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

(section 4)

Part 1 – Table 1

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2817	KADSURA COCCINEA	A, H	
2818	KAEMPFERIA GALANGA	A, H	
2819	KALMIA LATIFOLIA	A, H	Arbutin is a mandatory component of Kalmia latifolia. 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 %.
2820	KAOLIN	E	
2821	KELP DRY	A, H	Iodine is a mandatory component of Kelp dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2822	KELP POWDER	A, E, H	Iodine is a mandatory component of Kelp 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.
2823	KERATIN	E	Only for use in topical medicines for dermal 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2824	KEROSENE	E, H	Only for use as a homoeopathic ingredient. When used in liquid preparations, the concentration in the medicine must be no more than 25%.
2825	KHAYA SENEGALENSIS	A, E	Only to be used in a medicine where Bioactive Solutions Pty Ltd (Client ID 61631), 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. The maximum daily dose of the medicine must not contain more than the equivalent of 1g dry bark of Khaya senegalensis. 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)';

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (LONGUSE) 'Not for prolonged use. May harm liver'; - (GEN2) 'If symptoms persist, seek the advice of a healthcare professional'; - (CHILD3) 'Use in children under 12 years is not recommended'; and - (7DAYS) 'Do not use for more than 7 days'.
2826	KIDNEY BEAN	E	
2827	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2828	KIWI FRUIT	E	
2829	KNAUTIA ARVENSIS	A, H	
2830	KOREAN GINSENG ROOT DRY	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2831	KOREAN GINSENG ROOT POWDER	A, H	
2832	KRAMERIA IXIENA	A, H	
2833	KRAMERIA LAPPACEA	A, H	
2834	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only' - (UNDILU) 'Not to be applied undiluted to the skin except on the advice of a health care practitioner'. When the dosage form is other than essential oil, the maximum concentration in topical medicines must be no more than 25% w/w and the medicine requires the

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.
2835	L-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%.
2836	L-BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2837	L-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%.
2838	L-LIMONENE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2839	L-LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
2840	L-MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2841	L-MENTHYL 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%.
2842	L-ROSE OXIDE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2843	LABDANUM 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%.
2844	LABDANUM GUM EXTRACT ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance and the total fragrance concentration in a medicine is no more than 1%.
2845	LABDANUM OIL	A, E, H	
2846	LABURNUM ANAGYROIDES	A, H	Sparteine is a mandatory component of Laburnum

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			anagyroides. The concentration of sparteine in the medicine must be no more than 0.001%.
2847	LACTALBUMIN	E	
2848	LACTIC ACID	A, E, H	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 form time to time. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
2849	LACTITOL	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol may have a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			laxative effect or cause diarrhoea' (or words to that effect); - (LACT) 'Contains lactose' (or words to that effect); and - (COWMK) 'Derived from cows milk'.
2850	LACTITOL MONOHYDRATE	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol monohydrate may have a laxative effect or cause diarrhoea' (or words to that effect) - (LACT) 'Contains lactose' (or words to that effect) - (COWMK) 'Derived from cows milk'.
2851	LACTOBACILLUS ACIDOPHILUS	A	
2852	LACTOBACILLUS AMYLOVORUS	A	
2853	LACTOBACILLUS BREVIS	A	
2854	LACTOBACILLUS CASEI	A	

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2855	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2856	LACTOBACILLUS CRISPATUS	A	
2857	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2858	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2859	LACTOBACILLUS FERMENTUM	A	
2860	LACTOBACILLUS GALLINARUM	A	
2861	LACTOBACILLUS GASSERI	A	
2862	LACTOBACILLUS HELVETICUS	A	
2863	LACTOBACILLUS JOHNSONII	A	
2864	LACTOBACILLUS KEFIRANOFACIENS	A	
2865	LACTOBACILLUS KEFIRGRANUM	A	
2866	LACTOBACILLUS KEFIRI	A	
2867	LACTOBACILLUS PARACASEI	A	
2868	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2869	LACTOBACILLUS PLANTARUM	A	
2870	LACTOBACILLUS REUTERI	A	

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
2871	LACTOBACILLUS RHAMNOSUS	A	
2872	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2873	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2874	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2875	LACTOSCATONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2876	LACTOSE	E	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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]'.
2877	LACTOSE MONOHYDRATE	E	When the medicine is for oral ingestion and the total amount of all sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose monohydrate, 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 monohydrate then the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose monohydrate [or words to that effect]'.
2878	LACTUCA SATIVA	A, H	
2879	LACTUCA VIROSA	A, H	
2880	LACTULOSE	E	
2881	LACTULOSE SOLUTION	A	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 form time to time.
2882	LAGENARIA VULGARIS	A, H	
2883	LAMINARIA CLOUSTONI	A, E, H	Iodine is a mandatory component of Laminaria cloustoni. Only for external use when the concentration of iodine in the medicine (excluding salts

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			derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2884	LAMINARIA DIGITATA	A, E, H	Iodine is a mandatory component of Laminaria digitata. 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.
2885	LAMINARIA JAPONICA	A, E, H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
2886	LAMIUM ALBUM	A, H	
2887	LANETH-5	E	Only for use in topical medicines for dermal application.
2888	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2889	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2890	LANOLIN WAX	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2891	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2892	LARIX ARABINOGALACTAN	A, E	The concentration of polysaccharides in the ingredient must be greater than or equal to 85%. The ingredient must be derived from Larix occidentalis or Larix larcinia. Only for use in oral medicines or topical medicines for dermal application, and not to be included in topical products intended for use in the eye. The maximum recommended daily dose of Larix arabinogalactan in oral medicines must not be more than 15 grams. The concentration of Larix arabinogalactan in topical medicines for dermal application must not exceed 5.0%.
2893	LARIX DECIDUA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2894	LARIX KAEMPFERI	A, H	The maximum recommended daily dose must be no more than 1 mg of the equivalent dry herbal material of Larix kaempferi.
2895	LARREA TRIDENTATA	A, H	The medicine requires the following warning statement on the medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.
2896	LATHYRUS SATIVUS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lathyrus sativus. The medicine must not contain lathyrogenic amino acids.
2897	LAURAMINE OXIDE	E	
2898	LAUREL LEAF OIL	A, H	
2899	LAURETH-10	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2900	LAURETH-12	E	Only for use in topical medicines for dermal application.
2901	LAURETH-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2902	LAURETH-23	E	Only for use in topical medicines for dermal application.
2903	LAURETH-3	E	Only for use in topical medicines for dermal application.
2904	LAURETH-4	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
2905	LAURETH-7	E	Only for use in topical medicines for dermal application.
2906	LAURETH-8	E	
2907	LAURIC ACID	A, E	When for use as an active ingredient is for use in oral medicines only and the maximum recommended daily dose must not exceed 1500 mg.
2908	LAURIL MACROGOL 400 DIMETICONE	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%.
2909	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2910	LAUROYL LYSINE	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 5.0%.
2911	LAURUS NOBILIS	A, E, H	When the plant preparation is oil or distillate, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is less than or equal to 15 millilitres, a restricted flow insert must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater than 25% and the nominal capacity of the container is greater than 15 millilitres, a child resistant closure must be fitted on the container. When the concentration of Laurus nobilis oil or distillate in the preparation is greater

