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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
739	BACILLUS COAGULANS	A	Only to be used in a medicine where Pathway International Pty Ltd (Client ID 23355), 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 2 September 2021. Only permitted for use in medicines: - limited to oral routes of administration; and - when the strain of Bacillus coagulans is confirmed to be Microbial Type Culture Collection (MTCC) accession number 5260. The strain of Bacillus coagulans must be declared on the label. The maximum recommended daily dose of the medicine must not provide more than 6 billion CFU of Bacillus coagulans. The following warning statements are required on the medicine label: - (CHILD2) ‘Not suitable for

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			children'. - (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).'
740	BACKHOUSIA CITRIODORA	A, E, H	The herbal substance must be derived from leaf oil only. Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10g/kg or 10g/L or 1%. The medicine requires the following warning statements on the medicine label: - (IRRIT) 'If irritation develops - discontinue use' - (CHILD3) 'Use in children under 12 years is not recommended' - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect).
741	BACOPA MONNIERI	A, H	
742	BALLOTA NIGRA	A, H	
743	BALM OF GILEAD BUD DRY	A, H	
744	BALM OF GILEAD BUD POWDER	A, H	
745	BALSAM COPAIBA	E	Permitted for use only in

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			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
746	BAMBUSA BREVIFLORA	A, E, H	
747	BAMBUSA TEXTILIS	A, H	
748	BANANA	E	
749	BANANA DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
750	BAPTISIA CONFUSA	A, H	
751	BAPTISIA TINCTORIA	A, H	
752	BARBAREA VULGARIS	A, H	
753	BARIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
754	BARIUM CHLORIDE	H	Only for use as an active homoeopathic ingredient.
755	BARIUM SULFATE	E	Only for use in topical medicines for dermal application.
756	BARLEY	E	Gluten is a mandatory

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			component of Barley when the route of administration is other than topical and mucosal.
757	BARLEY BRAN	E	Gluten is a mandatory component of Barley bran when the route of administration is other than topical and mucosal.
758	BARLEY GERM	E	Gluten is a mandatory component of Barley germ when the route of administration is other than topical and mucosal.
759	BARLEY LEAF	E	
760	BASIC BUTYLATED METHACRYLATE COPOLYMER	E	Only for use in oral medicines.
761	BASIC FUCHSIN	E	Only for use as a colour ingredient in topical medicines for dermal application.
762	BASIC RED 1	E	Only for use as a colour in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
763	BASIC VIOLET 11:1	E	Only for use as a colour in topical medicines for dermal application and not intended

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			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
764	BASIL OIL COMOROS	A, E, H	Methyl chavicol is a mandatory component of Basil oil Comoros. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25mL. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25mL or less, a restricted flow insert must fitted on the container, and the medicine requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
765	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

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
766	BASSIA SCOPARIA	A, H	
767	BATYL ALCOHOL	E	Only for use in topical medicines for dermal application.
768	BAY LEAF	E	
769	BAY OIL	A, E, H	When the concentration of Bay oil in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is no more than 15 mL, there must be a restricted flow insert fitted on the container. When the concentration of Bay oil in the medicine is more than 25% and the nominal capacity of the container is more than 15 mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
770	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%.
771	BEET RED	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
772	BEETROOT	E, H	
773	BEGONIA FIMBRISTIPULA	A, H	
774	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.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
775	BEHENIC ACID	E	When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 milligrams of behenic acid.
776	BEHENOXY DIMETHICONE	E	Only for use in topical medicines for dermal application.
777	BEHENOYL STEARIC ACID	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 2.4%.
778	BEHENYL ALCOHOL	E	Only for use in topical medicines for dermal application.
779	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

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			0.00001%.
780	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%.
781	BELLADONNA HERB PREPARED	A, H	Alkaloids calculated as hyoscyamine and atropine are mandatory components of Belladonna herb prepared and must be declared in the application. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%. The concentration of atropine from all ingredients in the product must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.
782	BELLIS PERENNIS	A, H	
783	BEMOTRIZINOL	A	Only for use as an active

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
784	BENINCASA HISPIDA	A, E, H	
785	BENTONITE	E	
786	BENZALDEHYDE	E	
787	BENZALDEHYDE GLYCERYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
788	BENZALKONIUM CHLORIDE	E	Only for use in topical medicines for dermal application and nasal sprays. The concentration in the medicine must be no more than 5%.

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789	BENZETHONIUM CHLORIDE	E	Only for use as a preservative in topical medicines for dermal application.
790	BENZOIC ACID	E, H	Medicines containing benzoates require the following warning statement on the medicine label: - (TBNZO8) 'Contains benzoates' (or words to this effect)' if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used] (or words to this effect)' if product contains one benzoate source.
791	BENZOIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
792	BENZOIN SIAM	A, E, H	
793	BENZOIN SUMATRA	A, E, H	
794	BENZOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

Permissible ingredients and requirements			
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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%.
795	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%.
796	BENZYL ACETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as a fragrance the total fragrance concentration in a medicine must be no more than 1%.
797	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

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			recommended for use by pregnant and lactating women' (or words to that effect).
798	BENZYL BENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing benzoates require the warning statement: - (TBNZO8) 'Contains benzoates' (or words to this effect) if the medicine contains two or more benzoate sources or 'Contains [insert the approved name of benzoate used]' (or words to this effect) if product contains one benzoate source.
799	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%.
800	BENZYL CINNAMATE	E	Only for use in: (a) topical medicines for dermal application when the concentration of benzyl cinnamate in the medicine is not greater than 0.15%; or (b) medicines in combination

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
801	BENZYL DIMETHYL CARBINYL-N-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
802	BENZYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
803	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

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			1%.
804	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%.
805	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%.
806	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%.
807	BENZYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
808	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%.
809	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%.
810	BENZYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.

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			The total flavour proprietary excipient formulation in a medicine must be no more than 5%.
811	BENZYLIDENE ACETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
812	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).

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
813	BERBERIS AQUIFOLIUM	A, H	
814	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).
815	BERBERIS VULGARIS	A, E, H	
816	BERGAMOT OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour, the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The medicine requires the following warning statement on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect)
817	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
818	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.
819	BERGAMOT OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
820	BERTHOLLETIA EXCELSA	A, E, H	
821	BETA RAPA	A, E, H	
822	BETA VULGARIS	A, E, H	

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
823	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%.
824	BETA-CARYOPHYLLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
825	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%.
826	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
827	BETA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
828	BETA-HOMO CYCLOCITRAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
829	BETA-HYDROXY-BETA-METHYLBUTYRIC ACID	A	
830	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

Permissible ingredients and requirements			
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			medicine must be no more 1%.
831	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%.
832	BETA-ISO-METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
833	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%.
834	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

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
835	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%.
836	BETA-NAPHTHOL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
837	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

Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
838	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%.
839	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%.
840	BETA-TOCOPHEROL	E	
841	BETACAROTENE	A, E	When Vitamin A is declared as an equivalent of Betacarotene and the medicine is for oral or sublingual use in adults the medicine requires the following warning statement on the medicine label: - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700

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			micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'
842	BETADEX	E	
843	BETAGLUCAN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.01%.
844	BETAINE	E	Only for use in topical medicines for dermal application.
845	BETAINE HYDROCHLORIDE	E	
846	BETULA LENTA	A, H	Methyl salicylate is a mandatory component of Betula lenta. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant

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

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			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'.
847	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			15 mL, the medicine must be fitted with a child resistant closure; and d) the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) ‘Contains methyl salicylate’ (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
848	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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25% ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
849	BETULA PUBESCENS	A, E, H	
850	BICYCLO(2.2.1)HEPT-5-ENE-2-CARBOXYLIC ACID, 3-(1-METHYLETHYL)-, ETHYL ESTER, (1R,2R,3R,4S)-REL-	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
851	BICYCLO(2.2.2)OCT-5-ENE-2-CARBOXALDEHYDE, 6-METHYL-8-(1-METHYLETHYL)-	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
852	BIFIDOBACTERIUM ADOLESCENTIS	A	
853	BIFIDOBACTERIUM ANIMALIS	A	
854	BIFIDOBACTERIUM ANIMALIS SSP ANIMALIS	A	
855	BIFIDOBACTERIUM ANIMALIS SSP LACTIS	A	
856	BIFIDOBACTERIUM BIFIDUM	A	
857	BIFIDOBACTERIUM BREVE	A	
858	BIFIDOBACTERIUM INFANTIS	A	
859	BIFIDOBACTERIUM LACTIS	A	
860	BIFIDOBACTERIUM LONGUM	A	
861	BILBERRY	E	
862	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
863	BIOTA ORIENTALIS	A, H	
864	BIOTIN	A, E	
865	BIRCH LEAF DRY	A, E, H	Methyl salicylate is a mandatory component of birch leaf dry. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25% ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
866	BIRCH TAR OIL RECTIFIED	A, E, H	Cresol is a mandatory

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
867	BIS-BUTYLDIMETICONE POLYGLYCERYL-3	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.5%.
868	BIS-DIGLYCERYL POLYACYLADIPATE-2	E	Only for use in topical medicines for dermal application.
869	BIS-ETHYLHEXYL HYDROXYDIMETHOXY BENZYLMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
870	BIS-MACROGOL 900 METHYL ETHER DIMETHYL SILANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must be no more than 2.5%.
871	BIS-PEG-12 DIMETHICONE BEESWAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
872	BIS-STEARYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 2.30%.
873	BIS-STEARYL ETHYLENEDIAMINE/NEOPENTYL GLYCOL/STEARYL HYDROGENATED DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
874	BISABOLENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
875	BISABOLOL	E	If used as an excipient, the medicine is only for use in topical medicines for dermal application.
876	BITTER ALMOND OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The absence of amygdalin in the medicine must be declared.
877	BITTERN	A, E, H	Only to be used in a medicine where WA Salt Koolyanobbing Pty Ltd- Australia (Client ID 69736), 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 8 June 2022. Magnesium is a mandatory component of bittern. Only permitted for use in: - medicines limited to oral

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			routes of administration; and - topical medicines for dermal administration. When the medicine is: (a) used in medicines with an oral route of administration; (b) not promoted or marketed as laxative; and (c) the recommended daily dose for: (i) individuals greater than 9 years of age contains 250 mg or greater magnesium; (ii) children aged between 4 and 8 years (inclusive) contains 110 mg or greater magnesium; or (iii) children aged between 1 and 3 years (inclusive) contains 65 mg or greater magnesium; the following warning statements are required on the label: - (LAX5) 'This product contains magnesium'; and - (LAX4) 'This product may have laxative effect'. When the medicine is for an oral route of administration, the following warning statement is required on the label: - (BABY2) 'Not suitable for infants under the age of twelve months' (or words to that effect).
878	BIXA ORELLANA	A, E, H	
879	BLACK BONED CHICKEN	A	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
	POWDER		
880	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.'
881	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.'
882	BLACK CURRANT	E	
883	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
884	BLACK CURRANT FRESH	A, E, H	
885	BLACK CURRANT SEED OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
886	BLACK OF CURACAO SPIDER	H	Only for use as an active homoeopathic ingredient.
887	BLACK PEPPER OIL	A, E, H	
888	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%.
889	BLACK SNAKE	H	Only for use as an active homoeopathic ingredient.
890	BLACKBERRY	E	
891	BLACKBERRY OILS	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
892	BLACKBERRY WINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
893	BLACKCURRANT ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
894	BLACKCURRANT JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
895	BLACKSTRAP MOLASSES	E	When for oral or sublingual use, Sucrose is a mandatory component of Molasses - blackstrap.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) ‘Contains [insert name of sugar]’ if medicine contains one sugar OR ‘Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
896	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.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
897	BLADDERWRACK POWDER	A, H	Iodine is a mandatory component of Bladderwrack powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
898	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%.
899	BLETILLA STRIATA	A, H	
900	BLUE FLAG RHIZOME DRY	A, H	
901	BLUE FLAG RHIZOME POWDER	A, H	
902	BLUEBERRY	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
903	BLUEBERRY JUICE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
904	BLUMEA LACERA	A, H	
905	BOEHMERIA NIVEA	A, H	
906	BOERHAVIA DIFFUSA	A, H	
907	BOERHAVIA REPENS	A, H	
908	BOGBEAN LEAF DRY	A, H	
909	BOGBEAN LEAF POWDER	A, H	
910	BOIS DE ROSE OIL	A, E, H	
911	BOMBAX CEIBA	A, H	
912	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.
913	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,

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			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%. The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that is: - listed in the Register on or after 2 March 2020; or - supplied after 2 March 2021. (a) 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). (b) 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (ADULT) 'Adults only' (or words to that effect). (c) 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). (d) 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).
914	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

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			or 0.35%. The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that: - is listed in the Register on or after 2 March 2020; or - is supplied after 2 March 2021. (a) 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). (b) 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). (c) When for excipient use and the maximum recommended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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). (d) 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).
915	BORIC ACID	A, H	Boron is a mandatory component of boric acid. The percentage of boron from boric acid should be calculated based on the molecular weight of boric acid. The maximum recommended daily dose must not provide more than 6mg of boron. In preparations for dermal use, which are not for paediatric or antifungal use, the concentration of boron in the medicine must not be more than 3500 mg/kg or 3500 mg/L or 0.35%. The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that: - is listed in the Register on or

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			after 2 March 2020; or - is supplied after 2 March 2021. (a) 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). (b) 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). (c) 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			on the label: - (BORON) 'Contains boron' (or words to that effect). (d) 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).
916	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%.
917	BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
918	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.

