as an excipient:
		a) the plant part must be from fruit or fruit fresh, and
		b) the plant preparation must be limited to fresh, dry, powder, oil, fresh juice, dry juice, or concentrated juice.
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.
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
	CITRUS AURANTIFOLIA	CITRUS AURANTIFOLIA A, E, H

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			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.
1455	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1456	CITRUS CHACHIENSIS	A, H	
1457	CITRUS EXTRACT	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
1458	CITRUS FIBRE	Е	
1459	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.
1460	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

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			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.
1461	CITRUS MAXIMA	A, H	
1462	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; orb) in preparations containing0.05% or less of citrus medicaoil or distillate; or
			c) for use in soaps or bath or shower gels that are washed off the skin.
1463	CITRUS OIL DISTILLED	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1464	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

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			must not be more than 1% of the total medicine.
1465	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.
1466	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.
1467	CITRUS SINENSIS PEEL MOLASSES EXTRACT	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1468	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.
1469	CITRUS X PARADISI	A, E, H	
1470	CITRUS X WILSONII	A, H	
1471	CIVET	Е	Permitted for use only in combination with 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 ABSOLUTE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1473	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%.
1474	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%.
1475	CLARY OIL	A, E, H	
1476	CLEMATIS ARMANDII	A, H	
1477	CLEMATIS CHINENSIS	A, E, H	
1478	CLEMATIS RECTA	A, H	
1479	CLEMATIS VITALBA	A, H	
1480	CLERODENDRUM TRICHOTOMUM	A, H	
1481	CLINOPODION POLYCEPHALUM	A, H	
1482	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1483	CLIVER HERB DRY	A, H	
1484	CLIVER HERB POWDER	A, H	
1485	CLOVE BUD OIL	A, E, H	When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%:
			(a) the nominal capacity of the container must not be more than 25 mL;

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			(b) a restricted flow insert must be fitted on the container; (c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'; and (d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container.
1486	CLOVE DRY	A, E, H	
1487	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.
1488	CLOVE OIL TERPENES	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1489	CLOVE POWDER	A, E, H	
1490	CLOVE STEM OIL	A, E, H	When the total concentration of clove oils (including clove bud oil, clove leaf oil, and clove stem oil) in the medicine is more than 25%:
			(a) the nominal capacity of the container must not be more than 25 mL;
			(b) a restricted flow insert must be fitted on the container;
			(c) the container must include the following warning statements on the medicine label:
			- (CHILD) 'Keep out of reach of children' (or words to that effect)
			- (NTAKEN) 'Not to be taken'; and
			(d) When the nominal capacity of the container is more than 15 mL, a child resistant closure must also be fitted on the container.
1491	CLUPEA HARENGUS LIPID	A	Only for use in oral medicines.
	EXTRACT		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.
1492	CNICUS BENEDICTUS	A, H	
1493	CNICUS JAPONICUS	A, H	
1494	CNIDIUM MONNIERI	A, H	
1495	CNIDIUM OFFICINALE	A, H	
1496	COBALTOUS NITRATE HEXAHYDRATE	Н	Only for use as an active homoeopathic ingredient.

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1497	COCAMIDE DEA	Е	Only for use in topical medicines for dermal application.
1498	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1499	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	Е	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%.
1500	COCAMIDOPROPYL BETAINE	Е	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be:
			a) no more than 1% in leave or 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.
1501	COCCOLOBIA UVIFERA	A, H	
1502	COCCULUS ORBICULATUS	A, H	
1503	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for excipient use only as a colour in oral and topical medicines.
1504	COCHLEARIA OFFICINALIS	A, H	
1505	COCILLANA DRY	A, H	
1506	COCILLANA POWDER	A, H	

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1507	COCO-BETAINE	Е	Only for use in topical medicines for dermal application.
1508	COCO-CAPRYLATE	Е	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.
1509	COCO-GLUCOSIDE	Е	Only for use in topical medicines for dermal 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%
1510	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.
1511	COCOA EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1512	COCOA POWDER	A, E, H	
1513	COCOGLYCERIDES	E	
1514	COCONUT	E	
1515	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1516	COCONUT OIL	A, E, H	
1517	COCOS NUCIFERA	A, E, H	

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1518	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.
1519	CODONOPSIS LANCEOLA	TA A, H	

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1520	CODONOPSIS PILOSULA	A, H	
1521	CODONOPSIS TANGSHEN	A, H	
1522	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 mus 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

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			- (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	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

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		Volume
		provide more than 100 mg of total caffeine within a 3 hour period. When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect). - (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80 mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following
		warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines'
1524	COFFEE	E, H Caffeine is a mandatory component of coffee. When the medicine is packaged for supply as a divided preparation and is for

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

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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

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

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			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).
1525	COFFEE OIL	Е	Permitted for use only in combination with 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	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%.
1527	COGNAC OIL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1528	COGNAC OIL GREEN	A, E, H	
1529	COGNAC OIL WHITE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

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

			volume
			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	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%.

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Volume 2			
			When the medicine is for internal use or oral application, a maximum recommended dose of the medicine must not provide more than 100 mg of total caffeine within a 3 hour period.
			When the maximum recommended daily dose of the medicine provides greater than 10 mg of total caffeine and the medicine is for internal use or oral application, the following warning statements are required on the label: - (ADULT) 'Adults only' (or words to that effect).
			- (CAFF) 'Contains [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine
			intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.'
			When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label:
			- (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.'
			- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1533	COLCHICUM AUTUMNALE	Н	Only for use as an active homoeopathic ingredient.