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			than 25%, 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'.
2912	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2913	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2914	LAURYL GLUCOSIDE	E	Only for use as an excipient ingredient in topical medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 12%.
2915	LAURYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
2916	LAURYL PCA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
2917	LAURYL PEG-10 TRIS(TRIMETHYLSILOXY)SILYL ETHYL DIMETICONE	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%.
2918	LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	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 be no more than 3.5%.
2919	LAURYL PEG/PPG-18/18 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 9%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2920	LAURYL POLYGLUCOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 1% in leave-on medicines and 3% in wash-on/wash-off medicines.
2921	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2922	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2923	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			0.007%.
2924	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2925	LAVANDIN 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%.
2926	LAVANDIN OIL ABRIAL	A, E, H	
2927	LAVANDIN OIL GROSSO	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2928	LAVANDULA ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, 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 or distillate preparations, if the concentration of camphor is more than 10%, and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 fitted on the container. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
2929	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 or distillate 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 also have a child resistant closure fitted on the container.
2930	LAVANDULA X INTERMEDIA	A, E, H	Camphor is a mandatory component of Lavandula x intermedia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oil or distillates, the concentration of camphor must be no more than 2.5%. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be no more than 25 millilitres.
2931	LAVENDER OIL	A, E, H	Camphor is a mandatory component of lavender oil. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils, the concentration of camphor must be no more than 2.5%. In essential oil preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be no more than 25 millilitres.
2932	LAWSONIA INERMIS	A, H	
2933	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2934	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2935	LEAF ACETAL	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%.
2936	LECITHIN	A, E	
2937	LEDEBOURIELLA SESELOIDES	A, H	
2938	LEDUM GROENLANDICUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2939	LEDUM PALUSTRE	A, H	Arbutin is a mandatory component of Ledum palustre. 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 %. When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001mg of the equivalent dry herbal material of Ledum palustre.
2940	LEMNA MINOR	A, H	
2941	LEMON	E	When used internally, oxedrine is a mandatory component of lemon. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2942	LEMON BALM LEAF DRY	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2943	LEMON BALM LEAF POWDER	A, E, H	
2944	LEMON OIL	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. 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) steam distilled or rectified; or b) for internal use; or c) contains 0.05% or less of lemon oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2945	LEMON OIL DISTILLED	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil distilled. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			milligrams.
2946	LEMON OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2947	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2948	LEMON PEEL DRIED	A, E, H	When used internally, oxedrine is a mandatory component of lemon peel dried. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2949	LEMONGRASS OIL	A, E, H	
2950	LENS CULINARIS	A, H	
2951	LENTIL	E	
2952	LENTINULA EDODES	A, E, H	
2953	LEONTOPODIUM ALPINUM	E	Only for use in topical medicines for dermal 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%.
2954	LEONURUS CARDIACA	A, E, H	
2955	LEONURUS SIBIRICUS	A, E, H	
2956	LEPIDIUM APETALUM	A, H	
2957	LEPIDIUM MEYENII	A	Only for use in oral medicines when the plant part is tuber and the plant preparation is dry. The maximum recommended daily dose must be no more than 3.5g of Lepidium meyenii dried tuber (or its extract equivalent).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2958	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2959	LEPTOSPERMUM SCOPARIUM OIL	A	Only for use as an active ingredient when the route of administration is topical or oral application in a mouthwash preparation. If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL. When the concentration is more than 25%, and the nominal capacity of the container less than 15mL, 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 word to that effect) - (NTAKEN) ‘Not to be taken’ When the concentration is more than 25%, the nominal capacity of the container is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 15 mL but no more than 25 mL, a child resistant closure and 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 word to that effect) - (NTAKEN) 'Not to be taken'
2960	LESPEDEZA CAPITATA	A, H	
2961	LETTUCE	E	
2962	LEUCINE	A, E	
2963	LEUZEA UNIFLORUM	A, H	
2964	LEVISTICUM OFFICINALE	A, H	
2965	LEVOCARNITINE	A	
2966	LEVOCARNITINE FUMARATE	A	
2967	LEVOCARNITINE HYDROCHLORIDE	A	
2968	LEVOCARNITINE MAGNESIUM CITRATE	A	
2969	LEVOCARNITINE TARTRATE	A	
2970	LEVOMEFOLATE CALCIUM	A	Available for medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			intended for internal use only. Levomefolic acid is a mandatory component of Levomefolate calcium. The maximum recommended daily dose must not provide more than 500 micrograms of Levomefolic acid from Levomefolate calcium. 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 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)'.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2971	LEVOMEFOLATE GLUCOSAMINE	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate glucosamine. The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine. 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 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).'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2972	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
2973	LEVULINIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2974	LIGHT KAOLIN	E	
2975	LIGHT LIQUID PARAFFIN	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.
2976	LIGHT MAGNESIUM OXIDE	A, E, H	
2977	LIGUSTICUM SINENSE	A, H	
2978	LIGUSTICUM STRIATUM	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
2979	LIGUSTRUM LUCIDUM	A, H	
2980	LILIUM BROWNII	A, H	
2981	LILIUM CANDIDUM	A, E, H	
2982	LILIUM LANCIFOLIUM	A, H	
2983	LILIUM LONGIFLORUM	A, H	
2984	LIME FRUIT	E	
2985	LIME 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%.
2986	LIME OIL COLDPRESSED	A, E, H	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) contains 0.5% or less of lime oil coldpressed; or