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			The concentration in the medicine must be no more than 0.5%.
919	BORONIA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
920	BORONIA MEGASTIGMA	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
921	BOSWELLIA CARTERII	A, E, H	
922	BOSWELLIA SERRATA	A, E, H	
923	BOSWELLIA THURIFERA	A, H	
924	BOVINE CALCIUM CHONDROITIN SULFATE	A	
925	BOVINE CHONDROITIN SULFATE	A	
926	BOVINE COLOSTRUM POWDER	A	The medicine requires the warning statement: - (BOVCOL) 'Products containing bovine colostrum

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			powder contain lactose and cow's milk proteins (or words to that effect). This product is not suitable for use in children under the age of 12 months except on professional health advice.'
927	BOVINE LACTOFERRIN	A	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk.'
928	BOVINE POTASSIUM CHONDROITIN SULFATE	A	
929	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%.
930	BOVINE WHEY IG-RICH FRACTION	A	Only for use in oral medicines. The medicine requires the following warning statements on the medicine label: - (COWMK) 'Derived from cows milk' - (BABY3) 'Not suitable for use in children under the age of 12 months - except on the advice of a health professional)'.

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
931	BRANDY	E	
932	BRASSICA CAMPESTRIS/ALEURITES FORDI OIL COPOLYMER	E	Only for use in topical medicines for dermal application and not for use in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
933	BRASSICA CHINENSIS	A, H	Allyl isothiocyanate is a mandatory component of Brassica chinensis when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
934	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%.
935	BRASSICA NAPUS	A, E, H	Allyl isothiocyanate is a mandatory component of Brassica napus when the plant part is seed.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
936	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%.
937	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%.
938	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			10 mg/L or 0.001%.
939	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%.
940	BRASSICA OLERACEA VAR. ITALICA	A, H	Allyl isothiocyanate is a mandatory component of Brassica oleracea var. italica when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
941	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%.
942	BRASSICA PEKINENSIS	A, H	Allyl isothiocyanate is a mandatory component of

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%.
943	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%.
944	BRAZIL NUT	E	
945	BRILLIANT BLACK BN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
946	BRILLIANT BLUE FCF	E	Permitted for use only as a colour for oral, topical and dental use.
947	BRILLIANT BLUE FCF ALUMINIUM LAKE	E	Permitted for use only as a colour for oral and topical use.
948	BRILLIANT BLUE FCF BARIUM LAKE	E	Permitted for use only as a colour for oral and topical use.

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
949	BRILLIANT SCARLET 4R	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
950	BRILLIANT SCARLET 4R ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines for topical and oral routes of administration.
951	BRIZA MEDIA	A, H	
952	BROCCOLI	E	
953	BROMELAINS	A	May be derived from either the stem or fruit of the pineapple (Ananas comosus). If used in a divided preparation, the allowed units are papain units and million papain units. If used in an undivided preparation, the allowed units are million papain units per gram.
954	BROMINE	H	Only for use as an active homoeopathic ingredient. The concentration of bromine in the preparation must be no more than 14mg/Kg or 14mg/L or 0.0014% for oral and sublingual use.
955	BROMOSTYROL	E	Not for use in infants Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
956	BROMUS CATHARTICUS	A, H	
957	BROMUS INERMIS	A, H	
958	BROMUS RAMOSUS SUBSP. RAMOSUS	A, H	
959	BRONOPOL	E	Only for use in topical medicines for dermal application.
960	BROUSSONETIA PAPYRIFERA	A, H	
961	BROWN FK	E	Permitted for use only as a colour for topical use.
962	BRUNFELSIA UNIFLORA	A, H	The maximum daily dose must be no more than the equivalent of 1mg of the dry herbal material.
963	BRUSSEL SPROUT	E	
964	BRYONIA ALBA	A, H	
965	BRYONIA DIOICA	A, H	
966	BUCHU LEAF DRY	A, H	
967	BUCHU LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
968	BUCHU LEAF POWDER	A, E, H	
969	BUCKWHEAT	E, H	Only for use as an active homoeopathic or excipient ingredient.
970	BUDDLEJA OFFICINALIS	A, H	
971	BULNESIA SARMIENTI	A, E, H	
972	BUNIAS ORIENTALIS	A, H	
973	BUPLEURUM FALCATUM	A, H	
974	BURDOCK LEAF DRY	A, H	
975	BURDOCK LEAF POWDER	A, H	
976	BURDOCK ROOT DRY	A, H	
977	BURDOCK ROOT POWDER	A, H	
978	BUSHMASTER SNAKE	H	Only for use as an active homoeopathic ingredient.
979	BUTAN-1-OL	E	The residual solvent limit for Butan-1-ol is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
980	BUTANE	E	Only for use as an excipient propellant ingredient.
981	BUTOXYETHANOL	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
982	BUTTER	E	
983	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%.
984	BUTTER ESTERS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
985	BUTTER STARTER DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
986	BUTYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
987	BUTYL ACETATE	E	The residual solvent limit for Butyl acetate is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
988	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%.
989	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
990	BUTYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
991	BUTYL ESTER OF PVM/MA COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' (or words to that effect) - (EYE2) 'May be irritant to the eyes' (or words to that effect).
992	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%.
993	BUTYL HYDROXYBENZOATE	E	Only for use in topical medicines for dermal application. Medicines containing

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
994	BUTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
995	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%.
996	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
997	BUTYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
998	BUTYL METHOXYDIBENZOYLMETHANE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in preparation must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
999	BUTYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
1000	BUTYL STEARATE	E	Only for use in topical medicines for dermal application.
1001	BUTYL UNDECYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1002	BUTYLATED HYDROXYANISOLE	E	
1003	BUTYLATED HYDROXYTOLUENE	E	
1004	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%.
1005	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
1006	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%.
1007	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%.
1008	BUTYRALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1009	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1010	C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.012%.
1011	C10-12 ALKANE/CYCLOALKANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1012	C10-30 CHOLESTEROL/LANOSTEROL ESTERS	E	Only for use in topical medicines for dermal application.
1013	C11-13 ALKANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1014	C11-14-ISO-ALCOHOL C-13 RICH	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1015	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.
1016	C12-13 PARETH-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.125%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
1017	C12-15 ALKYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 1.2%.
1018	C12-15 ALKYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1019	C12-20 ACID PEG-8 ESTER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1020	C12-20 ALKYL GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.75%.
1021	C12-22 ALKYL ACRYLATE/HYDROXYETHYLACRYLATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye or on damaged skin. The concentration of C12-22 alkyl acrylate/hydroxyethylacrylate copolymer in the medicine must not be more than 5%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1022	C13-14 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1023	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%.
1024	C15-19 ALKANE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 7%.
1025	C18-36 ACID GLYCOL ESTER	E	Only for use topical medicines for dermal application.
1026	C18-36 ACID TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1027	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
1028	C20-40 ALCOHOLS	E	Only for use in topical medicines for dermal application.
1029	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%.
1030	C20-40 PARETH-24	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.25%.
1031	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%.
1032	C30-45 ALKYL CETEARYL DIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 1%.
1033	C9-11 ISOPARAFFIN	E	Only for use in topical medicines for dermal application.
1034	C9-11 PARETH-3	E	Only for use in topical medicines for dermal application.
1035	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%
1036	CABBAGE	E	
1037	CABREUVA OIL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1038	CADE OIL	A, E, H	
1039	CAESALPINIA SAPPAN	A, H	
1040	CAFFEINE	A, E	When used as an excipient, only for use in topical

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines for dermal application. Only for use as an active ingredient for oral use in adults when the medicine consists principally of one or more designated active ingredients prescribed in Schedule 14 to the Regulations (other than caffeine). When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 100mg 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 an undivided preparation and is for internal use or oral application, the medicine must not contain a concentration of total caffeine greater than 4%. 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%. The requirements specified in paragraphs (a) to (d) below apply to a medicine that contains the ingredient that:

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (d) below. a) 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%. b) 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. c) 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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			of instant coffee contains approximately 80mg of caffeine.' - (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' d) 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).
1041	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
1042	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.
1043	CALCIFEDIOL MONOHYDRATE	A	Only to be used in a medicine where DSM Nutritional Products Pty Ltd (Client ID 31685), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 30 June

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2021. 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).
1044	CALCIFIED LITHOTHAMNION SPECIES	A	Only for use in oral medicines.
1045	CALCIFIED LITHOTHAMNION	A	Only for oral use.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	TOPHIFORME		
1046	CALCIUM ALGINATE	E	
1047	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.
1048	CALCIUM ASCORBATE	A, E, H	
1049	CALCIUM ASCORBATE DIHYDRATE	A, E, H	
1050	CALCIUM ASPARTATE	A	
1051	CALCIUM ASPARTATE HYDROCHLORIDE DIHYDRATE	A	Only for use in oral medicines.
1052	CALCIUM BEHENATE	E	Behenic acid is a mandatory component of Calcium behenate. When for oral ingestion, the maximum recommended daily dose must not provide more than 383.5 mg of Behenic acid.
1053	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE	A, H	
1054	CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE MONOHYDRATE	A, H	
1055	CALCIUM CARBONATE	A, E, H	
1056	CALCIUM CASEINATE	E	
1057	CALCIUM CHLORIDE	E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	DIHYDRATE		
1058	CALCIUM CITRATE	A, E, H	
1059	CALCIUM CITRATE TETRAHYDRATE	A, E, H	
1060	CALCIUM DIASPARTATE	A	Only for use in oral medicines.
1061	CALCIUM FLUORIDE	H	The percentage of fluoride from Calcium fluoride should be calculated based on the molecular weight of Calcium fluoride. The concentration of fluoride in the product from all ingredients must be no more than 10mg/kg or 10mg/L or 0.1%.
1062	CALCIUM FOLINATE	A	Folinic acid is a mandatory component of calcium folinate. The maximum daily dose must not provide more than 500 micrograms of folinic acid. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose. When used in preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects, the following warning statement is required on the medicine label: - (NEUR) 'Warning: Do not