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			The total concentration of Colchicum autumnale in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
1534	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1535	COLLAGEN	E	
1536	COLLINSONIA CANADENSIS	A, H	
1537	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1538	COLOPHONY	A, E, H	
1539	COMMIPHORA HABESSINICA	A, H	
1540	COMMIPHORA KATAF	A, H	
1541	COMMIPHORA MYRRHA	A, E, H	
1542	COMMON INDIAN COBRA	Н	Only for use as an active homoeopathic ingredient.
1543	CONCENTRATED FISH OMEGA- 3 TRIGLYCERIDES	A	Only for oral use.
1544	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'.
1545	CONIFER GREEN NEEDLE COMPLEX	A	Only for topical and oral use. Must be made by petroleum

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			ether extraction of needles of the conifer species Pinus sylvestris (Scotch Pine) and Picea abies (Norwegian Spruce).
1546	CONIFER PHYTOSTEROL COMPLEX	A	
1547	CONIOSELINUM TATARICUM	A, H	
1548	CONIUM MACULATUM	Н	Only for use as an active homoeopathic ingredient. The homoeopathic potency of Conium maculatum in the final medicine must be 12X or greater.
1549	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%.
1550	CONYZA CANADENSIS	A, H	
1551	COPAIBA OIL	A, E, H	
1552	COPAIFERA LANGSDORFFII	A, E, H	
1553	COPERNICIA CERIFERA	A, E, H	
1554	COPOVIDONE	Е	
1555	COPPER	Н	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%.
1556	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.

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			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) 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
1558	COPPER (II) LYSINATE	A, H	not contain more than 5mg of copper. Copper is a mandatory
1336			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.
1559	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1560	COPPER CHLOROPHYLL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
1561	COPPER CHLOROPHYLLIN	Е	Only for use as a colour in oral and topical medicines.
1562	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%.
1563	COPPER TRIPEPTIDE-1	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1564	COPTIS CHINENSIS	A, H	
1565	COPTIS JAPONICA	A, H	
1566	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%.
1567	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1568	CORIANDER DRY	A, H	

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1570	CORIANDER POWDER	A, H	
1571	CORIANDRUM SATIVUM	A, E, H	
1572	CORMUS DOMESTICA	A, H	
1573	CORN GLYCERIDES	Е	
1574	CORN SILK DRY	A, H	
1575	CORN SILK POWDER	A, H	
1576	CORN SYRUP	Е	Permitted for use only in combination with 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	CORN SYRUP SOLIDS	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1578	CORNUS FLORIDA	A, H	
1579	CORNUS OFFICINALIS	A, H	
1580	CORTISONE ACETATE	Н	Only available as an active homoeopathic ingredient.
1581	CORYDALIS AMBIGUA	A, E, H	
1582	CORYDALIS BUNGEANA	A, H	
1583	CORYDALIS CAVA	A, H	
1584	CORYDALIS FABACEA	A, H	
1585	CORYDALIS FORMOSA	A, H	
1586	CORYDALIS TURTSCHANINOVII	A, H	
1587	CORYLUS AMERICANA	A, H	
1588	CORYLUS AVELLANA	A, H	
1589	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

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			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	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

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			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.
1591	COSMOS BIPINNATUS	A, H	
1592	COSTUS ROOT OIL	A, H	
1593	COSTUS SPICATUS	A, H	
1594	COTTONSEED OIL	A, E, H	
1595	COUCH GRASS RHIZOME DRY	A, H	
1596	COUCH GRASS RHIZOME POWDER	A, H	
1597	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.
1598	CRANBERRY	Е	
1599	CRATAEGUS CUNEATA	A, E, H	
1600	CRATAEGUS GERMANICA	A, H	
1601	CRATAEGUS LAEVIGATA	A, E, H	
1602	CRATAEGUS MONOGYNA	A, E, H	
1603	CRATAEGUS PINNATIFIDA	A, E, H	
1604	CRATEVA MAGNA	A, E, H	
1605	CREATINE	A, E	
1606	CREATINE MONOHYDRATE	A, E	
1607	CREATINE PHOSPHATE	A, E	
1608	CREATININE	Е	Only for use in topical medicines for dermal application and not for use in

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			medicines intended for use in the eye.
			The concentration in the medicine must be no more than 0.2%.
1609	CREOSOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1610	CREOSOTE	Н	Only for use as an active homoeopathic ingredient. Creosote must not be derived from coal or beechwood.
1611	CRESOL	Е	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%.
1612	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%.
1613	CROCUS SATIVUS	A, E, H	When Crocus sativus is used as an excipient: (a) the ingredient must only be included in medicines when in combination with other permitted ingredients as a

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			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.
1614	CROSCARMELLOSE SODIUM	E	
1615	CROSPOVIDONE	E	
1616	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1617	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1618	CRYPTOMERIA JAPONICA	A, H	
1619	CUBEB OIL	A, H	
1620	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%.
1621	CUCUMBER	Е	
1622	CUCUMIS MELO	A, H	
1623	CUCUMIS SATIVUS	A, E, H	
1624	CUCURBITA MAXIMA	A, E, H	
1625	CUCURBITA MOSCHATA	A, H	
1626	CUCURBITA PEPO	A, E, H	
1627	CULLEN CORYLIFOLIUM	A, H	
1628	CUMIC ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1629	CUMIN OIL	A, E, H	
1630	CUMINALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1631	CUMINUM CYMINUM	A, H	
1632	CUMINYL NITRILE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1633	CUPRESSUS ARIZONICA	A, H	
1634	CUPRESSUS FUNEBRIS	A, E, H	
1635	CUPRESSUS SEMPERVIRENS	A, E, H	
1636	CUPRIC ACETATE MONOHYDRATE	Н	Only for use as an active homoeopathic ingredient.
1637	CUPRIC ARSENITE	Н	Only for use as an active homoeopathic ingredient.
1638	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