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			c) for use in soaps or bath or shower gels that are washed off the skin.
2987	LIME OIL DISTILLED	A, E, H	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) contains 0.5% or less of lime oil distilled; or c) for use in soaps or bath or shower gels that are washed off the skin.
2988	LIME 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%.
2989	LIME OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2990	LIME TREE FLOWER DRY	A, H	
2991	LIME TREE FLOWER POWDER	A, H	
2992	LIME, ESSENCE	E	
2993	LIMES TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2994	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
2995	LINALOOL	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2996	LINALOOL 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%.
2997	LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2998	LINALYL ACETATE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
2999	LINALYL BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3000	LINALYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3001	LINALYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3002	LINALYL 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%.
3003	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3004	LINALYL 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%.
3005	LINDERA STRYCHNIFOLIA	A, H	
3006	LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			0.5%.
3007	LINOLEIC ACID	E	
3008	LINOLENIC ACID	E	
3009	LINSEED DRY	A, E, H	
3010	LINSEED OIL	A, E, H	
3011	LINSEED POWDER	A, E, H	
3012	LINUM USITATISSIMUM	A, E, H	
3013	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline When used in an undivided preparation, the unit 'Thousand lipase units per gram' is permitted. When used in a divided preparation, the unit 'Thousand lipase unit' is permitted.
3014	LIPPIA DULCIS	A, H	
3015	LIQUID GLUCOSE	E	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)

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3016	LIQUID PARAFFIN	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.
3017	LIQUIDAMBAR FORMOSANA	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3018	LIQUIDAMBAR ORIENTALIS	A, H	
3019	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3020	LIQUIDAMBAR STYRACIFLUA RESIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3021	LIQUIDAMBAR TAIWANIANA	A, H	
3022	LIQUORICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3023	LIQUORICE DRY	A, E, H	
3024	LIQUORICE LIQUID EXTRACT	A, E, H	
3025	LIQUORICE POWDER	A, E, H	
3026	LITCHI CHINENSIS	A, H	
3027	LITHIUM CARBONATE	H	Only for use as an active

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			homoeopathic ingredient.
3028	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3029	LITSEA CUBEBA	A, E, H	
3030	LITSEA CUBEBA 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%.
3031	LOBARIA PULMONARIA	A, H	
3032	LOBELIA DRY	A, H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3033	LOBELIA INFLATA	A, H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3034	LOBELIA POWDER	A, H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3035	LOLIUM PERENNE	A, H	
3036	LOLIUM TEMULENTUM	A, H	
3037	LONGIFOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total longifolene concentration in a medicine must be no more than 1%.
3038	LONICERA CAPRIFOLIUM	A, E, H	
3039	LONICERA JAPONICA	A, E, H	
3040	LONICERA PERICLYMENUM	A, H	
3041	LOPHATHERUM GRACILE	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3042	LOQUAT	E	
3043	LORANTHUS PARASITICUS	A, H	
3044	LOROPETALUM CHINENSIS	A, H	
3045	LOTUS CORNICULATUS	A, H	
3046	LOVAGE OIL	A, E, H	
3047	LOVAGE ROOT DRY	A, H	
3048	LOVAGE ROOT POWDER	A, H	
3049	LUDWIGIA PROSTRATA	A, H	
3050	LUFFA CYLINDRICA	A, H	
3051	LUFFA PURGANS	A, H	
3052	LUTEIN	A, E, H	When used as an excipient, permitted for use as a colour for oral and topical use.
3053	LYCHEE	E	
3054	LYCIUM BARBARUM	A, H	
3055	LYCIUM CHINENSE	A, E, H	
3056	LYCOPENE	A, E	
3057	LYCOPERSICON ESCULENTUM	A, E, H	Steroidal alkaloids calculated as solanine is a mandatory component of Lycopersicon esculentum. The maximum daily dose must not provide more than 10 mg

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			of steroidal alkaloids calculated as solanine.
3058	LYCOPODIUM ANNOTINUM	A, H	
3059	LYCOPODIUM CLAVATUM	A, H	
3060	LYCOPODIUM COMPLANATUM	A, H	
3061	LYCOPUS EUROPAEUS	A, H	
3062	LYCOPUS LUCIDUS	A, H	
3063	LYCOPUS VIRGINICUS	A, H	Pulegone is a mandatory component of Lycopus virginicus. The concentration of pulegone in the medicine must be no more than 4%.
3064	LYGODIUM JAPONICUM	A, H	
3065	LYSIMACHIA CHRISTINAE	A, H	
3066	LYSIMACHIA VULGARIS	A, H	
3067	LYSINE	A, E	
3068	LYSINE HYDROCHLORIDE	A, E	
3069	LYTHRUM HYSSOPIFOLIA	A, H	
3070	LYTHRUM SALICARIA	A, H	
3071	LYTHRUM VERTICILLATUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3072	MACADAMIA INTEGRIFOLIA	A, E	
3073	MACADAMIA NUT	E	
3074	MACADAMIA NUT OIL	E	
3075	MACADAMIA TERNIFOLIA	A, E, H	
3076	MACE	E	Safrole is a mandatory component of Mace. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%.
3077	MACE OIL	A, H	Safrole is a mandatory component of Mace oil. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%. When the concentration of mace oil in the preparation is

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			more than 50% and the nominal capacity of the container is 25 mL or less, a restricted flow insert must be fitted on the container.
3078	MACROCYSTIS PYRIFERA	A, E, H	Iodine is a mandatory component of Macrocystis pyrifera. 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.
3079	MACROGOL 1000	E	
3080	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3081	MACROGOL 1500	E	
3082	MACROGOL 1500 CASTOR OIL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			for use in the eye or on damaged skin. The concentration in the medicine must be no more than 2%.
3083	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3084	MACROGOL 20000	E	
3085	MACROGOL 300	E	
3086	MACROGOL 3000	E	
3087	MACROGOL 3350	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 form time to time.
3088	MACROGOL 40	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3089	MACROGOL 400	E	
3090	MACROGOL 4000	E	
3091	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3092	MACROGOL 600	E	
3093	MACROGOL 6000	E	
3094	MACROGOL 600000	E	
3095	MACROGOL 800	E	
3096	MACROGOL 8000	E	
3097	MACROGOL 900	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.95%.
3098	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3099	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3100	MAGNESIUM AMINO ACID CHELATE	A, E, H	Only for use in oral medicines. The concentration of Magnesium must be no more than 25% of the magnesium amino acid chelate.
3101	MAGNESIUM ASCORBATE	A, E, H	
3102	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3103	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3104	MAGNESIUM ASPARTATE	A, E, H	
3105	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3106	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3107	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3108	MAGNESIUM CHLORIDE 4.5-	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	HYDRATE		
3109	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	
3110	MAGNESIUM CITRATE	A, E, H	
3111	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3112	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3113	MAGNESIUM DIGLUTAMATE	A, E, H	
3114	MAGNESIUM GLUCONATE	A, E, H	
3115	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3116	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3117	MAGNESIUM GLYCINATE DIHYDRATE	A	Only for use in oral medicines. The purpose for use for all metal amino acid chelates is restricted to mineral supplementation. Magnesium is a mandatory component of Magnesium glycinate dihydrate. Based on molecular weights the declared quantity of Magnesium from Magnesium glycinate dihydrate must be no less than 11.1% and must be no