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida - seek specific medical advice (or words to that effect).'
1063	CALCIUM GLUCONATE MONOHYDRATE	A, E, H	
1064	CALCIUM GLYCEROPHOSPHATE	A, E, H	
1065	CALCIUM GLYCINATE	A	Only for use in oral medicines.
1066	CALCIUM GLYCINATE DIHYDRATE	A	
1067	CALCIUM HEXAFLUOROSILICATE	H	Only for use as an active homoeopathic ingredient.
1068	CALCIUM HYDROGEN PHOSPHATE	A, E, H	
1069	CALCIUM HYDROGEN PHOSPHATE DIHYDRATE	A, E, H	
1070	CALCIUM HYDROGEN PHOSPHATE MONOHYDRATE	A, E, H	
1071	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1072	CALCIUM HYDROXYCITRATE	A, H	
1073	CALCIUM HYPOPHOSPHITE	H	Only for use as an active homoeopathic ingredient.
1074	CALCIUM IODIDE	H	Only for use as an active homoeopathic ingredient.
1075	CALCIUM KETOGLUCONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration must be no more than 1%
1076	CALCIUM L-THREONATE	A	Only for use in oral medicines.
1077	CALCIUM LACTATE	A, E, H	
1078	CALCIUM LACTATE GLUCONATE	A, E, H	
1079	CALCIUM LACTATE PENTAHYDRATE	A, E, H	
1080	CALCIUM LACTATE TRIHYDRATE	A, E, H	
1081	CALCIUM LYSINATE	A	Only for use in oral medicines.
1082	CALCIUM METHIONINATE	A	Only for use in oral medicines.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1083	CALCIUM OROTATE	A, E, H	
1084	CALCIUM OXIDE	E	Only for use in topical medicines for dermal application.
1085	CALCIUM PANTOTHENATE	A, E, H	
1086	CALCIUM PHOSPHATE	A, E, H	
1087	CALCIUM PYRUVATE	A	
1088	CALCIUM SACCHARATE	E	
1089	CALCIUM SILICATE	E	
1090	CALCIUM SODIUM CASEINATE	A, H	The medicine requires the following warning statement on the medicine label: - (COWMK) 'Derived from cow's milk'.
1091	CALCIUM SODIUM LACTATE	A, E, H	
1092	CALCIUM STEARATE	E	
1093	CALCIUM SUCCINATE	A, E, H	
1094	CALCIUM SULFATE	A, E, H	
1095	CALCIUM SULFATE DIHYDRATE	A, E, H	
1096	CALCIUM SULFIDE	H	Only for use as an active homoeopathic ingredient.
1097	CALCIUM THREONINATE	A	
1098	CALENDULA FLOWER DRY	A, E, H	
1099	CALENDULA FLOWER POWDER	A, H	
1100	CALENDULA OFFICINALIS	A, E, H	
1101	CALLERYA RETICULATA	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1102	CALLICARPA PEDUNCULATA	A, H	
1103	CALLISTEMON CITRINUS	A, H	
1104	CALLISTEPHUS CHINENSIS	A, H	
1105	CALLITRIS COLUMELLARIS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1106	CALLITRIS COLUMELLARIS SUBSP. INTRATROPICA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1107	CALLITRIS RHOMBOIDEA	A, H	
1108	CALLUNA VULGARIS	A, E, H	
1109	CALOCHORTUS TOLMIEI	A, H	
1110	CALTHA PALUSTRIS	A, H	
1111	CALUMBA ROOT DRY	A, H	
1112	CALUMBA ROOT POWDER	A, H	
1113	CALVATIA GIGANTEA	A, E, H	
1114	CALYCANTHUS FLORIDUS	A, H	
1115	CALYCANTHUS PRAECOX	A, H	
1116	CAMELLIA JAPONICA	A, H	
1117	CAMELLIA OLEIFERA	A, E, H	If Camellia oleifera (seed oil) is used as a solvent, it is

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			restricted to topical or sunscreen preparations for dermal application only.
1118	CAMELLIA SINENSIS	A, E, H	Caffeine is a mandatory component of Camellia sinensis. 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 4%. 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%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) 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%. c) 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. d) 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			pregnancy or breastfeeding.' e) 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).
1119	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%.
1120	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			excipient formulation in a medicine must be no more than 5%.
1121	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%.
1122	CAMPHOR BENZALKONIUM METHOSULFATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the preparation must not be more than 6%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1123	CAMPHOR OIL BROWN	A, H	camphor, cineole and safrole are mandatory components of camphor oil brown. In solid and semi solid preparations, the concentration of camphor must be no more

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have the restricted flow insert

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.
1124	CAMPHOR OIL WHITE	A, E, H	Camphor and safrole are mandatory components of camphor oil white. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When for internal use then the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			concentration of safrole in a medicine must be no more than 0.1%. When for topical use then the concentration of safrole in a medicine must be no more than 1.0%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25mL.
1125	CAMPSIS GRANDIFLORA	A, H	
1126	CANADA BALSAM	A, H	
1127	CANANGA ODORATA	A, E, H	
1128	CANANGA OIL	A, E, H	
1129	CANARIUM INDICUM	A, H	The plant part must be seed and the plant preparation is oil. The medicine requires the following warning statement on the medicine label: - (DERIVED) 'This product contains material derived from nuts' (or words to that effect).
1130	CANARIUM LUZONICUM	A, H	
1131	CANDELILLA WAX	A, E, H	
1132	CANDIDA ALBICANS	H	Only for use as an active homoeopathic ingredient.
1133	CANDIDA UTILIS	A, E, H	When used as an excipient, only for use in medicines in combination with other permitted ingredients as a flavour proprietary excipient

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%.
1134	CANINE MILK	H	Only for use as an active homoeopathic ingredient.
1135	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%.
1136	CANTHARIDES	H	Only available as an active homoeopathic ingredient.
1137	CANTHAXANTHIN	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1138	CAPRIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
1139	CAPROIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1140	CAPRYLIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1141	CAPRYLIC/CAPRIC GLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1142	CAPRYLIC/CAPRIC/ISOSTEARIC /ADIPIC TRIGLYCERIDE	E	
1143	CAPRYLIC/CAPRIC/MYRISTIC/S TEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine is not to exceed 3%
1144	CAPRYLIC/CAPRIC/STEARIC TRIGLYCERIDE	E	Only for use in topical medicines for dermal application.
1145	CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER	E	Only to be used in a medicine where A S Harrison & Co Pty Ltd (Client ID 50284), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 27 September 2020. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%.
1146	CAPRYLOYL GLYCINE	E	Only for use in topical

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%
1147	CAPRYLOYL SALICYLIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must not be more than 0.3%.
1148	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%
1149	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%.
1150	CAPSELLA BURSA-PASTORIS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1151	CAPSICUM	E, H	Only for use as an active homoeopathic or excipient ingredient.
1152	CAPSICUM ANNUUM	A, E, H	
1153	CAPSICUM DRY	A, E, H	
1154	CAPSICUM FRUIT OLEORESIN	A, E	
1155	CAPSICUM FRUTESCENS	A, E, H	
1156	CAPSICUM POWDER	A, E, H	
1157	CARALLUMA ADSCENDENS VAR. FIMBRIATA	A	The plant part must be herb and the plant preparation must be a hydroethanolic extract.
1158	CARAMEL	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1159	CARAPICHEA IPECACUANHA	A, H	Emetine is a mandatory component of Carapichea ipecacuanha. The concentration of emetine in the medicine must be no more than 0.2%. Except when used in a medicine containing only homoeopathic preparations, a child resistant closure must be fitted onto the container.
1160	CARAWAY DRY	A, H	
1161	CARAWAY OIL	A, E, H	
1162	CARAWAY POWDER	A, H	
1163	CARBOMER 1342	E	Only for use as an excipient in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			topical medicines for dermal application.
1164	CARBOMER 2001	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must be no more than 1% in formulations at pH 7 (approximately neutral) and 0.1% in formulations at a different pH.
1165	CARBOMER 934	E	Only for use in topical medicines for dermal application.
1166	CARBOMER 934P	E	Only for use in topical medicines for dermal application.
1167	CARBOMER 940	E	Only for use in topical medicines for dermal application.
1168	CARBOMER 941	E	Only for use as an excipient in topical medicines for dermal application.
1169	CARBOMER 954	E	Only for use as an excipient in topical medicines for dermal application.
1170	CARBOMER 980	E	Only for use as an excipient in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
1171	CARBOMER 981	E	Only for use as an excipient in topical medicines for dermal application.
1172	CARBOMER COPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1173	CARBOMER HOMOPOLYMER (TYPE B)	E	Only for use as an excipient in topical medicines for dermal application.
1174	CARBOMER U-10	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1175	CARBON	E, H	Only for use as an active homoeopathic or excipient ingredient.
1176	CARBON BLACK	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1177	CARBON DIOXIDE	E	
1178	CARDAMOM FRUIT DRY	A, H	
1179	CARDAMOM FRUIT POWDER	A, E, H	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
1180	CARDAMOM OIL	A, E, H	
1181	CARDIOSPERMUM HALICACABUM	A, H	
1182	CARICA PAPAYA	A, E, H	
1183	CARLINA ACAULIS	A, H	
1184	CARMELLOSE	E	
1185	CARMELLOSE CALCIUM	E	
1186	CARMELLOSE SODIUM	E	
1187	CARMINE	E	Permitted for use only as a colour for oral and topical use.
1188	CARMOISINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1189	CARMOISINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1190	CARNAUBA WAX	A, E, H	
1191	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%.
1192	CAROB BEAN EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1193	CAROB GUM	E	
1194	CAROB POD	E	
1195	CAROTENES	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1196	CARPINUS BETULUS	A, H	
1197	CARPINUS CORDATA	A, H	
1198	CARRAGEENAN	E	
1199	CARROT	E	
1200	CARROT SEED OIL	A, E, H	
1201	CARTHAMUS TINCTORIUS	A, E, H	Carthamus tinctorius (sunflower 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).
1202	CARUM CARVI	A, H	
1203	CARVACROL	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1204	CARVACRYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1205	CARVEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1206	CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
1207	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%.
1208	CARYA ILLINOINENSIS	A, H	
1209	CARYA OVATA	A, H	
1210	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%.
1211	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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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' [or words to that effect]. When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' [or words to that effect]. When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
1212	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines, if the maximum recommended daily dose contains less than 10 mg of hydroxyanthracene derivatives and is promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX1) 'Drink plenty of water' (or words to that effect); and - (LAX2) 'Prolonged use may cause serious bowel problems'.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1213	CASCARILLA OIL	A, H	The medicine must not contain more than 1mg of the equivalent dry herbal material per the maximum recommended daily dose.
1214	CASEIN	E	
1215	CASHEW NUT	E	
1216	CASSIA ALATA LEAF EXTRACT	E	Only for use as an excipient ingredient in sunscreens for dermal application and not to be intended for use in the eye. The extraction ratio of the Cassia alata can only be 1:3 in 62.5% glycerine:water. The concentration in the medicine must be no more than 0.0275%.
1217	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%.
1218	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.
1219	CASSIA FISTULA	A, 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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			daily dose contains more than 10 mg of hydroxyanthracene derivatives the medicine requires the following warning statements on the medicine label: - (CHILD3) 'Use in children under 12 years is not recommended'; - (LAX2) 'Prolonged use may cause serious bowel problems'; and - (LAX3) 'Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product' (or words to that effect). When promoted or marketed as a laxative, the medicine requires the following warning statement on the medicine label: - (LAX1) 'Drink plenty of water' (or words to that effect). When not promoted or marketed as laxative, the medicine requires the following warning statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'; and - (LAX4) 'This product may have laxative effect'. When used in oral medicines,

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'.
1220	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%.
1221	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%.
1222	CASTANEA MOLLISSIMA	A, H	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
1223	CASTANEA SATIVA	A, H	
1224	CASTOR OIL	A, E	
1225	CASTOREUM	H	Only permitted for use as an active homoeopathic ingredient.
1226	CASUARINA EQUISITIFOLIA	A, H	
1227	CATALPA BIGNONIOIDES	A, H	
1228	CATALPA OVATA	A, H	
1229	CATECHU	A, H	
1230	CATHARANTHUS ROSEUS	A, H	Vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine are mandatory components of Catharanthus roseus. The concentration of vinblastine, vincamine, vincristine, vindesine, vinorelbine and yohimbine in the medicine must be no more than 10mg/kg or 10 mg/L or 0.001%.
1231	CAULIFLOWER	E	
1232	CAULOPHYLLUM THALICTROIDES	A, E, H	
1233	CAUSTICUM	H	Only for use as an active homoeopathic ingredient.
1234	CEANOTHUS AMERICANUS	A, H	
1235	CEDAR LEAF OIL	A, E, H	
1236	CEDARWOOD OIL	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1237	CEDARWOOD OIL ATLAS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1238	CEDARWOOD OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1239	CEDARWOOD OIL VIRGINIA	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
1240	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%.
1241	CEDRENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1242	CEDROL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1243	CEDRUS ATLANTICA	A, E, H	
1244	CEDRUS DEODARA	A, H	
1245	CEDRUS LIBANI	H	Only for use as an active homoeopathic ingredient.
1246	CEDRYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1247	CEDRYL METHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1248	CELERY LEAF	E, H	
1249	CELERY SEED DRY	A, E, H	
1250	CELERY SEED OIL	A, E, H	
1251	CELERY SEED POWDER	A, H	
1252	CELLACEFATE	E	
1253	CELLULASE	A	Must be derived from Trichoderma longibrachiatum only. If used as an undivided preparation, the allowed unit is Cellulase unit per gram or Thousand cellulase unit per gram. If used as an divided preparation, the allowed unit is Thousand cellulase unit or cellulase unit.
1254	CELLULOSE	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1255	CELOSIA ARGENTEA	A, H	
1256	CELOSIA ARGENTEA L. VAR. CRISTATA	A, H	
1257	CENTAUREA CYANUS	A, E, H	
1258	CENTAURIUM ERYTHRAEA	A, H	
1259	CENTELLA ASIATICA	A, E, H	
1260	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%.
1261	CENTIPEDA CUNNINGHAMII	A, E, H	
1262	CENTIPEDA MINIMA	A, H	
1263	CEPHALANOPSIS SEGETUM	A, H	
1264	CERAMIDE 1	E	Only for use in topical medicines for dermal application.
1265	CERAMIDE 2	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 0.05%.
1266	CERAMIDE 3	E	Only for use in topical medicines for dermal application.
1267	CERATONIA SILIQUA	A, E, H	
1268	CERATOSTIGMA WILLMOTTIANUM	A, H	
1269	CERESIN	E	Only for use in topical medicines for dermal application.
1270	CESTRUM LATIFOLIUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The plant part must be leaf and must be a water extract. The concentration must be no more than 0.5%.
1271	CETEARETH-12	E	Only for use in topical medicines for dermal application.
1272	CETEARETH-2	E	Only for use in topical medicines for dermal application.
1273	CETEARETH-20	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1274	CETEARETH-25	E	Only for use in topical medicines for dermal application.
1275	CETEARETH-30	E	Only for use in topical medicines for dermal application.
1276	CETEARETH-33	E	Only for use as an excipient ingredient for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%. Residual levels of 1,4-dioxane oxide (and related substances) are to be kept below the level of detection.
1277	CETEARYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1278	CETEARYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
1279	CETEARYL NONANOATE	E	Only for use in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must not be more