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			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.
1639	CUPRIC CITRATE HEMIPENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric citrate hemipentahydrate. The percentage of copper from cupric citrate hemipenthydrate should be calculated based on the molecular weight of cupric citrate hemipenthydrate. The medicine must not contain more than 750 micrograms of copper from cupric citrate hemipentahydrate per the recommended daily dose OR the medicine must not contain more than 2.13 milligrams of cupric citrate hemipentahydrate per the recommended daily dose.
1640	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%.
1641	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

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			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%.
1642	CUPRIC SULFATE MONOHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate monohydrate. The percentage of copper from cupric sulfate monohydrate should be calculated based on the molecular weight of cupric sulfate monohydrate. When for internal use the
			maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.
1643	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

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			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 pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.
1644	CURCULIGO ORCHIOIDES	A 11	
1645	CURCUMA AROMATICA	A, H A, H	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.' 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: (a) 36 mg for children from 2-3 years (inclusive); (b) 48 mg for children from 4-11 years (inclusive); and (c) 123 mg for children from 12-17 years (inclusive). Not permitted for use in children aged below 2 years.
1646	CURCUMA LONGA	A, E, H	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

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			you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.' 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: (a) 36 mg for children from 2-3 years (inclusive); (b) 48 mg for children from 4-11 years (inclusive); and (c) 123 mg for children from 12-17 years (inclusive). Not permitted for use in children aged below 2 years.
1647	CURCUMA ZANTHORRHIZA	A, H	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.' 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: (a) 36 mg for children from 4-11 years (inclusive); (b) 48 mg for children from 4-11 years (inclusive); and (c) 123 mg for children from 12-17 years (inclusive). Not permitted for use in children aged below 2 years.

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1648	CURCUMA ZEDOARIA	A, H	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.'
			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:
			(a) 36 mg for children from 2-3 years (inclusive);
			(b) 48 mg for children from 4- 11 years (inclusive); and
			(c) 123 mg for children from 12-17 years (inclusive).
			Not permitted for use in children aged below 2 years.
1649	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
			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.'
			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:

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			(a) 36 mg for children from 2-3 years (inclusive); (b) 48 mg for children from 4-11 years (inclusive); and (c) 123 mg for children from 12-17 years (inclusive). Not permitted for use in children aged below 2 years.
1650	CUSCUTA EPITHYMUM	A, H	
1651	CUSCUTA EUROPAEA	A, H	
1652	CUSCUTA HYGROPHILAE	A, H	
1653	CUSCUTA RACEMOSA	A, H	
1654	CUSPARIA FEBRIFUGA	A, H	
1655	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1656	CYANOCOBALAMIN	A, E, H	
1657	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	Е	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%.
1658	CYATHULA OFFICINALIS	A, H	
1659	CYCLAMEN ALDEHYDE	Е	Only for use as an excipient ingredient in topical medicines.
1660	CYCLAMEN PURPURASCENS	A, H	
1661	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

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			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'.
1662	CYCLOHEXADECENONE-8	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1663	CYCLOHEXANE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1664	CYCLOHEXANE, 1-ETHENYL-1- METHYL-2-(1- METHYLETHENYL)-4-(1-	Е	Permitted for use only in combination with other

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	METHYLETHYL)-, DIDEHYDRO DERIV.		permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1665	CYCLOHEXANEETHANOL	Е	Permitted for use only in combination with 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 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%.
1667	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%.
1668	CYCLOHEXYL PHENETHYL ETHER	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
1669	CYCLOHEXYL SALICYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1670	CYCLOHEXYLETHYL ACETATE	Е	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%.
1671	CYCLOMETHICONE	Е	Only for use as an excipient ingredient in topical medicines.
1672	CYCLOPENTADECANONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1673	CYDONIA OBLONGA	A, H	
1674	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

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			medicine must not be more than 5%.
1675	CYMBOPOGON MARTINI	A, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon martini and the concentration of aldehydes calculated as citral in the medicine must be no more than 5%.
1676	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%.
1677	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%.
1678	CYNANCHUM ATRATUM	A, H	
1679	CYNANCHUM STAUNTONII	A, E, H	
1680	CYNARA SCOLYMUS	A, E, H	
1681	CYNODON DACTYLON	A, E, H	
1682	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1683	CYPERUS LONGUS	A, H	
1684	CYPERUS ROTUNDUS	A, H	
1685	CYPRESS OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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1686	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1687	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.
1688	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.
1689	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.