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			more than 12.2% of the Magnesium glycinate dihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3118	MAGNESIUM HYDROGEN PHOSPHATE	H	
3119	MAGNESIUM HYDROXIDE	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 medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose and the medicine is listed in the Register on or after 1 October 2017 the medicine must have the following statements on the medicine label: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)]'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (LAX4) 'This product may have laxative effect'. When the medicine is not promoted or marketed as laxative, contains more than 2 g magnesium hydroxide per maximum recommended daily dose and the medicine is listed in the Register before 1 October 2017 the medicine requires the following statements on the medicine label if supplied after 1 April 2019: - (LAX5) 'This product contains [name of the herb(s) or the chemical component(s)] - (LAX4) 'This product may have laxative effect'.
3120	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3121	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3122	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3123	MAGNESIUM OROTATE	A, E, H	
3124	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3125	MAGNESIUM OXIDE	A, E, H	
3126	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	
3127	MAGNESIUM PHOSPHATE TRIBASIC	A, E, H	Magnesium is a mandatory component of Magnesium phosphate tribasic. The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate tribasic.
3128	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3129	MAGNESIUM STEARATE	E	
3130	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
3131	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3132	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3133	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3134	MAGNESIUM TRISILICATE	E	
3135	MAGNOLIA GLAUCA	A, H	
3136	MAGNOLIA LILIFLORA	A, H	
3137	MAGNOLIA OBOVATA	A, H	
3138	MAGNOLIA OFFICINALIS	A, E, H	
3139	MAGNOLIA SALICIFOLIA	A, H	
3140	MAIZE	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3141	MAIZE BRAN	E	
3142	MAIZE OIL	A, E, H	
3143	MAIZE STARCH	A, E, H	
3144	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3145	MALIC ACID	E	Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
3146	MALPIGHIA GLABRA	A, E, H	
3147	MALT EXTRACT	E	
3148	MALTITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s) may have a laxative effect or cause diarrhoea [or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			effect]'.
3149	MALTITOL SOLUTION	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) 'Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that effect).
3150	MALTODEXTRIN	E	Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			to that effect).
3151	MALTOL	E	
3152	MALTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3153	MALTOSE	E	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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			the following warning statement on the medicine label: - (LACT) ‘Contains lactose' (or words to that effect).
3154	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3155	MALUS PUMILA	A, E, H	
3156	MALUS SYLVESTRIS	A, H	
3157	MALVA MOSCHATA	A, H	
3158	MALVA SYLVESTRIS	A, E, H	
3159	MALVA VERTICILLATA	A, H	
3160	MANDARIN	E	
3161	MANDARIN 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3162	MANDARIN OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of mandarin oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3163	MANDARIN 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%.
3164	MANDARIN RESIDUE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			5%.
3165	MANDARINAL 32048	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3166	MANDRAGORA OFFICINARUM	A, H	Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum. The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyamine in the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
3167	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3168	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3169	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3170	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3171	MANGANESE AMINO ACID CHELATE	A, E, H	Only for use in oral medicines. The concentration of Manganese must be no more than 25% of the manganese amino acid chelate.
3172	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3173	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3174	MANGANESE GLUCONATE	A, E, H	
3175	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3176	MANGANESE OXIDE	A, E, H	
3177	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3178	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3179	MANGIFERA INDICA	A, E, H	
3180	MANGO	E, H	
3181	MANIHOT ESCULENTA	A, H	
3182	MANNITOL	E	When the quantity of sugar alcohols per maximum recommended daily dose is more than 2g, the quantity of the sugar alcohols must be declared on the label and the medicine requires the following warning statement on the medicine label: - (SUGOLS) ‘Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea' (or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			effect).
3183	MARANTA ARUNDINACEA	A, H	
3184	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3185	MARJORAM OIL SPANISH	A, E, H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3186	MARJORAM OIL SWEET	A, E, H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			effect).
3187	MARRUBIUM VULGARE	A, E, H	
3188	MARSDENIA CUNDURANGO	A, H	
3189	MARSHMALLOW ROOT DRY	A, H	
3190	MARSHMALLOW ROOT POWDER	A, H	
3191	MASSOIA LACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3192	MASTIC	A, H	
3193	MATE 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3194	MATRICARIA CHAMOMILLA	A, E, H	
3195	MATRICARIA FLOWER DRY	A, E, H	
3196	MEADOWSWEET HERB DRY	A, H	Methyl salicylate is a mandatory component of meadowsweet herb 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and 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); - (IRRIT) 'If irritation develops, discontinue use.'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
3197	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3198	MEDICAGO SATIVA	A, E, H	The level of l-canavanine must be no more than that of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			dried leaf. When fresh leaf extract is used and the extraction ratio is between 34:1 and 46:1, the quantity of l-canavanine in the extract must not be more than that in the fresh leaf.
3199	MEDIUM CHAIN TRIGLYCERIDES	E	
3200	MELALEUCA ALTERNIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca alternifolia. 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
3201	MELALEUCA CAJUPUTI	A, E, H	Cineole is a mandatory component of Melaleuca cajuputi. 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3202	MELALEUCA DISSITIFLORA	A, H	Cineole is a mandatory component of Melaleuca dissitiflora. 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			must also have a child resistant closure.
3203	MELALEUCA ERICIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca ericifolia. 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.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3204	MELALEUCA LINARIIFOLIA	A, H	Cineole is a mandatory component of Melaleuca linariifolia. 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.
3205	MELALEUCA OIL	A, E, H	Cineole and cajuput oil are a mandatory components of

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Melaleuca Oil. When the plant preparation is oil and the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL 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 nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3206	MELALEUCA QUINQUENERVIA	A, E, H	Cineole is a mandatory component of Melaleuca quinquenervia. In liquid preparations, when the concentration of cineole