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 5%.
1280	CETEARYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1281	CETETH-10	E	Only for use in topical medicines for dermal application.
1282	CETETH-2	E	Only for use in topical medicines for dermal application.
1283	CETETH-24	E	Only for use in topical medicines for dermal application.
1284	CETETH-5	E	Only for use in topical medicines for dermal application.
1285	CETOMACROGOL 1000	E	Only for use in topical medicines for dermal application.
1286	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1287	CETOMACROGOL 500 PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
1288	CETOSTEARYL ALCOHOL	E	
1289	CETOSTEARYL ALCOHOL/COCO-GLUCOSIDE COMPLEX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5.0 %
1290	CETRARIA ISLANDICA	A, H	
1291	CETRIMONIUM BROMIDE	E	Only for use in topical medicines for dermal application.
1292	CETRIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1293	CETYL ACETATE	E	Only for use in topical medicines for dermal application.
1294	CETYL ALCOHOL	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
1295	CETYL DIMETHICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1296	CETYL DIMETICONE	E	Only for use in topical medicines for dermal application.
1297	CETYL DIMETICONE/BIS-VINYLDIMETICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
1298	CETYL ESTERS WAX	E	Only for use in topical medicines for dermal application.
1299	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%.
1300	CETYL LACTATE	E	Only for use in topical medicines for dermal application.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1301	CETYL OCTANOATE	E	Only for use in topical medicines for dermal application.
1302	CETYL PALMITATE	E	Only for use in topical medicines for dermal application.
1303	CETYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1304	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%.
1305	CETYLPYRIDINIUM CHLORIDE	A, E	When used as an excipient ingredient, only for use in topical medicines for dermal application. When used as an active ingredient: a) permitted for use only in medicated throat lozenges; b) the medicine must not contain more than 2 mg of cetylpyridinium chloride per lozenge; c) the maximum recommended daily dose of the medicine must not provide more than 24 mg of cetylpyridinium chloride; and

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			d) the medicine label must specify that the medicine is only to be used for 7 days (or less).
1306	CHAENOMELES LAGENARIA	A, H	
1307	CHAENOMELES SPECIOSA	A, H	
1308	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.
1309	CHAMAECYPARIS LAWSONIANA	A, H	
1310	CHAMAELIRIUM LUTEUM	A, H	
1311	CHAMAEMELUM NOBILE	A, E, H	
1312	CHAMOMILE FLOWER DRY	A, E, H	
1313	CHAMOMILE OIL ENGLISH	A, E, H	
1314	CHAMOMILE OIL GERMAN	A, E, H	
1315	CHANGIUM SMYRNIOIDES	A, H	
1316	CHEIRANTHUS CHEIRI	A, H	
1317	CHELIDONIUM MAJUS	A, E, H	When for oral or sublingual use, the medicine requires the following warning statement on the medicine label: - (CELAND) 'WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			healthcare professional'.
1318	CHELONE GLABRA	A, H	
1319	CHENOPODIUM ALBUM	A, H	
1320	CHENOPODIUM VULVARIA	A, H	
1321	CHERRY	E	
1322	CHERRY DISTILLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1323	CHESTNUT SWEET	E, H	
1324	CHICKEN COMB EXTRACT	A	
1325	CHILLI	E, H	
1326	CHIMAPHILA UMBELLATA	A, H	Arbutin is a mandatory component of Chimaphila umbellata. The concentration of arbutin in the medicine must be no more than 25 mg/Kg or 25mg /L or 0.0025 % unless used on the hair. When for use on hair, the concentration of arbutin in the medicine must be no more than 0.74 %.
1327	CHIONANTHUS VIRGINICA	A, H	
1328	CHLORELLA	E	Iodine is a mandatory component of Chlorella.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
1329	CHLORELLA PYRENOIDOSA	E	
1330	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.
1331	CHLORHEXIDINE ACETATE	E	Only for use in topical medicines for dermal application.
1332	CHLORHEXIDINE GLUCONATE	E	Only for use in topical medicines for dermal application.
1333	CHLOROACETAMIDE	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
1334	CHLOROBUTANOL HEMIHYDRATE	E	Only for use in topical preparations for dermal application. The concentration in the medicine must be no more than 0.5%.
1335	CHLOROCRESOL	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1336	CHLOROFORM	E	The residual solvent limit must be no more than 0.6 mg per recommended daily dose and the concentration in the medicine must be no more than 0.006%.
1337	CHLOROPHYLL	A, E	Only for use as a colour in oral and topical medicines.
1338	CHLOROPHYLL-COPPER COMPLEXES	E	Only for use as a colour in oral and topical medicines.
1339	CHLOROPHYLLIN-COPPER COMPLEX	E	Only for use as a colour in oral and topical medicines.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1340	CHLOROPHYLLIN-COPPER COMPLEX ALUMINIUM LAKE	E	Only for as a colour in oral and topical medicines.
1341	CHLOROXYLENOL	E	Only for use in topical medicines for dermal application.
1342	CHLORPHENESIN	E	Only for use in topical medicines for dermal application.
1343	CHOCOLATE BROWN HT	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
1344	CHOLESTEROL	E, H	Only for use as an active ingredient in homoeopathic medicines or an excipient ingredient in topical preparations.
1345	CHOLESTERYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
1346	CHOLESTERYL MACADAMIATE	E	Only for use in topical medicines for dermal application.
1347	CHOLESTERYL/BEHENYL/OCTYLDODECYL LAUROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 0.5%.
1348	CHOLETH-24	E	Only for use in topical medicines for dermal application.
1349	CHOLINE BITARTRATE	A, E	
1350	CHOLINE DIHYDROGEN CITRATE	A	Only for use in oral medicines.
1351	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%.
1352	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.
1353	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1354	CHONDRUS EXTRACT	A, E, H	Iodine is a mandatory component of Chondrus extract. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
1355	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

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			picolinate, chromium nicotinate and high chromium yeast).
1356	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.
1357	CHROMIUM PICOLINATE	A	Chromium is a mandatory component of Chromium picolinate. The maximum recommended daily dose must not provide more than 50 micrograms of chromium from organic sources. Chromium picolinate is considered to be an organic form of chromium.
1358	CHRYSANTHEMUM BALSAMITA	A, H	
1359	CHRYSANTHEMUM INDICUM	A, H	
1360	CHRYSANTHEMUM LEUCANTHEMUM	A, H	
1361	CHRYSANTHEMUM MARSHALLII	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1362	CHRYSANTHEMUM SINENSE	A, H	
1363	CHRYSOPOGON ZIZANIOIDES	A, E, H	
1364	CHRYSOSPORIUM PRUINOSUM	A, H	
1365	CIBOTIUM BAROMETZ	A, H	
1366	CICHORIUM INTYBUS	A, E, H	
1367	CICUTA VIROSA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1368	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.
1369	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.
1370	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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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1371	CINCHONA PUBESCENS	A, H	Quinidine and quinine are mandatory components of Cinchona pubescens. The medicine must contain no more than 50 micrograms of quinine and no more than 10 micrograms concentration of quinidine per g or mL.
1372	CINEOLE	E	In liquid preparations when the concentration of cineole in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1373	CINNAMALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1374	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%.
1375	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and - Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist'. In essential oil preparations or distillates, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container. In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. In essential oil preparations or distillates, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 25% the nominal capacity of the container must be no more than 25 millilitres and the medicine must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. In liquid preparations other than essential oils or distillates, when the concentration of cineole in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When for internal use then the concentration of safrole in a medicine must be no more than 0.1%. When for uses other than internal use, the concentration of safrole in a medicine must be no more than 1.0%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1376	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%.
1377	CINNAMOMUM VERUM	A, E, H	When used as an active ingredient coumarin is a mandatory component of Cinnamomum verum and the concentration of coumarin in the medicine must be no more than 0.001%. Cinnamon bark oil is a mandatory component of Cinnamomum verum when the plant part is bark and the plant preparation is essential oil, distillate, fixed oil or infused oil. The concentration of cinnamon bark oil in the medicine must be no more than 2%. Cinnamon leaf oil is a mandatory component of Cinnamomum verum when the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			plant part is leaf. When the concentration of cinnamon leaf oil in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but no more than 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the container must be fitted with a restricted flow insert.
1378	CINNAMON BARK OIL	A, E, H	The concentration of cinnamon bark oil in the product must be no more than 2%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1379	CINNAMON DRY	A, H	Cinnamon bark oil is a mandatory component of cinnamon dry. The concentration of cinnamon bark oil in the product must be no more than 2%. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1380	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			cinnamon leaf oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, the container must be fitted with a restricted flow insert and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). - (NTAKEN) 'Not to be taken'. When used as an active ingredient, the concentration of coumarin in the medicine must be no more than 0.001%.
1381	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%.
1382	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
1383	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%.
1384	CINNAMYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1385	CINNAMYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1386	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
1387	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%.
1388	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%.
1389	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%.
1390	CINOXATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 6%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
1391	CIS-2-METHYL-4-PROPYL-1,3-OXATHIANE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1392	CIS-3-HEXEN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1393	CIS-3-HEXENAL	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1394	CIS-3-HEXENYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1395	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%.
1396	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%.
1397	CIS-3-HEXENYL BUTYRATE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1398	CIS-3-HEXENYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1399	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%.
1400	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%.
1401	CIS-3-HEXENYL ISOVALERATE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1402	CIS-3-HEXENYL LACTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1403	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%.
1404	CIS-3-HEXENYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1405	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%.
1406	CIS-4-HEPTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1407	CIS-6-NONEN-1-AL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1408	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%.
1409	CIS-BETA-OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1410	CIS-HEXAHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1411	CIS-JASMONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1412	CISTANCHE DESERTICOLA	A, H	
1413	CISTANCHE SALSA	A, H	
1414	CISTUS LADANIFERUS	A, E, H	
1415	CITRAL	E	
1416	CITRAL DIETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1417	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%.
1418	CITRIC ACID	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When used as an active ingredient in preparations for topical use, the medicine requires the following warning

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'
1419	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'
1420	CITRIC ACID MONOHYDRATE	A, E	Where intended for topical use, sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished product is safe for its intended purpose. When used as an active ingredient in preparations for topical use, the medicine requires the following warning statements on the medicine label: - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect) - (SUNPRO) 'Wear protective clothing, hats and eyewear when exposed to the sun.' (or words to that effect) - (IRRIT) 'If irritation develops, discontinue use.' - (SKTEST) 'If you have sensitive skin, test this product on a small area of skin before applying it to a large area.' - (CHILD3) 'Use in children

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			under 12 years is not recommended.'
1421	CITRIC AND FATTY ACID ESTERS OF GLYCEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1422	CITROL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1423	CITRON	E	
1424	CITRONELLA OIL	A, E, H	Medicines for topical use containing citronella oil require the following warning statement on the medicine label: - (CITRON) 'Contains citronella oil'.
1425	CITRONELLA TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
1426	CITRONELLAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1427	CITRONELLIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1428	CITRONELLOL	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
1429	CITRONELLYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1430	CITRONELLYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1431	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%.
1432	CITRONELLYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1433	CITRONELLYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1434	CITRONELLYL OXYACETALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1435	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1436	CITRONELLYL TIGLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1437	CITRULLINE	A	Only to be used in a medicine where Kyowa Hakko Bio Co Ltd (Client ID 11072), 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 2 March 2022. Only permitted for use in medicines: - limited to oral routes of administration; and - when the maximum recommended daily dose does not provide more than 6g of citrulline.
1438	CITRULLUS COLOCYNTHIS	H	Only for use as an active homoeopathic ingredient. When for oral use, the concentration of Citrullus colocynthis must be more than 4X (i.e. 1X 2X 3X).