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1690	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.
1691	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%.
1692	D-ALPHA-TOCOPHEROL	A, E	
1693	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1694	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1695	D-ALPHA-TOCOPHERYL PHOSPHATES	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3%.
1696	D-BORNEOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1697	D-CARVONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1698	D-FENCHONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1699	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'.
1700	D-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1701	D-PULEGONE	Е	Permitted for use only in combination with other

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			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%.
1702	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.
1703	DACTYLIS GLOMERATA	A, H	
1704	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1705	DAEMONOROPS DRACO	A, E, H	
1706	DAHLIA PINNATA	A, H	
1707	DALBERGIA ODORIFERA	A, H	
1708	DAMIANA LEAF POWDER	A	
1709	DANDELION LEAF DRY	A, H	
1710	DANDELION LEAF POWDER	A, H	
1711	DANDELION ROOT DRY	A, H	
1712	DANDELION ROOT POWDER	A, H	
1713	DAPHNE GENKWA	A, H	
1714	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1715	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

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			300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1716	DAUCUS CAROTA	A, E, H	
1717	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%.
1718	DEA-OLETH-3 PHOSPHATE	Е	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).
1719	DECAHYDRO-1,1,7-TRIMETHYL-3A,7-METHANO-3AH-CYCLOPENTACYCLOOCT-3-YL FORMATE	Е	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

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			formate must not be more than 1% of the total medicine.
1720	DECAHYDRO-2,2,6,6,7,8,8- HEPTAMETHYL-2H-INDENO(4,5- B) FURAN	Е	Permitted for use only in combination with 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- NAPHTHYLACETATE	Е	Permitted for use only in combination with 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	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%.
1723	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%.
1724	DECALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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1725	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%
1726	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%.
1727	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.
1728	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%.
1729	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1730	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%.
1731	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1732	DECYL OLEATE	Е	Only for use in topical medicines for dermal application.
1733	DECYLENE GLYCOL	Е	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%.
1734	DEER ANTLER CARTILAGE	Н	Only for use as an active homoeopathic ingredient.
1735	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

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			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.
1736	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

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			(New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1737	DEERTONGUE ABSOLUTE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1738	DEHYDROACETIC ACID	Е	Only for use in topical medicines for dermal application.
1739	DEHYDROMENTHOFUROLACT ONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1740	DEHYDROXANTHAN GUM	Е	Only for use in topical medicines for dermal 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%.
1741	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1742	DELTA-DAMASCONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
1743	DELTA-DECALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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-DODECALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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-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%.
1746	DELTA-OCTALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1747	DELTA-TETRADECALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1748	DELTA-TOCOPHEROL	Е	
1749	DELTA-UNDECALACTONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in 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%.
1750	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1751	DENATONIUM BENZOATE	Е	
1752	DENDROBIUM NOBILE	A, H	
1753	DESCURAINIA SOPHIA	A, H	
1754	DESMODIUM STYRACIFOLIUM	A, H	
1755	DEVIL'S CLAW TUBER DRY	A, H	
1756	DEVIL'S CLAW TUBER POWDER	A, H	
1757	DEXPANTHENOL	A, E	
1758	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%.

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1759	DEXTRAN 40	A, E	
1760	DEXTRATES	Е	
1761	DEXTRIN	E	
1762	DEXTRIN PALMITATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than
1763	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.
1764	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%.
1765	DI-C12-15 ALKYL FUMARATE	Е	Only for use in topical medicines for dermal 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%.
1766	DI-N-PROPYL ISOCINCHOMERONATE	Е	Only for use in topical medicines for dermal application.

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			The concentration in the medicine must be no more than 25%.
1767	DI-PPG-3 MYRISTYL ETHER ADIPATE	Е	Only for use in topical medicines for dermal 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%.
1768	DIACETIN	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1770	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1771	DIACETYLATED MONOGLYCERIDES	Е	Permitted for use only in combination with other

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			permitted ingredients as a coating solution.
1772	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines
1773	DIANTHUS SUPERBUS	A, H	
1774	DIAZOLIDINYL UREA	Е	Only for use in topical medicines for dermal application.
1775	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1776	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 o older provides 350 mg or more total magnesium from inorganic magnesium salts;

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volume 2			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.
1777	DIBASIC POTASSIUM PHOSPHATE	A, E, H	When used as an active ingredient and the medicine is intended as a mineral supplementation, potassium is a mandatory component of dibasic potassium phosphate.
			When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5.
			When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
1778	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.
1779	DIBASIC SODIUM PHOSPHATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a

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			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.
1780	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.
1781	DIBASIC SODIUM PHOSPHATE DODECAHYDRATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate 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.
1782	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

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			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.
1783	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.
784	DIBENZYL KETONE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1785	DIBUTYL ADIPATE	Е	Only for use in topical medicines for dermal application.
1786	DIBUTYL SEBACATE	Е	
1787	DIBUTYLAMINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1788	DICAPRYLYL CARBONATE	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1789	DICAPRYLYL ETHER	Е	Only for use in topical medicines for dermal application.
1790	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%.
1791	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%.
1792	DICHLOROBENZYL ALCOHOL	E	
1793	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.
1794	DICTAMNUS ALBUS	A, H	
1795	DICTAMNUS DASYCARPUS	A, H	
1796	DICYCLOHEXYL DISULFIDE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1797	DIEFFENBACHIA SEGUINE	Н	Only for use as an active homoeopathic ingredient.
1798	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1799	DIETHYL CITRACONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1800	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.
1801	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

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			medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1802	DIETHYL PHTHALATE	Е	
1803	DIETHYLAMINE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1804	DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1805	DIETHYLAMINOMETHYLCOUM ARIN	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1806	DIETHYLDIMETHYL-2- CYCLOHEXENONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1807	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%.
1808	DIETHYLENE GLYCOL MONOETHYL ETHER	Е	Only for use in topical medicines for dermal application.
1809	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%.
1810	DIETHYLHEXYL SEBACATE	Е	Only for use in topical medicines for dermal application.
1811	DIETHYLHEXYL SYRINGYLIDENEMALONATE	Е	Only for use in topical medicines for dermal 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%.
1812	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%.