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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.
3207	MELICOPE PTELEIFOLIA	A, H	
3208	MELILOTUS OFFICINALIS	A, E, H	Coumarin is a mandatory component of Melilotus officinalis. The concentration of coumarin in the medicine must be no more than 0.001%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3209	MELISSA OFFICINALIS	A, E, H	
3210	MELON	E	
3211	MENADIONE SODIUM BISULFITE	E	
3212	MENAQUINONE 7	A	For oral use only. The medicine must not provide more than 180 micrograms per maximum daily dose in adults, 90 micrograms per maximum daily dose in children between 10-18 years, and 45 micrograms per maximum daily dose in children less than 10 years of age.
3213	MENISPERMUM CANADENSE	A, H	
3214	MENTHA AQUATICA	A, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha aquatica. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3215	MENTHA ARVENSIS	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha arvensis. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label:

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3216	MENTHA ARVENSIS LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%. In addition, when the ingredient is included in a medicine that is listed in the

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha arvensis leaf oil. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3217	MENTHA ARVENSIS OIL	E	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 be not contain more than 5%. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha arvensis oil, b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			recommended daily dose must not contain more than 1 gram of menthol.
3218	MENTHA HAPLOCALYX	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha haplocalyx. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3219	MENTHA PULEGIUM	A, H	D-Pulegone, menthol and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 millilitres, the concentration of D-pulegone in the medicine must be no more than 4%. When the concentration of D-Pulegone in the preparation is more than 4% and the nominal

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container. The medicine requires the following warning statements on the medicine label: - (NTAKEN) 'Not to be taken'; and - (CHILD) 'Keep out of reach of children' (or words to that effect). When the medicine is for topical use: a) the maximum recommended daily dose must not contain more than 150 mg of Mentha pulegium oil or distillate; b) the medicine must not be intended for use in the eye or on damaged skin; c) the maximum concentration of menthol must not exceed 5%; and d) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). When the medicine is for internal use: a) the maximum recommended daily dose must not contain more than 50 mg of Mentha pulegium oil or distillate; and b) the maximum recommended daily dose must not contain more than 1 gram of menthol.
3220	MENTHA SPICATA	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020 the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020 the medicine may comply with

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			requirements under (a)-(c). a) Menthol is a mandatory component of Mentha spicata. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3221	MENTHA X CARDIACA	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha x cardiaca. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3222	MENTHA X PIPERITA	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018 the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and supplied on or after 1 January 2020 the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020 the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of Mentha x

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			piperita. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3223	MENTHADIENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3224	MENTHANYL 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%.
3225	MENTHOFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3226	MENTHOL	A, E	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			requirements under (a)-(b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(b); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(b). a) When the medicine is for topical use: (i) the medicine must not to be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with eyes (or words to that effect).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			b) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3227	MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3228	MENTHONE GLYCERINE 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%.
3229	MENTHONE THIOL FRACTION	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3230	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3231	MENTHYL 2-HYDROXYETHYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3232	MENTHYL 2-HYDROXYPROPYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3233	MENTHYL ANTHRANILATE	A	Only for use in topical medicines for dermal 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%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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).
3234	MENTHYL 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%.
3235	MENTHYL LACTATE	E	
3236	MENYANTHES TRIFOLIATA	A, H	
3237	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3238	MERCURY	H	Only for use as an active homoeopathic ingredient.
3239	MESPILUS GERMANICA	A, H	
3240	METACRESOL	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3241	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3242	METHANOL	E	The residual solvent limit is 30 mg per recommended daily dose. The concentration in the medicine must be no more than 0.3%.
3243	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 1%.
3244	METHIONINE	A, E	
3245	METHYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3246	METHYL 2-OCTYNOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3247	METHYL 3,6-DIMETHYLRESORCYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3248	METHYL ACETATE	E	The residual solvent limit is 50 mg per recommended daily dose.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 0.5%.
3249	METHYL ACETOPHENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3250	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3251	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3252	METHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3253	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3254	METHYL 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%.
3255	METHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
3256	METHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3257	METHYL CARBITOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3258	METHYL CEDRYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
3259	METHYL CHAVICOL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The ingredient is not to be included in medicines intended for oral use. The quantity of methyl chavicol in a medicine must be no more than 0.01%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3260	METHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3261	METHYL CIS-5-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3262	METHYL CYCLOPENTENOLONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3263	METHYL CYCLOPENTYLIDENEACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3264	METHYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3265	METHYL DIHYDROABIETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3266	METHYL DIISOPROPYL PROPIONAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3267	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3268	METHYL ETHYL KETONE	E	The residual solvent limit is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
3269	METHYL EUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3270	METHYL FUROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%.
3271	METHYL GLUCETH-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 3%. Residue levels of ethylene oxide are to be kept below the level of detection.
3272	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3273	METHYL GLUCETH-20 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%.
3274	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	SESQUIHYDRATE		application.
3275	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3276	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3277	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3278	METHYL HEPTENONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3279	METHYL HEPTYL KETONE	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3280	METHYL HEXYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3281	METHYL HEXYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3282	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3283	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3284	METHYL 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.
3285	METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3286	METHYL ISOBUTYL KETONE	E	The residual solvent limit is 50 mg per maximum daily dose. The concentration in the medicine must be no more than 0.5%.
3287	METHYL ISOEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3288	METHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
3289	METHYL JASMONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3290	METHYL LAURATE	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%.
3291	METHYL LINOLEATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3292	METHYL LINOLENATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3293	METHYL MAGNESIUM CHLORIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3294	METHYL METHACRYLATE	E	
3295	METHYL METHACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be intended for use on damaged

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			skin. The concentration in the medicine must not be more than 4.85%.
3296	METHYL METHOXY PYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3297	METHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3298	METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3299	METHYL NONYL 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%.
3300	METHYL NONYLENATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3301	METHYL OCTIN CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3302	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3303	METHYL PHENYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3304	METHYL PHENYL CARBINYL-ISO-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3305	METHYL PHENYL GLYCIDATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3306	METHYL 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%.
3307	METHYL PHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3308	METHYL ROSINATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3309	METHYL SALICYLATE	E	Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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. In addition, when the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a) & (b); - before 1 July 2018 and supplied on or after 1 January 2020, the medicine must comply with all requirements under (a) & (b); or - before 1 July 2018 and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			supplied before 1 January 2020, the medicine may comply with the requirements under (a) & (b). a) The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). b) When for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and 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); - (IRRIT) 'If irritation