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1439	CITRULLUS VULGARIS	A, H	
1440	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.
1441	CITRUS AURANTIUM	A, E, H	Oxedrine is a mandatory component of Citrus aurantium when intended for internal use. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 mg. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 1.4% or less of citrus aurantium oil or distillate; or c) for use in soaps or bath or shower gels that are washed off

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			the skin.
1442	CITRUS BIOFLAVONOIDS EXTRACT	A, E, H	
1443	CITRUS CHACHIENSIS	A, H	
1444	CITRUS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1445	CITRUS FIBRE	E	
1446	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.
1447	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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			milligrams. When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus limon oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1448	CITRUS MAXIMA	A, H	
1449	CITRUS MEDICA	A, E, H	When the plant preparation is oil or distillate, the warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) in preparations containing 0.05% or less of citrus medica oil or distillate; or c) for use in soaps or bath or shower gels that are washed off the skin.
1450	CITRUS OIL DISTILLED	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1451	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.
1452	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.
1453	CITRUS SINENSIS PEEL MOLASSES EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1454	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.
1455	CITRUS X PARADISI	A, E, H	
1456	CITRUS X WILSONII	A, H	

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
1457	CIVET	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1458	CIVET ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1459	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%.
1460	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%.
1461	CLARY OIL	A, E, H	

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1462	CLEMATIS ARMANDII	A, H	
1463	CLEMATIS CHINENSIS	A, E, H	
1464	CLEMATIS RECTA	A, H	
1465	CLEMATIS VITALBA	A, H	
1466	CLERODENDRUM TRICHOTOMUM	A, H	
1467	CLINOPODION POLYCEPHALUM	A, H	
1468	CLINOPODIUM NEPETA SUBSP. GLANDULOSUM	A, H	
1469	CLIVER HERB DRY	A, H	
1470	CLIVER HERB POWDER	A, H	
1471	CLOVE BUD OIL	A, E, H	When the concentration of Clove Bud Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Clove Bud Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on 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 clove bud oil in the preparation is more than 25% and the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			nominal capacity of the container is more than 15 mL , a restricted flow insert must be fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1472	CLOVE DRY	A, E, H	
1473	CLOVE LEAF OIL	A, E, H	When the concentration of Clove Leaf Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Clove Leaf Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the 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 clove leaf oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL, a restricted flow insert must be

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'
1474	CLOVE OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1475	CLOVE POWDER	A, E, H	
1476	CLOVE STEM OIL	A, E, H	When the concentration of Clove Stem Oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the concentration of Clove Stem Oil in the preparation is more than 25% and the nominal capacity of the container is more 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect)

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (NTAKEN) 'Not to be taken' When the concentration of Clove Stem oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL , a restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
1477	CLUPEA HARENGUS LIPID EXTRACT	A	Only for use in oral medicines. The maximum recommended daily dose must not provide more than 2750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids.
1478	CNICUS BENEDICTUS	A, H	
1479	CNICUS JAPONICUS	A, H	
1480	CNIDIUM MONNIERI	A, H	
1481	CNIDIUM OFFICINALE	A, H	
1482	COBALTOUS NITRATE HEXAHYDRATE	H	Only for use as an active homoeopathic ingredient.
1483	COCAMIDE DEA	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1484	COCAMIDE MEA	E	Only for use in topical medicines for dermal application.
1485	COCAMIDOPROPYL BETAINAMIDE MEA CHLORIDE	E	Only for use in topical medicines for dermal application and not to be included in topical products intended for use in the eye. The concentration in the medicine must be no more than 1%.
1486	COCAMIDOPROPYL BETAINE	E	Only for topical, mucous membrane (buccal mucosa) and dental use and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be: a) no more than 1% in leave on medicines b) no more than 15% in wash on /wash off medicines c) 1.2% for buccal mucosa and dental medicines. Levels of impurities 3-dimethylaminopropylamine (DMAPA) and amidoamine (dimethylaminopropylcocoamide; AA) must be controlled to below the level of detection.
1487	COCCOLOBIA UVIFERA	A, H	
1488	COCCULUS ORBICULATUS	A, H	
1489	COCHINEAL	E, H	Only for use as an active homoeopathic ingredient or for

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			excipient use only as a colour in oral and topical medicines.
1490	COCHLEARIA OFFICINALIS	A, H	
1491	COCILLANA DRY	A, H	
1492	COCILLANA POWDER	A, H	
1493	COCO-BETAINE	E	Only for use in topical medicines for dermal application.
1494	COCO-CAPRYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration is to be no more than 12.5% in the medicine.
1495	COCO-GLUCOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.025%
1496	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.
1497	COCOA EXTRACT	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1498	COCOA POWDER	A, E, H	
1499	COCOGLYCERIDES	E	
1500	COCONUT	E	
1501	COCONUT ACID	E	Only for use in topical medicines for dermal application.
1502	COCONUT OIL	A, E, H	
1503	COCOS NUCIFERA	A, E, H	
1504	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:

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (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.
1505	CODONOPSIS LANCEOLATA	A, H	
1506	CODONOPSIS PILOSULA	A, H	
1507	CODONOPSIS TANGSHEN	A, H	
1508	COFFEA ARABICA	A, E, H	Caffeine is a mandatory component of Coffea arabica. When the medicine is packaged for supply as an undivided preparation and is for internal use or oral application, the medicine must

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			not contain a concentration of total caffeine greater than 4%. 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%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) 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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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			c) 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. d) 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.’ e) 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.'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1509	COFFEA CANEPHORA	A, E, H	Caffeine is a mandatory component of Coffea canephora. 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 4%. 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%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021;

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) 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%. c) 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. d) 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.'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			- (CAFFPREG) 'Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.' e) 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).
1510	COFFEE	E, H	Caffeine is a mandatory component of coffee. 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 4%. 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%. The requirements specified in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) 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%. c) 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. d) When the maximum recommended daily dose of the medicine provides greater than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.' e) 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).
1511	COFFEE OIL	E	Permitted for use only in combination with other

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1512	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%.
1513	COGNAC OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1514	COGNAC OIL GREEN	A, E, H	
1515	COGNAC OIL WHITE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1516	COIX LACHRYMA-JOBI	A, H	
1517	COLA ACUMINATA	A, E, H	Caffeine is a mandatory

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			component of Cola acuminata. 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 4%. 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%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) When the medicine is

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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%. c) 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. d) 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.’ e) 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1518	COLA NITIDA	A, E, H	Caffeine is a mandatory component of Cola nitida. 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 4%. 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%. The requirements specified in paragraphs (a) to (e) below apply in relation to a medicine that contains the ingredient that: - is listed in the Register on or after 2 September 2019; or - is supplied after 2 March 2021. A medicine that contains the

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			ingredient and that: - was listed in the Register before 2 September 2019; and - is supplied before 2 March 2021; may comply with the requirements in paragraphs (a) to (e) below. a) When for internal use or oral application, the maximum recommended daily dose of the medicine must provide no more than 400mg of total caffeine. b) 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%. c) 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. d) 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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.' e) When the maximum recommended daily dose of the medicine provides greater than 80 mg of total caffeine and the medicines is for internal use or oral application, the following warning statements are required on the label: - (CAFFLMT) 'Limit the use of caffeine-containing products (including tea and coffee) when taking this product.' - (CAFFCYP) 'Caffeine interacts with enzyme CYP1A2 in the liver. Consult your health professional before taking with other medicines' (or words to that effect).
1519	COLCHICUM AUTUMNALE	H	Only for use as an active homoeopathic ingredient.
1520	COLECALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must not be more than 25 micrograms of Vitamin D.
1521	COLLAGEN	E	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
1522	COLLINSONIA CANADENSIS	A, H	
1523	COLLOIDAL ANHYDROUS SILICA	A, E, H	Only for use when the route of administration is other than inhalation.
1524	COLOPHONY	A, E, H	
1525	COMMIPHORA HABESSINICA	A, H	
1526	COMMIPHORA KATAF	A, H	
1527	COMMIPHORA MYRRHA	A, E, H	
1528	COMMON INDIAN COBRA	H	Only for use as an active homoeopathic ingredient.
1529	CONCENTRATED FISH OMEGA-3 TRIGLYCERIDES	A	Only for oral use.
1530	CONCENTRATED SQUID OMEGA-3 TRIGLYCERIDES	A	Only for oral use. 'Concentrated squid omega-3-triglycerides' must be obtained from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the preparation AND be presented in a therapeutic dosage form for therapeutic use. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood'.
1531	CONIFER GREEN NEEDLE COMPLEX	A	Only for topical and oral use. Must be made by petroleum ether extraction of needles of the conifer species Pinus

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			sylvestris (Scotch Pine) and Picea abies (Norwegian Spruce).
1532	CONIFER PHYTOSTEROL COMPLEX	A	
1533	CONIOSELIUM UNIVITTATUM	A, H	
1534	CONIUM MACULATUM	H	Only for use as an active homoeopathic ingredient. The concentration must be no more than exceed 12X homoeopathic dilution.
1535	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%.
1536	CONYZA CANADENSIS	A, H	
1537	COPAIBA OIL	A, E, H	
1538	COPAIFERA LANGSDORFFII	A, E, H	
1539	COPERNICIA CERIFERA	A, E, H	
1540	COPOVIDONE	E	
1541	COPPER	H	Only for use as an active homoeopathic ingredient. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1542	COPPER (II) ASPARTATE	A, H	Copper is a mandatory component of copper (II) aspartate. The percentage of copper from copper (II) aspartate should be calculated based on the molecular weight of copper (II) aspartate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1543	COPPER (II) GLYCINATE	A, H	Copper is a mandatory component of copper (II) glycinate. The percentage of copper from copper (II) glycinate should be calculated based on the molecular weight of Copper (II) glycinate. The concentration of copper compounds in products must be no more than 5%. The maximum daily dose must not contain more than 5mg of copper.
1544	COPPER (II) LYSINATE	A, H	Copper is a mandatory component of copper (II) lysinate. The percentage of copper from

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
1545	COPPER ACETYL TYROSINATE METHYLSILANOL	E	Only for use in topical medicines for dermal application.
1546	COPPER CHLOROPHYLL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1547	COPPER CHLOROPHYLLIN	E	Only for use as a colour in oral and topical medicines.
1548	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