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

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			The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1813	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.'
1814	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%.
1815	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%.
1816	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%.
1817	DIGLYCOL/CHDM/ISOPHTHALA TES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1818	DIHEXYL FUMARATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1819	DIHYDRO JASMONE	Е	Permitted for use only in combination with 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 TERPINYLACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1821	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%.
1822	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%.
1823	DIHYDRO-ISOJASMONE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1824	DIHYDROACTINIDIOLIDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1825	DIHYDROAMBRETTOLIDE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1826	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'.
1827	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%.

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

1828	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%.
1829	DIHYDROCUMINYL ALCOHOL	Е	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1830	DIHYDROEUGENOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1831	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	Е	Only for use in topical medicines for dermal 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%.
1832	DIHYDROINDENYL-2,4- DIOXANE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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

			medicine must be no more than 1%.
1833	DIHYDROLINALOOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1834	DIHYDROMYRCENOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a
1835	DIHYDROMYRCENYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1836	DIHYDROXYACETONE	Е	Only for use in topical medicines for dermal application.
1837	DIISOPROPYL ADIPATE	Е	Only for use in topical medicines for dermal 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%.

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

1838	DIISOPROPYL SEBACATE	Е	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%.
1839	DIISOSTEARYL DIMER DILINOLEATE	Е	Only for use in topical medicines for dermal application.
1840	DILAURYL THIODIPROPIONATE	Е	Only for use in topical medicines for dermal application.
1841	DILL HERB OIL	A, E, H	
1842	DILL SEED OIL	A, E, H	
1843	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%.
1844	DIMETHICONE 12500	Е	
1845	DIMETHICONE 4000	Е	Only for use in topical medicines for dermal 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%.
1846	DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.

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

1847	DIMETHICONE SILYLATE	Е	Only for use in topical medicines for dermal 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%.
1848	DIMETHICONE/METHICONE COPOLYMER	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
1849	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	Е	Only for use in topical medicines for dermal 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%.
1850	DIMETHYL 3-CYCLOHEXENE-1- CARBOXALDEHYDE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1851	DIMETHYL 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%.

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

1852	DIMETHYL BENZYL CARBINOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than
1853	DIMETHYL BENZYL CARBINYL	E	Permitted for use only in
1000	ACETATE		combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a 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 BUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1855	DIMETHYL BENZYL CARBINYL ISOBUTYRATE	Е	Permitted for use only in combination with 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 PHENYLETHYL CARBINOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.

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

			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1857	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%.
1858	DIMETHYL POLYSILOXANE	Е	Permitted for use only in combination with 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 SUCCINATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1860	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%.
1861	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.

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

1862	DIMETHYL SULFOXIDE	Е	Permitted for use only in combination with 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	DIMETHYLACETAL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a
			medicine must be no more than 5%.
1864	DIMETHYLCYCLOHEXYLETHO XY ISOBUTYLPROPANOATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1865	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1866	DIMETHYLOL DIMETHYL HYDANTOIN	Е	Only for use in topical medicines for dermal application.
1867	DIMETICONE 1.5	Е	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%.
1868	DIMETICONE 10	Е	
1869	DIMETICONE 100	Е	Only for use in topical medicines for dermal application.

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1870	DIMETICONE 1000	E	
1871	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%
1872	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%.
1873	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1874	DIMETICONE 200	Е	Only for use in topical medicines for dermal application.
1875	DIMETICONE 30	Е	Only for use in topical medicines for dermal 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%.
1876	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.
1877	DIMETICONE 360	Е	Only for use in topical medicines for dermal application.

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1878	DIMETICONE 450	Е	Only for use in topical medicines for dermal application.
1879	DIMETICONE 5	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1880	DIMETICONE 50	E	Only for use in topical medicines for dermal application.
1881	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1882	DIMETICONE 6	Е	Only for use in topical medicines for dermal 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%.
1883	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1884	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1885	DIMETICONE CROSSPOLYMER-3	Е	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%.

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

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1886	DIMETICONE/PEG-10/15 CROSSPOLYMER	Е	Only for use in topical medicines for dermal 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%.
1887	DIMETICONOL	Е	Only for use in topical medicines for dermal application.
1888	DIMETICONOL STEARATE	Е	Only for use in topical medicines for dermal 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%.
1889	DIMETICONOL/PROPYLSILSESQ UIOXANE/SILICATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 10%.
1890	DIMOCA PRUS LONGAN	л Ш	
1891	DIMOCARPUS LONGAN DIOCTYL ADIPATE	A, H E	Only for use in topical medicines for dermal application.
1892	DIOCTYL MALEATE	Е	Only for use in topical medicines for dermal application.
1893	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal application.
1894	DIOCTYL TEREPHTHALATE	Е	Permitted for use only in combination with other

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

			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1895	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%
1896	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.
1897	DIOSCOREA COLLETTII	A, H	
1898	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1899	DIOSCOREA JAPONICA	A, H	
1900	DIOSCOREA OPPOSITIFOLIA	A, H	
1901	DIOSCOREA POLYSTACHYA	A, H	
1902	DIOSCOREA SEPTEMLOBA	A, H	
1903	DIOSCOREA VILLOSA	A, E, H	
1904	DIOSPYROS KAKI	A, E, H	
1905	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:

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		Volume
		- (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).
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRA TE	Е	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%.
DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAISOSTEARATE	E	Only for use in topical medicines for dermal 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%.
DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE	Е	Only for use in topical medicines for dermal 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%.
DIPHENYL DIMETHICONE	Е	Only for use in topical medicines for dermal application.
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%.
	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAISOSTEARATE DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE DIPHENYL DIMETHICONE	HEXACAPRYLATE/HEXACAPRA TE DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TE TRAISOSTEARATE DIPENTAERYTHRITYL TRI- POLYHYDROXYSTEARATE E DIPHENYL DIMETHICONE E

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1911	DIPHENYL OXIDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1912	DIPOTASSIUM GLYCYRRHIZATE	Е	Only for use in topical medicines for dermal 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%.
1913	DIPROPIONYL	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1914	DIPROPYLENE GLYCOL	Е	Only for use in topical medicines for dermal application.
1915	DIPROPYLENE GLYCOL DIBENZOATE	Е	Only for use in topical medicines for dermal 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%.
1916	DIPROPYLENE GLYCOL SALICYLATE	Е	Only for use in topical medicines for dermal application.