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			develops, discontinue use'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
3310	METHYL STEARATE	E	
3311	METHYL THIOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3312	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal 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%.
3313	METHYL-3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%.
3314	METHYL-BETA-METHYL THIOLPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3315	METHYL-PARA-TERT-BUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3316	METHYLBENZYL 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%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
3317	METHYLCELLULOSE	A, E	
3318	METHYLCHLOROISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application that are rinsed off the skin. The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3319	METHYLCYCLOHEXADIENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3320	METHYLDIBROMO GLUTARONITRILE	E	Only for use in topical medicines for dermal application.
3321	METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			intended for use in the eye. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			words to this effect).
3322	METHYLISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application that are rinsed off the skin. The concentration of methylisothiazolinone in the medicine must be no more than 0.01%. When combined with methylchloroisothiazolinone, the total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3323	METHYLMERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3324	METHYLPROPANEDIOL	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3325	METHYLSILANOL/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 on damaged skin. The concentration in the medicine must be no more than 0.1%.
3326	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3327	MICA	E	Only for use when the route of administration is oral, dental or topical. The concentration in oral medicines must be no more than 2.5%. The concentration in dental toothpastes must be no more

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			than 0.5%.
3328	MICROCALICIUM ARENARIUM	A, H	
3329	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3330	MICROCOS PANICULATA	A, H	
3331	MICROCRYSTALLINE CELLULOSE	E	
3332	MICROCRYSTALLINE WAX	E	Only for use as an excipient in medicines for topical, oral or oral application routes of administration. When microcrystalline wax is used as an excipient ingredient, the route of administration 'oral' is only permitted when the dosage form is 'chewing gum'.
3333	MILK FAT	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3334	MILK THISTLE FRUIT DRY	A, H	
3335	MILK THISTLE FRUIT POWDER	A, H	
3336	MILLET	E	
3337	MILLETTIA DIELSIANA	A, H	
3338	MIMOSA 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%.
3339	MIMULUS GUTTATUS	A, H	
3340	MINT OIL DEMENTHOLISED	A, E, H	When the ingredient is included in a medicine that is listed in the Register: - on or after 1 July 2018, the medicine must comply with all requirements under (a)-(c); - before 1 July 2018 and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			supplied on or after 1 January 2020, the medicine must comply with all requirements under (a)-(c); or - before 1 July 2018 and supplied before 1 January 2020, the medicine may comply with requirements under (a)-(c). a) Menthol is a mandatory component of mint oil dementholised. b) When the medicine is for topical use: (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the maximum concentration of menthol must not exceed 5%; and (iii) the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use; and - (EYE) Avoid contact with

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			eyes (or words to that effect). c) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3341	MINTLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3342	MITCHELLA REPENS	A, H	
3343	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3344	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3345	MIXED TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
3346	MODIFIED FOOD STARCH	E	
3347	MOLASSES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3348	MOLYBDENUM	H	Only for use as an active homoeopathic ingredient. When Molybdenum is sourced from Molybdenum trioxide then the maximum daily dose must be no more than 125 micrograms. When Molybdenum is sourced from yeast - high molybdenum then the maximum recommended daily dose must be no more than 62.5 micrograms.
3349	MOLYBDENUM TRIOXIDE	A	Molybdenum is a mandatory component of Molybdenum trioxide. The maximum daily dose of molybdenum from

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			Molybdenum trioxide must be no more than 125 micrograms. The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide.
3350	MOMORDICA BALSAMINA	A, H	
3351	MOMORDICA CHARANTIA	A, H	
3352	MOMORDICA COCHINCHINENSIS	A, H	When Lycopene, Lutein or Betocarotene are declared as components, the plant part is restricted to fruit flesh, fruit peel or seed aril.
3353	MONARDA DIDYMA	A, H	
3354	MONO- AND DI- GLYCERIDES	E	
3355	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3356	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3357	MONOBASIC POTASSIUM PHOSPHATE	A, E, H	When used in a solid medicine containing this ingredient, the pH of a 10 g/L aqueous

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			solution must not be more than 11.5. When used in a liquid or a semi-solid medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
3358	MONOBASIC SODIUM PHOSPHATE	A, E, H	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).'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3359	MONOBASIC SODIUM PHOSPHATE DIHYDRATE	E	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).
3360	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3361	MONOPHOSPHOTHIAMINE	A	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3362	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3363	MONOPOTASSIUM GLUTAMATE	A, E	
3364	MONOSODIUM DIHYDROGEN CITRATE	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).'
3365	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3366	MONSTERA DELICIOSA	A, H	
3367	MONTAN WAX	E	
3368	MORDANT RED 11	E	Permitted for use only as a colour for topical use. The concentration in the medicine must be no more than 0.05%..

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3369	MORINDA CITRIFOLIA	A, H	Only for use when the plant part is fruit and the plant preparation is fruit juice or fruit powder. Fruit powder must be produced by freeze drying the whole fruit (excluding the seeds).
3370	MORINDA OFFICINALIS	A, H	
3371	MORINGA OLEIFERA	A, H	
3372	MORUS ALBA	A, H	
3373	MORUS BOMBYCIS	A, H	
3374	MORUS NIGRA	A, E, H	
3375	MOSKENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3376	MOTHERWORT HERB DRY	A, H	
3377	MOTHERWORT HERB POWDER	A, H	
3378	MUCUNA PRURIENS	A, H	Levodopa (of Mucuna pruriens) is a mandatory component of Mucuna

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			pruriens. The concentration of Levodopa (of Mucuna pruriens) in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
3379	MULBERRY	E	
3380	MUNG BEAN	E	
3381	MURRAYA KOENIGII	A, H	
3382	MURRAYA PANICULATA	A, H	
3383	MUSA X PARADISIACA	A, H	
3384	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3385	MUSK TIBETENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3386	MUSK XYLOL	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3387	MUSKS	H	Only for use as an active homoeopathic ingredient.
3388	MUSTARD	E	Allyl isothiocyanate is a mandatory component of mustard 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%.
3389	MUSTARD OIL	E	Allyl isothiocyanate is a mandatory component of mustard 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%.
3390	MUSTARD SEED OIL	E	Allyl isothiocyanate is a mandatory component of mustard seed oil when the plant part is seed.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3391	MYOSOTIS ARVENSIS	A, H	
3392	MYRCENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3393	MYRCENYL 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%.
3394	MYRICA CERIFERA	A, E, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3395	MYRISTIC ACID	E	
3396	MYRISTIC 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%.
3397	MYRISTICA FRAGRANS	A, E, H	Safrole is a mandatory component of Myristica fragrans. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the plant preparation is oil or distillate and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and requires the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect).
3398	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3399	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3400	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3401	MYROXYLON BALSAMUM	A, E, H	
3402	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3403	MYRRH	A, H	
3404	MYRRH OIL	A, E, H	
3405	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3406	MYRRHIS ODORATA	A, H	
3407	MYRSINE AFRICANA	A, H	
3408	MYRTENAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3409	MYRTENYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3410	MYRTLE ESSENCE MAX	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3411	MYRTLE OIL	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%.
3412	MYRTUS COMMUNIS	A, E, H	
3413	N-BUTYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3414	N-GLUCONYL ETHANOLAMINE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3415	N-HEXYL 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%.
3416	N-NONYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3417	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3418	NARDOSTACHYS CHINENSIS	A, H	
3419	NARINGIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3420	NASTURTIUM OFFICINALE	A, E, H	
3421	NATURAL FISH OIL	A, E	When therapeutic indications for this product are made against Vitamin A or colecalciferol (Vitamin D), they are mandatory components of natural fish 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.'