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1549	COPPER TRIPEPTIDE-1	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 3%.
1550	COPTIS CHINENSIS	A, H	
1551	COPTIS JAPONICA	A, H	
1552	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%.
1553	CORDYCEPS SINENSIS	A, E, H	Must not contain material of animal origin such as insect larvae.
1554	CORIANDER DRY	A, H	
1555	CORIANDER OIL	A, E, H	
1556	CORIANDER POWDER	A, H	
1557	CORIANDRUM SATIVUM	A, E, H	
1558	CORN GLYCERIDES	E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1559	CORN SILK DRY	A, H	
1560	CORN SILK POWDER	A, H	
1561	CORN SYRUP	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1562	CORN SYRUP SOLIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1563	CORNUS FLORIDA	A, H	
1564	CORNUS OFFICINALIS	A, H	
1565	CORTISONE ACETATE	H	Only available as an active homoeopathic ingredient.
1566	CORYDALIS AMBIGUA	A, E, H	
1567	CORYDALIS BUNGEANA	A, H	
1568	CORYDALIS CAVA	A, H	
1569	CORYDALIS FABACEA	A, H	
1570	CORYDALIS FORMOSA	A, H	
1571	CORYDALIS TURTSCHANINOVII	A, H	
1572	CORYLUS AMERICANA	A, H	
1573	CORYLUS AVELLANA	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1574	CORYMBIA CITRIODORA	A, E, H	Cineole is a mandatory component of Corymbia citriodora. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
1575	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
1576	COSMOS BIPINNATUS	A, H	
1577	COSTUS ROOT OIL	A, H	
1578	COSTUS SPICATUS	A, H	
1579	COTTONSEED OIL	A, E, H	
1580	COUCH GRASS RHIZOME DRY	A, H	
1581	COUCH GRASS RHIZOME POWDER	A, H	
1582	COUMARIN	E, H	Only for use as an active homoeopathic ingredient or excipient ingredient.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When used as an active homoeopathic ingredient, the concentration in the medicine must be no more than 0.001%. When used as an excipient, must only be used in topical medicines for dermal application. The requirements specified in paragraph (a) below apply to medicines that contain the ingredient that are: - listed in the Register on or after 2 March 2020; or - supplied after 2 March 2021. a) When used as an excipient: - the concentration of coumarin in the medicine must not be more than 0.001%; and - the label of the medicine must specify that the product should only be used by adults.
1583	CRANBERRY	E	
1584	CRATAEGUS CUNEATA	A, E, H	
1585	CRATAEGUS LAEVIGATA	A, E, H	
1586	CRATAEGUS MONOGYNA	A, E, H	
1587	CRATAEGUS PINNATIFIDA	A, E, H	
1588	CRATEVA MAGNA	A, E, H	
1589	CREATINE	A, E	
1590	CREATINE MONOHYDRATE	A, E	
1591	CREATINE PHOSPHATE	A, E	
1592	CREATININE	E	Only for use in topical medicines for dermal application and not for use in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1593	CREOSOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1594	CREOSOTE	H	Only for use as an active homoeopathic ingredient.
1595	CRESOL	E	Only for use as a preservative in topical medicines. The concentration of phenols (including cresols and xylenols and any other homologue of phenol) boiling below 220 degrees centigrade must be no more than 3%.
1596	CRESYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
1597	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%.
1598	CROCUS SATIVUS	A, H	
1599	CROSCARMELLOSE SODIUM	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1600	CROSPOVIDONE	E	
1601	CROTON CASCARILLA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1602	CROTON ELUTERIA	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1603	CRYPTOMERIA JAPONICA	A, H	
1604	CUBEB OIL	A, H	
1605	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%.
1606	CUCUMBER	E	
1607	CUCUMIS MELO	A, H	
1608	CUCUMIS SATIVUS	A, E, H	
1609	CUCURBITA MAXIMA	A, E, H	
1610	CUCURBITA MOSCHATA	A, H	
1611	CUCURBITA PEPO	A, E, H	
1612	CULLEN CORYLIFOLIUM	A, H	
1613	CUMIC ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1614	CUMIN OIL	A, E, H	
1615	CUMINALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1616	CUMINUM CYMINUM	A, H	
1617	CUMINYL NITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1618	CUPRESSUS ARIZONICA	A, H	
1619	CUPRESSUS FUNEBRIS	A, E, H	
1620	CUPRESSUS MACROCARPA	A, H	
1621	CUPRESSUS SEMPERVIRENS	A, E, H	
1622	CUPRIC ACETATE MONOHYDRATE	H	Only for use as an active homoeopathic ingredient.
1623	CUPRIC ARSENITE	H	Only for use as an active homoeopathic ingredient.
1624	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 750 micrograms of copper from cupric citrate per the recommended daily dose or the medicine must not contain more than 1.86 milligrams of cupric citrate per the recommended daily dose.
1625	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.
1626	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.

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			When for other than internal use, the concentration of copper compounds must be no more than 5%.
1627	CUPRIC SULFATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate. The percentage of copper from cupric sulfate should be calculated based on the molecular weight of cupric sulfate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%.
1628	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			copper compounds must be no more than 5%. When used topically, cupric sulfate is a mandatory component of cupric sulfate monohydrate.
1629	CUPRIC SULFATE PENTAHYDRATE	A, E, H	When for oral or sublingual use, copper is a mandatory component of cupric sulfate pentahydrate. The percentage of copper from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate. When for internal use the maximum daily dose must not contain more than 5 mg of copper. When for other than internal use, the concentration of copper compounds must be no more than 5%. When used topically cupric sulfate is a mandatory component of cupric sulfate pentahydrate. The percentage of cupric sulfate from cupric sulfate pentahydrate should be calculated based on the molecular weight of cupric sulfate pentahydrate.
1630	CURCULIGO ORCHIOIDES	A, H	
1631	CURCUMA AROMATICA	A, H	

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
1632	CURCUMA LONGA	A, E, H	
1633	CURCUMA XANTHORRHIZA	A, H	
1634	CURCUMA ZEDOARIA	A, H	
1635	CURCUMIN	A, E, H	When for excipient use, only permitted for use as a colour in topical and oral medicines.
1636	CUSCUTA EPITHYMUM	A, H	
1637	CUSCUTA EUROPAEA	A, H	
1638	CUSCUTA HYGROPHILAE	A, H	
1639	CUSCUTA RACEMOSA	A, H	
1640	CUSPARIA FEBRIFUGA	A, H	
1641	CYAMOPSIS TETRAGONOLOBA	A, E, H	
1642	CYANOCOBALAMIN	A, E, H	
1643	CYANOMETHYLPHENYL MENTHANE CARBOXAMIDE	E	For dental use only in proprietary ingredients. Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the medicine must be no more than 5%.
1644	CYATHULA OFFICINALIS	A, H	
1645	CYCLAMEN ALDEHYDE	E	Only for use as an excipient ingredient in topical medicines.
1646	CYCLAMEN PURPURASCENS	A, H	
1647	CYCLOHEXADECENONE-8	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1648	CYCLOHEXANE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1649	CYCLOHEXANE, 1-ETHENYL-1-METHYL-2-(1-METHYLETHENYL)-4-(1-METHYLETHYL)-, DIDEHYDRO DERIV.	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1650	CYCLOHEXANEETHANOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1651	CYCLOHEXYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1652	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%.
1653	CYCLOHEXYL PHENETHYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1654	CYCLOHEXYL SALICYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1655	CYCLOHEXYLETHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1656	CYCLOMETHICONE	E	Only for use as an excipient ingredient in topical medicines.
1657	CYCLOPENTADECANONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1658	CYDONIA OBLONGA	A, H	
1659	CYMBOPOGON FLEXUOSUS	A, E, H	When for topical use, aldehydes calculated as citral is a mandatory component of Cymbopogon flexuosus and the concentration of aldehydes calculated as citral in the medicine must not be more

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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 5%.
1660	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%.
1661	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%.
1662	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%.
1663	CYNANCHUM ATRATUM	A, H	
1664	CYNANCHUM STAUNTONII	A, E, H	
1665	CYNARA SCOLYMUS	A, E, H	
1666	CYNODON DACTYLON	A, E, H	
1667	CYNOMORIUM COCCINEUM SUBSP. SONGARICUM	A, H	
1668	CYPERUS LONGUS	A, H	

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1669	CYPERUS ROTUNDUS	A, H	
1670	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%.
1671	CYPRIPEDIUM PARVIFLORUM VAR. PUBESCENS	A, H	
1672	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.
1673	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.
1674	CYSTEINE HYDROCHLORIDE MONOHYDRATE	A, E	When used as an excipient, permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as 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.
1675	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.
1676	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%.
1677	D-ALPHA-TOCOPHEROL	A, E	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1678	D-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1679	D-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E	
1680	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%.
1681	D-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1682	D-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1683	D-FENCHONE	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1684	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%.
1685	D-PULEGONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. The concentration of d-pulegone in the medicine must not be more than 4%.
1686	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.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1687	DACTYLIS GLOMERATA	A, H	
1688	DACTYLORHIZA INCARNATA SUBSP. INCARNATA	A, H	
1689	DAEMONOROPS DRACO	A, E, H	
1690	DAHLIA PINNATA	A, H	
1691	DALBERGIA ODORIFERA	A, H	
1692	DAMIANA LEAF POWDER	A	
1693	DANDELION LEAF DRY	A, H	
1694	DANDELION LEAF POWDER	A, H	
1695	DANDELION ROOT DRY	A, H	
1696	DANDELION ROOT POWDER	A, H	
1697	DAPHNE GENKWA	A, H	
1698	DAPHNE MEZEREUM	A, H	The maximum recommended daily dose must be no more than the equivalent of 1mg of the dry herbal material.
1699	DATE	E	
1700	DATURA STRAMONIUM	A, H	Only for use in oral medicines. Alkaloids calculated as hyoscyamine is a mandatory component of Datura stramonium. The concentration of alkaloids calculated as hyoscyamine from all ingredients in the product must be no more than 300 micrograms/Kg or 300 micrograms/L or 0.00003%.
1701	DAUCUS CAROTA	A, E, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1702	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%.
1703	DEA-OLETH-3 PHOSPHATE	E	Only for use in topical medicines for dermal application and not be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 1%. The medicine requires the following warning statements on the medicine label: - (EYE) 'Avoid contact with eyes' - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1704	DECAHYDRO-2,2,6,6,7,8,8-HEPTAMETHYL-2H-INDENO(4,5-B) FURAN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1705	DECAHYDRO-BETA-	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	NAPHTHYLACETATE		combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1706	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%.
1707	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%.
1708	DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1709	DECANAL	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1710	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%.
1711	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.
1712	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%.
1713	DECYL ACETATE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1714	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%.
1715	DECYL GLUCOSIDE	E	Only for use in topical medicines for dermal application.
1716	DECYL OLEATE	E	Only for use in topical medicines for dermal application.
1717	DECYLENE GLYCOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 0.5%.
1718	DEER ANTLER CARTILAGE	H	Only for use as an active homoeopathic ingredient.
1719	DEER VELVET ANTLER POWDER	A	Medicines that contain 'deer velvet antler powder' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1720	DEER VELVET ANTLER SLICE	A	Medicines that contain 'deer velvet antler slice' as the therapeutically active ingredient are subject to the following conditions: a) the medicines are for oral use only; b) the antlers (including the velvet) are sourced only from red deer (Cervus elaphus), elk/wapiti (Cervus canadensis), or a crossbreed of these species; c) the deer are sourced only from farmed stock bred and raised in New Zealand; d) the deer are sourced only from herds farmed for food in accordance with the Animal Products Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time; e) the antlers are removed from the deer only according to the Animal Welfare Act 1999 (New Zealand) and the regulations made under that Act, as in force or existing from time to time.
1721	DEERTONGUE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1722	DEHYDROACETIC ACID	E	Only for use in topical medicines for dermal application.
1723	DEHYDROMENTHOFUROLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1724	DEHYDROXANTHAN GUM	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1725	DELPHINIUM STAPHISAGRIA	A, H	The concentration of the equivalent dry Delphinium staphisagria in the medicine must be no more than 0.2%.
1726	DELTA-DAMASCONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1727	DELTA-DECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1728	DELTA-DODECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1729	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%.
1730	DELTA-OCTALACTONE	E	Permitted for use only in combination with other

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a 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	DELTA-TETRADECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1732	DELTA-TOCOPHEROL	E	
1733	DELTA-UNDECALACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1734	DEMINERALISED FISH PROTEOGLYCAN EXTRACT	A	
1735	DENATONIUM BENZOATE	E	
1736	DENDROBIUM NOBILE	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1737	DESCURAINIA SOPHIA	A, H	
1738	DESMODIUM STYRACIFOLIUM	A, H	
1739	DESMODIUM TRIQUETUM	A, H	
1740	DEVIL'S CLAW TUBER DRY	A, H	
1741	DEVIL'S CLAW TUBER POWDER	A, H	
1742	DEXPANTHENOL	A, E	
1743	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%.
1744	DEXTRAN 40	A, E	
1745	DEXTRATES	E	
1746	DEXTRIN	E	
1747	DEXTRIN PALMITATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1748	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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			other active or excipient ingredients. The ratio of DHA to EPA must be 2:1.
1749	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%.
1750	DI-C12-15 ALKYL FUMARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1751	DI-N-PROPYL ISOCINCHOMERONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
1752	DI-PPG-3 MYRISTYL ETHER ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1753	DIACETIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1754	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%.
1755	DIACETYL TARTARIC ACID ESTERS OF MONO- AND DIGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1756	DIACETYLATED MONOGLYCERIDES	E	Permitted for use only in combination with other permitted ingredients as a coating solution.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1757	DIAMMONIUM LAURYL SULFOSUCCINATE	E	Only for use as an excipient ingredient in topical medicines.
1758	DIANTHUS SUPERBUS	A, H	
1759	DIAZOLIDINYL UREA	E	Only for use in topical medicines for dermal application.
1760	DIBASIC MAGNESIUM CITRATE TETRAHYDRATE	A	Only for use in oral medicines.
1761	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.
1762	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			of the preparation must not exceed 11.5.
1763	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.
1764	DIBASIC SODIUM PHOSPHATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1765	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1766	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1767	DIBASIC SODIUM PHOSPHATE HEPTAHYDRATE	A, E, H	When used as an active ingredient and the preparation is intended as a mineral supplementation, sodium is a mandatory component of dibasic sodium phosphate heptahydrate. When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1768	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. When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more than 120 mg, the medicine