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1917	DIDCACHE ACDED	A 11	
1917	DIPSACUS ASPER DIPSACUS JAPONICUS	A, H A, H	
1919	DIPTERYX ODORATA	A, E, H	When used as an active ingredient coumarin is a mandatory component of Dipteryx odorata and the concentration of coumarin in the medicine must be no more than 0.001%.
1920	DISODIUM ASCORBYL SULFATE	Е	Only for use in topical medicines for dermal application.
1921	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1922	DISODIUM COCOAMPHODIPROPIONATE	Е	Only for use in topical medicines for dermal 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%.
1923	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%.
1924	DISODIUM EDETATE	Е	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%.
1925	DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended

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

			for use in the eye or on damaged skin.
			The concentration in the medicine must be no more than 1%.
1926	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%.
1927	DISODIUM INOSINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1928	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%.
1929	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%.
1930	DISODIUM NADH	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.

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1931	DISODIUM OLEAMIDO PEG-2 SULFOSUCCINATE	Е	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%.
1932	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).
1933	DISODIUM PYROPHOSPHATE	E	Disodium pyrophosphate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing disodium pyrophosphate must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 2.4 g of phosphorus. The following statement (or words to the same effect) is required on the medicine label:

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			- (PHOS) 'Contains phosphorus'.
1934	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%.
1935	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%.
1936	DISODIUM STEAROYL GLUTAMATE	Е	Only for use in topical medicines for dermal 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%.
1937	DISPERSIBLE CELLULOSE	E	
1938	DISTARCH PHOSPHATE	Е	Only for use in topical medicines for dermal 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%.
1939	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%.

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1940	DISTEARETH-6 DIMONIUM CHLORIDE	Е	Only for use in topical medicines for dermal application.
1941	DISTEARYL PHTHALIC ACID AMIDE	Е	Only for use in topical medicines for dermal 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	DISTEARYLDIMONIUM CHLORIDE	Е	Only for use in topical medicines for dermal 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%.
1943	DIVINYLDIMETHICONE/DIMET HICONE 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%.
1944	DL-ALPHA-TOCOPHEROL	A, E	
1945	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1946	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1947	DL-BORNEOL	Е	
1948	DL-LIMONENE	Е	Only for use in topical medicines for dermal application.
1949	DL-THREONINE	A, E	
1950	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.

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1951 1952	DOCUSATE SODIUM DODECAHYDRO-3A,6,6,9A-	E E	Permitted for use only in
	TETRAMETHYLNAPHTHO(2,1-B)FURAN		combination with other permitted ingredients as a fragrance. If used in a fragrance the total
			fragrance concentration in a medicine must be no more than 1%.
1953	DODECANENITRILE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1954	DODECENE	Е	Only for use in topical medicines for dermal 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%.
1955	DODECYL ACETATE	Е	Permitted for use only in combination with 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	DODECYL ISOBUTYRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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1957	DOLICHOS LABLAB	A, H	
1958	DOLOMITE	A, E, H	
1959	DRACAENA DRACO	A, H	
1960	DRIED BUTTERMILK	Е	
1961	DRIED CALCIUM SULFATE	A, E, H	
1961	DRIED MAGNESIUM SULFATE DRIED MAGNESIUM SULFATE	A, E, H A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g. Magnesium is a mandatory component of dried magnesium sulfate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total
			magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;
			the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause
			diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.

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

1963	DRIMIA INDICA	A, H	
1964	DRIMIA MARITIMA	A, H	
1965	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).
1966	DROSERA ANGLICA	A, H	
1967	DROSERA BURMANNI	A, H	
1968	DROSERA INTERMEDIA	A, H	
1969	DROSERA RAMENTACIA	A, H	
1970	DROSERA ROTUNDIFOLIA	A, E, H	
1971	DROSERA ROTUNDIFOLIA MIS	A, H	
1972	DRYNARIA FORTUNEI	A, H	
1973	DRYOBALANOPS AROMATICA	A, H	
1974	DRYOPTERIS FILIX-MAS	Н	Only for use as an active homoeopathic ingredient.
1975	DULACIA INOPIFLORA	A, H	
1976	DUNALIELLA SALINA	A, E, H	
1977	DURVILLAEA ANTARCTICA EXTRACT	Е	Only for use in topical medicines for dermal application.
			The concentration in the medicine must be no more than 0.1%.
1978	DWARF PINE-NEEDLE OIL	Е	Permitted for use only in combination with other

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

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1070	DVGDV ANA AMBROGRAPES		permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1979	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1980	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).
1981	ECHINACEA ANGUSTIFOLIA	A, E, H	
1982	ECHINACEA PALLIDA	A, E, H	
1983	ECHINACEA PURPUREA	A, E, H	
1984	ECHINOPA SPINOSISSIMUS	A, H	
1985	ECLIPTA PROSTRATA	A, H	
1986	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%.