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3422	NAUCLEA OFFICINALIS	A, H	
3423	NELUMBO NUCIFERA	A, H	
3424	NELUMBO NUCIFERA FLOWER WAX	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%.
3425	NEOHESPERIDIN-DIHYDROCHALCONE	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%
3426	NEOMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3427	NEOPENTYL GLYCOL DIHEPTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
3428	NEOPENTYL GLYCOL DIISOSTEARATE	E	Only for use in topical medicines for dermal 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%.
3429	NEOPENTYL GLYCOL DIOCTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%.
3430	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3431	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3432	NEPETA CATARIA	A, H	Pulegone is a mandatory component of Nepeta cataria and must be declared in the application. The concentration of pulegone in the medicine must be no more than 4%.
3433	NERAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3434	NERIUM OLEANDER	A, H	The concentration of equivalent dry Nerium oleander in the product must be

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			no more than 1mg/Kg or 1mg/L or 0.0001%.
3435	NEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3436	NEROL OXIDE	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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3437	NEROLIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3438	NERONE	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%.
3439	NERYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3440	NERYL-ISO-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%.
3441	NICKEL	H	Only for use as an active homoeopathic ingredient.
3442	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3443	NICOTINAMIDE	A, E, H	
3444	NICOTINAMIDE ASCORBATE	A, E	
3445	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3446	NIGELLA DAMASCENA	A, H	
3447	NIGELLA SATIVA	A, E, H	
3448	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3449	NONADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3450	NONANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3451	NONANOIC 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%.
3452	NONFAT DRY MILK	E, H	If the product is for oral ingestion and contains lactose, then the medicine requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
3453	NONIVAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3454	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3455	NONOXINOL 12	E	For use in hand scrub formulations for healthcare professionals only. Only for use in topical medicines for dermal 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%.
3456	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3457	NONOXINOL 9	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			The concentration in the medicine must be no more than 25%.
3458	NONYL 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%.
3459	NOOTKATONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3460	NOPYL 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3461	NORDIHYDROGUAIARETIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3462	NOTOPTERYGIUM FORBESII	A, H	
3463	NOTOPTERYGIUM INCISIUM	A, H	
3464	NUPHAR JAPONICA	A, H	
3465	NUPHAR LUTEA	A, H	
3466	NUTMEG DRY	A, E, H	Safrole is a mandatory component of Nutmeg Dry. When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.
3467	NUTMEG OIL	A, E, H	Safrole is a mandatory component of Nutmeg oil.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the concentration of Nutmeg oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, the medicine must have a 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).
3468	NUTMEG POWDER	A, E, H	Safrole is a mandatory component of Nutmeg powder. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			1%.
3469	NUX VOMICA DRY	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Dry. The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3470	NUX VOMICA POWDER	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a mandatory component of Nux vomica powder. The concentration in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3471	NYCTANTHES ARBOR-TRISTIS	A, H	When the plant part is leaf: a) methyl salicylate is a mandatory component of Nyctanthes arbor-tristis; b) not to be included in medicines for use in the eye or on damaged skin; c) when used internally, the concentration of methyl salicylate in the medicine must

Column 1	Column 2 **Ingredient Name**	Column 3 **Purpose of the ingredient in the medicine**	Column 4 **Specific requirements(s) applying to the ingredient in Column 2**
			not be more than 0.001%; d) 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; e) 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; f) the following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect); and

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			g) when for use in topical medicines for dermal application, the concentration of methyl salicylate in the medicine must not be more than 25% and 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); - (IRRIT) 'If irritation develops, discontinue use'; and - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect).
3472	NYLON	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3473	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3474	NYLON-12	E	Only for use in topical medicines for dermal application.
3475	NYMPHAEA ALBA	A, E, H	
3476	NYMPHAEA CAERULEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine to be no more than 0.3%. Only for use in liquid extracts where the plant part is the flower and the solvent in 100% water.
3477	NYMPHAEA ODORATA	A, H	
3478	OAK CHIPS 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%.
3479	OAKMOSS	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3480	OAKMOSS 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%.
3481	OAT	E, H	Only for use as a homoeopathic ingredient. Gluten is a mandatory component of Oat when the route of administration is other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the warning statement: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3482	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal. When the route of administration is other than topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3483	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal. When the route of administration is other than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			topical or mucosal, the medicine requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3484	OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3485	OCIMENYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more 1%.
3486	OCIMUM BASILICUM	A, E, H	When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are mandatory components of Ocimum basilicum. The concentration of methyleugenol in the medicine must not exceed 1%. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, 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). When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole OR eugenol 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. When the concentration of cineole OR eugenol 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 the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of eugenol and the concentration of eugenol in the product must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			not be greater than 25%.
3487	OCIMUM KILIMANDSCHARICUM	A, H	Camphor is a mandatory component of Ocimum kilimandscharicum. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, 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 or distillate preparations, if the concentration of camphor is

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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 also have a child resistant closure fitted on the container.
3488	OCIMUM MINIMUM	A, H	
3489	OCIMUM TENUIFLORUM	A, H	When the plant part is oil or distillate, eugenol is a mandatory component of Ocimum tenuiflorum. When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of eugenol 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			insert fitted on the container. When the concentration of eugenol 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 the preparation is for topical use in the mouth, the preparation may not contain more than 5 mL of eugenol and the concentration of eugenol in the product must not be greater than 25%.
3490	OCOTEA ODORIFERA	A, H	Safrole is a mandatory component of Ocotea odorifera. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3491	OCTACOSANOL	E	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3492	OCTADECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3493	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3494	OCTAHYDRO-4,7-METHANO-3AH-INDENE-3A-CARBOXYLIC ACID, ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3495	OCTAHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more than 1%.
3496	OCTAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3497	OCTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3498	OCTANOHYDROXAMIC ACID	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3499	OCTANOIC ACID	A, E	When for topical use, the concentration in the medicine must be no more than 2% (w/w). When for excipient use, 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%.
3500	OCTENE-1	E	Permitted for use only in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3501	OCTHILINONE	E	Only for use in topical medicines for dermal application.
3502	OCTOCRYLENE	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 be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			clothing - hats and eyewear when exposed to the sun' (or words to this effect). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
3503	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3504	OCTYL 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3505	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3506	OCTYL 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%.
3507	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3508	OCTYL METHOXYCINNAMATE	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 be no more than

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (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).