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1769	DIBENZYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1770	DIBUTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1771	DIBUTYL PHTHALATE	E	Only for use in topical medicines for dermal application.
1772	DIBUTYL SEBACATE	E	
1773	DIBUTYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in the

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
1774	DICAPRYLYL CARBONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 34%.
1775	DICAPRYLYL ETHER	E	Only for use in topical medicines for dermal application.
1776	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%.
1777	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%.
1778	DICHLOROBENZYL ALCOHOL	E	
1779	DICHLOROMETHANE	E	The concentration in the medicine must be no more than 0.06%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The residual solvent limit for Dichloromethane is 6 mg per recommended daily dose.
1780	DICTAMNUS ALBUS	A, H	
1781	DICTAMNUS DESYCARPUS	A, H	
1782	DICYCLOHEXYL DISULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1783	DIEFFENBACHIA SEGUINE	H	Only for use as an active homoeopathic ingredient.
1784	DIETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
1785	DIETHYL CITRACONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1786	DIETHYL MALONATE	E	Permitted for use only in combination with other permitted ingredients as a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1787	DIETHYL PHTHALATE	E	
1788	DIETHYLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1789	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			words to this effect).
1790	DIETHYLAMINOMETHYLCOUMARIN	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1791	DIETHYLDIMETHYL-2-CYCLOHEXENONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1792	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%.
1793	DIETHYLENE GLYCOL MONOETHYL ETHER	E	Only for use in topical medicines for dermal application.
1794	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 3%.
1795	DIETHYLHEXYL SEBACATE	E	Only for use in topical medicines for dermal application.
1796	DIETHYLHEXYL SYRINGYLIDENEMALONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
1797	DIETHYLHEXYL-2,6-NAPHTHALATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes' (or words to that effect).
1798	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.'
1799	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%.
1800	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%.
1801	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%.
1802	DIGLYCOL/CHDM/ISOPHTHALATES/SIP COPOLYMER	E	Only for use in topical medicines for dermal application.
1803	DIHEXYL FUMARATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1804	DIHYDRO JASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1805	DIHYDRO TERPINYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1806	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%.
1807	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
1808	DIHYDRO-ISOJASMONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1809	DIHYDROACTINIDIOLIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1810	DIHYDROAMBRETTOLIDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1811	DIHYDROCARVYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1812	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%.
1813	DIHYDROCUMINYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
1814	DIHYDROEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1815	DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
1816	DIHYDROINDENYL-2,4-DIOXANE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1817	DIHYDROLINALOOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1818	DIHYDROMYRCENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1819	DIHYDROMYRCENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
1820	DIHYDROXYACETONE	E	Only for use in topical medicines for dermal application.
1821	DIISOPROPYL ADIPATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 15%.
1822	DIISOPROPYL SEBACATE	E	Only for use in topical medicines for dermal application and not be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1823	DIISOSTEARYL DIMER DILINOLEATE	E	Only for use in topical medicines for dermal application.
1824	DILAURYL THIODIPROPIONATE	E	Only for use in topical medicines for dermal application.
1825	DILL HERB OIL	A, E, H	
1826	DILL SEED OIL	A, E, H	
1827	DILL WEED OIL	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1828	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%.
1829	DIMETHICONE 12500	E	
1830	DIMETHICONE 4000	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1831	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%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1832	DIMETHICONE SILYLATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1833	DIMETHICONE/METHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
1834	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1835	DIMETHYL 3-CYCLOHEXENE-1-CARBOXALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1836	DIMETHYL ANTHRANILATE	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1837	DIMETHYL BENZYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1838	DIMETHYL BENZYL CARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1839	DIMETHYL BENZYL CARBINYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1840	DIMETHYL BENZYL CARBINYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1841	DIMETHYL PHENYLETHYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1842	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%.
1843	DIMETHYL POLYSILOXANE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
1844	DIMETHYL SUCCINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1845	DIMETHYL SULFATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1846	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%.
1847	DIMETHYL SULFONE	A	Only for use in oral and topical medicines.
1848	DIMETHYL SULFOXIDE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1849	DIMETHYLACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1850	DIMETHYLCYCLOHEXYLETHOXY ISOBUTYLPROPANOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1851	DIMETHYLGLYCINE HYDROCHLORIDE	A	Only for use in oral medicines.
1852	DIMETHYLOL DIMETHYL HYDANTOIN	E	Only for use in topical medicines for dermal application.
1853	DIMETICONE 1.5	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must not be more than 23%.
1854	DIMETICONE 10	E	
1855	DIMETICONE 100	E	Only for use in topical medicines for dermal application.
1856	DIMETICONE 1000	E	
1857	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%
1858	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%.
1859	DIMETICONE 20	E	Only for use in topical medicines for dermal application.
1860	DIMETICONE 200	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
1861	DIMETICONE 30	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
1862	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.
1863	DIMETICONE 360	E	Only for use in topical medicines for dermal application.
1864	DIMETICONE 450	E	Only for use in topical medicines for dermal application.
1865	DIMETICONE 5	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 10%.
1866	DIMETICONE 50	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1867	DIMETICONE 5000	E	Only for use in topical medicines for dermal application.
1868	DIMETICONE 6	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
1869	DIMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
1870	DIMETICONE COPOLYOL PHOSPHATE	E	Only for use in topical medicines for dermal application.
1871	DIMETICONE CROSSPOLYMER-3	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 15%.
1872	DIMETICONE/PEG-10/15 CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
1873	DIMETICONOL	E	Only for use in topical medicines for dermal application.
1874	DIMETICONOL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1875	DIMETICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must not be more than 10%.
1876	DIMOCARPUS LONGAN	A, H	
1877	DIOCTYL ADIPATE	E	Only for use in topical medicines for dermal application.
1878	DIOCTYL MALEATE	E	Only for use in topical medicines for dermal application.
1879	DIOCTYL SUCCINATE	E	Only for use in topical medicines for dermal

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application.
1880	DIOCTYL TEREPHTHALATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1881	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%
1882	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.
1883	DIOSCOREA COLLETTII	A, H	
1884	DIOSCOREA COLLETTII VAR. HYPOGLAUCA	A, H	
1885	DIOSCOREA JAPONICA	A, H	
1886	DIOSCOREA OPPOSITIFOLIA	A, H	
1887	DIOSCOREA POLYSTACHYA	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1888	DIOSCOREA SEPTEMLOBA	A, H	
1889	DIOSCOREA VILLOSA	A, E, H	
1890	DIOSPYROS KAKI	A, E, H	
1891	DIOXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the medicine must be no more than 3%. When used in primary sunscreen products, the medicine requires the following warning statements on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
1892	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use on damaged skin. The concentration in the medicine must be no more than 0.5%.
1893	DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TETRAISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 5%.
1894	DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1895	DIPHENYL DIMETHICONE	E	Only for use in topical medicines for dermal application.
1896	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%.
1897	DIPHENYL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1898	DIPOTASSIUM GLYCYRRHIZATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
1899	DIPROPIONYL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1900	DIPROPYLENE GLYCOL	E	Only for use in topical medicines for dermal application.
1901	DIPROPYLENE GLYCOL DIBENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4.2%.
1902	DIPROPYLENE GLYCOL SALICYLATE	E	Only for use in topical medicines for dermal application.
1903	DIPSACUS ASPER	A, H	
1904	DIPSACUS JAPONICUS	A, H	

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1905	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%.
1906	DISODIUM ASCORBYL SULFATE	E	Only for use in topical medicines for dermal application.
1907	DISODIUM COCOAMPHODIACETATE	E	Only for use in topical medicines for dermal application.
1908	DISODIUM COCOAMPHODIPROPIONATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
1909	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%.
1910	DISODIUM EDETATE	E	When for oral or sublingual use and the total amount of sodium from all ingredients in the maximum daily dose is more

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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than 120 mg, the medicine requires the following warning statement on the medicine label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
1911	DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1%.
1912	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%.
1913	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%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1914	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%.
1915	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%.
1916	DISODIUM NADH	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.02%.
1917	DISODIUM OLEAMIDO PEG-2 SULFOSUCCINATE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye. The concentration in the medicine must be no more than 1%.
1918	DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE	A	Only for use as an active ingredient in sunscreens for dermal application. The concentration in the

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 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).
1919	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%.
1920	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%.
1921	DISODIUM STEAROYL GLUTAMATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
1922	DISPERSIBLE CELLULOSE	E	
1923	DISTARCH PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
1924	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%.
1925	DISTEARETH-6 DIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal application.
1926	DISTEARYL PHTHALIC ACID AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1927	DISTEARYLDIMONIUM CHLORIDE	E	Only for use in topical medicines for dermal

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
1928	DIVINYLDIMETHICONE/DIMETHICONE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1.5%.
1929	DL-ALPHA-TOCOPHEROL	A, E	
1930	DL-ALPHA-TOCOPHERYL ACETATE	A, E, H	
1931	DL-ALPHA-TOCOPHERYL ACID SUCCINATE	A, E, H	
1932	DL-BORNEOL	E	
1933	DL-LIMONENE	E	Only for use in topical medicines for dermal application.
1934	DL-THREONINE	A, E	
1935	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.
1936	DOCUSATE SODIUM	E	
1937	DODECAHYDRO-3A,6,6,9A-TETRAMETHYLNAPHTHO(2,1-	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
	B)FURAN		permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1938	DODECANENITRILE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1939	DODECENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1940	DODECENE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.2%.
1941	DODECYL ACETATE	E	Permitted for use only in

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1942	DODECYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
1943	DOLICHOS LABLAB	A, H	
1944	DOLOMITE	A, E, H	
1945	DRACAENA DRACO	A, H	
1946	DRIED BUTTERMILK	E	
1947	DRIED CALCIUM SULFATE	A, E, H	
1948	DRIED MAGNESIUM SULFATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
1949	DRIMIA INDICA	A, H	
1950	DRIMIA MARITIMA	A, H	
1951	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
1952	DROSERA ANGLICA	A, H	
1953	DROSERA BURMANNI	A, H	
1954	DROSERA INTERMEDIA	A, H	
1955	DROSERA RAMENTACIA	A, H	
1956	DROSERA ROTUNDIFOLIA	A, E, H	
1957	DROSERA ROTUNDIFOLIA MIS	A, H	
1958	DRYNARIA FORTUNEI	A, H	
1959	DRYOBALANOPS AROMATICA	A, H	
1960	DRYOPTERIS FILIX-MAS	H	Only for use as an active homoeopathic ingredient.
1961	DULACIA INOPIFLORA	A, H	
1962	DUNALIELLA SALINA	A, E, H	
1963	DUPICAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
1964	DURVILLAEA ANTARCTICA EXTRACT	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.1%.
1965	DWARF PINE-NEEDLE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
1966	DYSPHANIA AMBROSIOIDES	A, H	Volatile oil components (of Dysphania ambrosioides) are mandatory components of Dysphania ambrosioides.
1967	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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).
1968	ECHINACEA ANGUSTIFOLIA	A, E, H	
1969	ECHINACEA PALLIDA	A, E, H	
1970	ECHINACEA PURPUREA	A, E, H	
1971	ECHINOPA SPINOSISSIMUS	A, H	
1972	ECLIPTA PROSTRATA	A, H	
1973	ECTOIN	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be used in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 3%.
1974	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%.
1975	EDETIC ACID	E	The concentration in the medicine must be no more than 0.25%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
1976	EGG LECITHIN	A, E	
1977	EGGSHELL MEMBRANE HYDROLYSATE	A	
1978	EGGSHELL MEMBRANE POWDER	A	
1979	EICHHORNIA CRASSIPES	A, H	
1980	ELAEAGNUS ANGUSTIFOLIA	A, H	
1981	ELAEIS GUINEENSIS	A, E, H	
1982	ELASTIN	E	Only for use in topical medicines for dermal application.
1983	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%.
1984	ELDER FLOWER BLACK DRY	A, E, H	
1985	ELDER FLOWER BLACK POWDER	A, H	
1986	ELECAMPANE RHIZOME DRY	A, H	
1987	ELECAMPANE RHIZOME POWDER	A, H	
1988	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more than 1%.
1989	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%.
1990	ELEMOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
1991	ELEOCHARIS DULCIS	A, H	
1992	ELETTARIA CARDAMOMUM	A, E, H	
1993	ELEUTHEROCOCCUS NODIFLORUS	A, H	
1994	ELEUTHEROCOCCUS ROOT DRY	A, H	
1995	ELEUTHEROCOCCUS ROOT POWDER	A, H	
1996	ELEUTHEROCOCCUS SENTICOSUS	A, H	
1997	ELSHOLTZIA SPLENDENS	A, H	
1998	ELYMUS REPENS	A, E, H	
1999	EMU OIL	A, E	Emu oil ingredients must meet the following two