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

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

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

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			medicine must be no more than 1%.
2001	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%.
2002	ELEMOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2003	ELEOCHARIS DULCIS	A, H	
2004	ELETTARIA CARDAMOMUM	A, E, H	
2005	ELEUTHEROCOCCUS NODIFLORUS	A, H	
2006	ELEUTHEROCOCCUS ROOT DRY	A, H	
2007	ELEUTHEROCOCCUS ROOT POWDER	A, H	
2008	ELEUTHEROCOCCUS SENTICOSUS	A, H	
2009	ELSHOLTZIA SPLENDENS	A, H	
2010	ELYMUS REPENS	A, E, H	
2011	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

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

			that the emus from which the raw material was extracted were healthy and fit for human consumption.
2012	EMULSIFYING WAX	Е	
2013	ENOXOLONE	Е	Only for use in topical medicines for dermal application.
2014	ENZYME MODIFIED CREAM	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2015	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 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'.
2016	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

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

			10 mg/kg or 10 mg/L or 0.001%.
2017	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%.
2018	EPIGAEA REPENS	A, H	
2019	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.
2020	EPILOBIUM PALUSTRE	A, H	
2021	EPILOBIUM PARVIFLORUM	A, H	
2022	EPIMEDIUM BREVICORNU	A, H	
2023	EPIMEDIUM GRANDIFLORUM	A, H	
2024	EPIMEDIUM SAGITTATUM	A, H	
2025	EQUISETUM ARVENSE	A, E, H	
2026	EQUISETUM HIEMALE	A, H	
2027	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

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

2028	ERGOTHIONEINE	Е	Only for use in topical medicines for dermal 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%.
2029	ERIGERON BREVISCAPUS	A, H	
2030	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%.
2031	ERIOCAULON BUERGERIANUM	A, H	
2032	ERIODICTYON CRASSIFOLIUM	A, H	
2033	ERIODICTYON GLUTINOSUM	A, H	
2034	ERODIUM CICUTARIUM	A, H	
2035	ERUCA SATIVA	A, H	
2036	ERYTHORBIC ACID	Е	
2037	ERYTHRITOL	Е	Only for use in topical medicines for dermal 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%.
2038	ERYTHROSINE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2039	ERYTHROSINE ALUMINIUM LAKE	Е	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.

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

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2040	ERYTHRULOSE	Е	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
2041	ESCHSCHOLZIA CALIFORNICA	A, H	
2042	ESTRONE	Н	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%.
2043	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.
2044	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.
2045	ETHER	E	The concentration of ether in the medicine must be no more than 10%.

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2046	ETHOHEXADIOL	Е	Only for use in topical medicines for dermal application. The total concentration of ethohexadiol in the medicine must not be more than 5%.
2047	ETHOXYLATED HYDROGENATED CASTOR OIL	Е	
2048	ETHOXYLATED NONYLPHENOL	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2049	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%.
2050	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) ACETATE	Е	Permitted for use only in combination with 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 (3AR,4S,7R,7AR)-REL- OCTAHYDRO-4,7- METHANO[3AH]INDENE-3A- CARBOXYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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

2052	ETHYL 2,3,6,6-TETRAMETHYL- 2- CYCLOHEXENECARBOXYLATE	Е	Permitted for use only in combination with 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 2,6,6,TRIMETHYL-1,3- CYCLOHEXADIENE-1- CARBOXYLATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2054	ETHYL 2-BUTENOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2055	ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE	Е	Permitted for use only in combination with 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-HEXYL ACETOACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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2057	ETHYL 2-METHYLBUTYRATE	Е	Permitted for use only in
			combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a 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 2-METHYLPENTANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2059	ETHYL 3-HEXENOATE	Е	Permitted for use only in combination with 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-HYDROXYBUTYRATE	Е	Permitted for use only in combination with 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- HYDROXYHEXANOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.
			If used in a flavour the total flavour concentration in a

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

			medicine must be no more than 5%.
2062	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%.
2063	ETHYL 3- METHYLTHIOPROPIONATE	Е	Permitted for use only in combination with 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 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%.
2065	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%.
2066	ETHYL ACETOACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2067	ETHYL ACRYLATE	E	
2068	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%.
2069	ETHYL ANTHRANILATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2070	ETHYL BENZOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2071	ETHYL 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%.
2072	ETHYL BUTYLACETYLAMINOPROPION ATE	E	Only for use in topical medicines for dermal application. The concentration

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

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			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)'.
2073	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%.
2074	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%.
2075	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%.
2076	ETHYL CAPRYLATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour.

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

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2083	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%.
2084	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%.
2085	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%.
2086	ETHYL LEVULATE	E	Permitted for use only in combination with other

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			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 LEVULINATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2088	ETHYL LINALOOL	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2089	ETHYL LINALYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2090	ETHYL LINOLEATE	Е	Only for use in topical medicines for dermal application.
2091	ETHYL LINOLENATE	Е	Only for use in topical medicines for dermal application.
2092	ETHYL MACADAMIATE	Е	Only for use in topical medicines for dermal application and not to be

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

			included in medicines intended for use in the eye.
			The concentration in the medicine must be no more than 10%.
2093	ETHYL MALTOL	Е	
2094	ETHYL MENTHANE CARBOXAMIDE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2095	ETHYL METHACRYLATE	Е	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.
2096	ETHYL METHYLPHENYLGLYCIDATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2097	ETHYL 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%.
2098	ETHYL MYRISTATE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2099	ETHYL OLEATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2100	ETHYL ORTHO- METHOXYBENZYL ETHER	Е	Permitted for use only in combination with other permitted ingredients as a fragrance.
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2101	ETHYL OXYHYDRATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2102	ETHYL PALMITATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			Volume
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2103	ETHYL 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%.
2104	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%.
2105	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%.
2106	ETHYL PHENYLGLYCIDATE	Е	Ethyl phenylglycidate must only be used in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.

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			The concentration of ethyl phenylglycidate in a medicine must not be more than 0.0000024% w/w (equivalent to 24 parts per billion).
2107	ETHYL PROPIONATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2108	ETHYL PYRUVATE	Е	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.
2109	ETHYL RICINOLEATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2110	ETHYL 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%.

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

			Volume
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2111	ETHYL SEBACATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2112	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%.
2113	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%.
2114	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%.
2115	ETHYL TRANS-2, CIS-4- DECADIENOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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2116	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.
2117	ETHYL TRANS-3-HEXENOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2118	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%.
2119	ETHYL VALERATE	Е	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2120	ETHYL VANILLIN	E	
2121	ETHYL-2-METHYL-1,3- DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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			medicine must be no more than 1%.
2122	ETHYL-2-METHYL-4- PENTENOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2123	ETHYL-2-METHYLPENTENOATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2124	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	Е	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.002%.
2125	ETHYLCELLULOSE	Е	
2126	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%.
2127	ETHYLENE GLYCOL	Е	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%.

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2128	ETHYLENE GLYCOL MONOPALMITOSTEARATE	Е	Only for use in topical medicines for dermal application.
2129	ETHYLENE/ACRYLIC ACID COPOLYMER	Е	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%.
2130	ETHYLENE/VINYL ACETATE COPOLYMER	Е	Only for use in topical medicines for dermal 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%.
2131	ETHYLENEDIAMINE	Е	Only for use in topical medicines for dermal application.
2132	ETHYLENEDIAMINE/HYDROGE NATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	Е	Only for use in topical medicines for dermal 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%.
2133	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	Е	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%.

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2134	ETHYLHEXYL BENZOATE	Е	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%.
2135	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%.
2136	ETHYLHEXYL TRIAZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2137	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%.

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2138	ETIDRONIC ACID	Е	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2139	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.
2140	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%:

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

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

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			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 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.
2143	EUCALYPTUS OIL	A, E, H	Cineole is a mandatory component of eucalyptus oil. When the concentration of eucalyptus oil in the preparation is more than 25%, the nominal capacity of the

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			Volume
			container must not be more than 25 millilitres. When the concentration of eucalyptus 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, 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); and - (NTAKEN) 'Not to be taken'. When the concentration of eucalyptus oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, 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); and - (NTAKEN) 'Not to be taken'.
2144	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

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			c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
2145	EUCALYPTUS ROSTRATA	A, E, H	Cineole is a mandatory component of Eucalyptus rostrata. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15

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			to 25 millilitres the medicine must also have a child resistant closure.
2146	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
2147	EUCOMMIA ULMOIDES	A, H	
2148	EUGENOL	Е	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

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			more than 25%, the nominal capacity of the container must be no more than 25 mL. b) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' c) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2149	EUGENYL ACETATE	Е	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total
			flavour concentration in a medicine must be no more than 5%.
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2150	EUGLENA GRACILIS WHOLE CELL DRY	A	The route of administration for medicines that contain Euglena

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			gracilis whole cell dry must be limited to oral.
			The maximum recommended daily dose of the medicine must not provide more than:
			(a) 100 mg of Euglena gracilis whole cell dry for children aged between 1 and 3 years (inclusive);
			(b) 150 mg of Euglena gracilis whole cell dry for children aged between 4 and 8 years (inclusive);
			(c) 225 mg of Euglena gracilis whole cell dry for individuals aged between 9 and 18 years (inclusive); and
			(d) 375 mg of Euglena gracilis whole cell dry for adults aged 19 years or older.
			The following warning statement (or words to the same effect) must be included on the medicine label:
			- (BABY2) 'Not suitable for infants under the age of twelve months'.
2151	EUONYMUS ATROPURPUREUS	A, H	
2152	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
2153	EUPATORIUM FORTUNEI	A, H	
2154	EUPATORIUM JAPONICUM	A, H	
2155	EUPATORIUM PERFOLIATUM	A, H	
2156	EUPATORIUM PURPUREUM	A, H	
2157	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines.
2158	EUPHORBIA CYPARISSIAS	A, H	
2159	EUPHORBIA DRY	A, H	
2160	EUPHORBIA HETERODOXA	A, H	
2161	EUPHORBIA HIRTA	A, H	

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2162	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%.
2163	EUPHORBIA PEKINENSIS	A, H	
2164	EUPHORBIA PEPLUS	Н	Only for use as an active homoeopathic ingredient.
2165	EUPHORBIA POWDER	A, H	
2166	EUPHORBIA RESINIFERA	A, H	
2167	EUPHORBIA SIEBOLDIANA	A, H	
2168	EUPHRASIA OFFICINALIS	A, H	
2169	EUROPEAN GARDEN SPIDER	Н	Only for use as an active homoeopathic ingredient.
2170	EUROPEAN HORNET	Н	Only for use as an active homoeopathic ingredient.
2171	EURYALE FEROX	A, H	
2172	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'.
2173	EVENING PRIMROSE OIL	A, E, H	
2174	EVERNIA PRUNASTRI EXTRACT	E E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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		medicine

Volume 2		
	If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.	