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			requirements: 1) the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and 2) the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption.
2000	EMULSIFYING WAX	E	
2001	ENOXOLONE	E	Only for use in topical medicines for dermal application.
2002	ENZYME MODIFIED CREAM	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2003	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			from all ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
2004	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%.
2005	EPIGAEA REPENS	A, H	
2006	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.
2007	EPILOBIUM PALUSTRE	A, H	
2008	EPILOBIUM PARVIFLORUM	A, H	

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2009	EPIMEDIUM BREVICORNU	A, H	
2010	EPIMEDIUM GRANDIFLORUM	A, H	
2011	EPIMEDIUM SAGITTATUM	A, H	
2012	EPOXY CEDRENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2013	EQUISETUM ARVENSE	A, E, H	
2014	EQUISETUM HIEMALE	A, H	
2015	ERGOCALCIFEROL	A, E	When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
2016	ERGOTHIONEINE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.0005%.
2017	ERIGERON BREVISCAPUS	A, H	
2018	ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components. The concentration of amygdalin in the medicine must be 0%.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration of hydrocyanic acid in the medicine must be no more than 1 microgram/kg or 1 microgram/L or 0.0000001%.
2019	ERIOCAULON BUERGERIANUM	A, H	
2020	ERIODICTYON CRASSIFOLIUM	A, H	
2021	ERIODICTYON GLUTINOSUM	A, H	
2022	ERODIUM CICUTARIUM	A, H	
2023	ERUCA SATIVA	A, H	
2024	ERYTHORBIC ACID	E	
2025	ERYTHRITOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
2026	ERYTHROSINE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2027	ERYTHROSINE ALUMINIUM LAKE	E	Permitted for use only as a colour in medicines limited to topical and oral routes of administration.
2028	ERYTHRULOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			for use in the eye. The concentration in the medicine must be no more than 2%. The medicine requires the following warning statement on the medicine label: - (EYE) 'Avoid contact with eyes'.
2029	ESCHSCHOLZIA CALIFORNICA	A, H	
2030	ESTRONE	H	Only for use as an active homoeopathic ingredient.
2031	ETHANOL	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'.
2032	ETHANOL ABSOLUTE	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale and must comply

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. When the concentration of ethanol from all ingredients in the medicine is more than 3%, the medicine requires the following warning statement on the medicine label: - (ETHAN) 'Contains ethanol or contains alcohol'
2033	ETHER	E	The concentration of ether in the medicine must be no more than 10%.
2034	ETHOHEXADIOL	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (EHEXAD) 'Contains ethohexadiol' (or words to that effect).
2035	ETHOXYLATED HYDROGENATED CASTOR OIL	E	
2036	ETHOXYLATED NONYLPHENOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2037	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%.
2038	ETHYL (2,4-DIMETHYL-[1,3] DIOXOLAN-2-YL) ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2039	ETHYL (3AR,4S,7R,7AR)-REL-OCTAHYDRO-4,7-METHANO[3AH]INDENE-3A-CARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2040	ETHYL 2,3,6,6-TETRAMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			1%.
2041	ETHYL 2,6,6,TRIMETHYL-1,3-CYCLOHEXADIENE-1-CARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2042	ETHYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2043	ETHYL 2-ETHYL-6,6-DIMETHYL-2-CYCLOHEXENECARBOXYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2044	ETHYL 2-HEXYL ACETOACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2045	ETHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2046	ETHYL 2-METHYLPENTANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2047	ETHYL 3-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2048	ETHYL 3-HYDROXYBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
2049	ETHYL 3-HYDROXYHEXANOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2050	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%.
2051	ETHYL 3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2052	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

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			5%.
2053	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%.
2054	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%.
2055	ETHYL ACRYLATE	E	
2056	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%.
2057	ETHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2058	ETHYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2059	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%.
2060	ETHYL BUTYLACETYLAMINOPROPIONATE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 7.5%. The medicine requires the following warning statement on the medicine label: - (EYE2) 'May be irritant to the eyes (or words to that effect)'.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2061	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%.
2062	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%.
2063	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%.
2064	ETHYL CAPRYLATE	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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 CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2066	ETHYL CROTONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2067	ETHYL ENANTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2068	ETHYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2069	ETHYL HYDROXYBENZOATE	E	Medicines containing hydroxybenzoates require the following warning statement on the medicine label: - (TOTBNZ) 'Contains hydroxybenzoates' (or words to this effect) if the medicine contains more than one hydroxybenzoate source OR 'Contains [insert the approved name of hydroxybenzoate used]' (or words to this effect) if product contains one hydroxybenzoate source.
2070	ETHYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2071	ETHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2072	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%.
2073	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%.
2074	ETHYL LEVULATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			flavour concentration in a medicine must be no more than 5%.
2075	ETHYL LEVULINATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2076	ETHYL LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2077	ETHYL LINALYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2078	ETHYL LINOLEATE	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2079	ETHYL LINOLENATE	E	Only for use in topical medicines for dermal application.
2080	ETHYL MACADAMIATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
2081	ETHYL MALTOL	E	
2082	ETHYL MENTHANE CARBOXAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2083	ETHYL METHACRYLATE	E	Only for use in topical medicines for dermal application.
2084	ETHYL METHYLPHENYLGLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			medicine must be no more 1%.
2085	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%.
2086	ETHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2087	ETHYL OLEATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2088	ETHYL ORTHO-METHOXYBENZYL ETHER	E	Permitted for use only in combination with other permitted ingredients as a

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2089	ETHYL OXYHYDRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2090	ETHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2091	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%.

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
2092	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%.
2093	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%.
2094	ETHYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2095	ETHYL RICINOLEATE	E	Permitted for use only in

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2096	ETHYL 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%.
2097	ETHYL SEBACATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2098	ETHYL STEARATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2099	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%.
2100	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%.
2101	ETHYL TRANS-2, CIS-4-DECADIENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2102	ETHYL TRANS-3-HEXENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2103	ETHYL UNDECYLENATE	E	Permitted for use only in combination with other

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2104	ETHYL VALERATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2105	ETHYL VANILLIN	E	
2106	ETHYL-2-METHYL-1,3-DIOXOLANE-2-ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2107	ETHYL-2-METHYL-4-PENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2108	ETHYL-2-METHYLPENTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2109	ETHYLBISIMINOMETHYL GUAIACOL MANGANESE CHLORIDE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 0.002%.
2110	ETHYLCELLULOSE	E	
2111	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%.
2112	ETHYLENE GLYCOL	E	The residual solvent limit for ethylene glycol is 6.2 mg per recommended daily dose. The concentration in the medicine must be no more than 0.062%.
2113	ETHYLENE GLYCOL MONOPALMITOSTEARATE	E	Only for use in topical medicines for dermal application.

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
2114	ETHYLENE/ACRYLIC ACID COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
2115	ETHYLENE/VINYL ACETATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 16%.
2116	ETHYLENEDIAMINE	E	Only for use in topical medicines for dermal application.
2117	ETHYLENEDIAMINE/HYDROGENATED DIMER DILINOLEATE COPOLYMER BIS-DI-C14-18 ALKYL AMIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 4%.
2118	ETHYLENEDIAMINE/STEARYL DIMER DILINOLEATE COPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin.

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Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			The concentration in the medicine must be no more than 6%.
2119	ETHYLHEXYL BENZOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 3.5%.
2120	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%.
2121	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
2122	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%.
2123	ETIDRONIC ACID	E	Only for use in topical medicines for dermal application only. The concentration in the medicine must be no more than 1%.
2124	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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2125	EUCALYPTUS FRUTICETORUM	A, E, H	Cineole is a mandatory component of Eucalyptus fruticetorum. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2126	EUCALYPTUS GLOBULUS	A, E, H	Cineole is a mandatory component of Eucalyptus globulus. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			closure.
2127	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.
2128	EUCALYPTUS OIL	A, E, H	Cineole is a mandatory component of Eucalyptus oil. When the plant preparation is oil and the total concentration

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			of the oil in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. When the plant preparation is oil and the total concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken' When the concentration of the oil in the preparation is more than 25% and the nominal capacity of the container is no more than 15 mL, a restricted flow insert must be fitted on the container. The medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect) - (NTAKEN) 'Not to be taken'
2129	EUCALYPTUS RADIATA	A, E, H	Cineole is a mandatory component of Eucalyptus radiata. In liquid preparations when the

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2130	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

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2131	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

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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.
2132	EUCOMMIA ULMOIDES	A, H	
2133	EUGENOL	E	When for oral ingestion, eugenol must not comprise more than 0.06% of the formulation. When used in topical medicines for dermal application, the following apply: a) When the concentration of Eugenol in the preparation is more than 25%, the nominal capacity of the container must be no more than 25 mL. b) When the concentration of Eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 mL but no more than 25mL, a child resistant closure and restricted flow insert must be fitted on the container. The medicine

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			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'
2134	EUGENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2135	EUONYMUS ATROPURPUREUS	A, H	
2136	EUONYMUS EUROPAEUS	A, H	The maximum recommended daily dose must be no more

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Permissible ingredients and requirements			
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Item	**Ingredient name**	**Purpose**	**Specific requirements**
			than the equivalent of 1mg of the dry herbal material.
2137	EUPATORIUM FORTUNEI	A, H	
2138	EUPATORIUM JAPONICUM	A, H	
2139	EUPATORIUM PERFOLIATUM	A, H	
2140	EUPATORIUM PURPUREUM	A, H	
2141	EUPHAUSIA SUPERBA OIL	A	Only for use in oral medicines. The medicine requires the following warning statement on the medicine label: - (SFOOD) 'Derived from seafood' or - (SHELL) 'Contains crustacean shellfish'.
2142	EUPHORBIA CYPARISSIAS	A, H	
2143	EUPHORBIA DRY	A, H	
2144	EUPHORBIA HETERODOXA	A, H	
2145	EUPHORBIA HIRTA	A, H	
2146	EUPHORBIA LATHYRIS	A, H	Levodopa (of Euphorbia lathyris) is a mandatory component of Euphorbia lathyris. The concentration of Levodopa (of Euphorbia lathyris) in the medicine must be no more than 10mg/kg or 10mg/L or 0.001%.
2147	EUPHORBIA PEKINENSIS	A, H	
2148	EUPHORBIA PEPLUS	H	Only for use as an active

Permissible ingredients and requirements			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			homoeopathic ingredient.
2149	EUPHORBIA POWDER	A, H	
2150	EUPHORBIA RESINIFERA	A, H	
2151	EUPHORBIA SIEBOLDIANA	A, H	
2152	EUPHRASIA OFFICINALIS	A, H	
2153	EUROPEAN GARDEN SPIDER	H	Only for use as an active homoeopathic ingredient.
2154	EUROPEAN HORNET	H	Only for use as an active homoeopathic ingredient.
2155	EURYALE FEROX	A, H	
2156	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’.
2157	EVENING PRIMROSE OIL	A, E, H	
2158	EVERNIA PRUNASTRI EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a

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Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Ingredient name**	**Purpose**	**Specific requirements**
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.