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3509	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3510	OCTYL SALICYLATE	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 be no more than 5%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			requires the following statements on the medicine label if supplied after 1 July 2019: - (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).
3511	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3512	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	Only for use in topical medicines for dermal application. The medicine requires the following warning statement on the medicine label: - (OBCARB) 'Contains octylbicycloheptenedicarboximide' (or words to that effect).
3513	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3514	OCTYLDODECETH-25	E	Only for use in topical medicines for dermal 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%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
3515	OCTYLDODECYL CITRATE 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 12%.
3516	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3517	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			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%.
3518	OCTYLDODECYL XYLOSIDE	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 1.5%.
3519	OENANTHATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3520	OENANTHE AQUATICA	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg of the equivalent dry

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			herbal material.
3521	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3522	OENOTHERA BIENNIS	A, E, H	
3523	OENOTHERA STRICTA	A, H	
3524	OKOUBAKA AUBREVILLEI	A, H	
3525	OLDENLANDIA DIFFUSA	A, E, H	
3526	OLEA EUROPAEA	A, E, H	
3527	OLEIC ACID	E	
3528	OLETH-10	E	Only for use in topical medicines for dermal application.
3529	OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of Oleth-2. The concentration of Dioxane

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3530	OLETH-20	E	Only for use in topical medicines for dermal application.
3531	OLETH-3	E	Only for use in topical medicines for dermal application.
3532	OLETH-3 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%.
3533	OLETH-5	E	Only for use in topical medicines for dermal application.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3534	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3535	OLIBANUM OIL	A, E, H	
3536	OLIGOFRUCTOSE	A, E	
3537	OLIVE	E	
3538	OLIVE OIL	A, E, H	
3539	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	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).'
3540	OMEGA-3-ACID ETHYL ESTERS 90	A	Only for use in oral medicines. The maximum recommended daily dose must not exceed 4000 mg of Omega-3-acid ethyl esters 90, AND must not provide more than 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			sources of omega-3 fatty acids. The medicine requires the following warning statements on the medicine label: - 'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect). -'To be taken with food' (or words to that effect). - 'Not recommended for used by pregnant and lactating women' (or words to that effect). - 'Use in children under 12 years is not recommended' (or words to that effect).
3541	ONION	E	
3542	ONION OIL	A, H	
3543	ONONIS SPINOSA	A, E, H	
3544	ONOPORDUM ACANTHIUM	A, H	
3545	ONOSMODIUM VIRGINIANUM	A, H	
3546	OPHIOPOGON JAPONICUS	A, H	
3547	OPOPANAX CHIRONIUM	A, E, H	When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour or a fragrance

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			proprietary excipient formulation. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3548	OPOPANAX 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%.
3549	OPUNTIA FICUS-INDICA	A, H	
3550	ORANGE	E	
3551	ORANGE FLOWER 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3552	ORANGE FLOWER OIL	A, E, H	When used internally, oxedrine is a mandatory component of orange flower oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3553	ORANGE 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%.
3554	ORANGE JUICE 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

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3555	ORANGE OIL	A, E, H	When used internally, oxedrine is a mandatory component of orange oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3556	ORANGE OIL BITTER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavor, the total flavour concentration in a 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 warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' or words to that effect must be include on the medicine label

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			unless the medicine is: a) for internal use; b) in preparations containing 1.4% or less of orange oil bitter; c) for use in soaps or bath or shower gels that are washed off the skin.
3557	ORANGE OIL BITTER COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. 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 orange oil bitter coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3558	ORANGE OIL COLD PRESSED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3559	ORANGE OIL DISTILLED	A, E, H	When used internally, oxedrine is a mandatory component of orange oil distilled. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3560	ORANGE OIL SWEET	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			fragrance concentration in a medicine must be no more 1%.
3561	ORANGE OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of orange oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3562	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3563	ORANGE PEEL DRIED BITTER	A, E, H	When used internally, oxedrine is a mandatory component of orange peel dried bitter. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3564	ORANGE PEEL OIL SWEET TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3565	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3566	ORIGANUM MAJORANA	A, H	Arbutin is a mandatory component of Origanum majorana. 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 %. When the plant preparation is oil or distillate, the nominal capacity of the container must

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be no more than 50 millilitres. When the concentration of Origanum majorana oil or distillate in the preparation is greater than 50%, a restricted flow insert must be fitted on the container and following warning statement is required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3567	ORIGANUM OIL	E	Permitted for use only in combination with other ingredients as a fragrance. If used as a fragrance the total concentration in the medicine must be no more than 1%.
3568	ORIGANUM OIL SPANISH	A, E, H	
3569	ORIGANUM VULGARE	A, E, H	
3570	ORNITHINE	A, E	
3571	ORNITHINE ASPARTATE	A, E	
3572	ORNITHINE MONOHYDROCHLORIDE	A, E	
3573	ORNITHOGALUM	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
	UMBELLATUM		
3574	OROSTACHYS FIMBRIATA	A, H	
3575	OROXYLUM INDICUM	A, H	
3576	ORRIS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3577	ORRIS CONCRETE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3578	ORRIS ROOT 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%.

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3579	ORRIS ROOT OIL	A, E, H	
3580	ORRIS ROOT RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3581	ORTHO-TERT-BUTYLCYCLOHEXYL 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%.
3582	ORTHOSIPHON ARISTATUS	A, H	
3583	ORYZA SATIVA	A, E, H	
3584	ORYZANOL	E	
3585	OSBECKIA CHINENSIS	A, H	

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
3586	OSMANTHUS 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%.
3587	OSMANTHUS FRAGRANS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3588	OTTELIA ALISMOIDES	A, H	
3589	OXACYCLOHEPTADEC-11-EN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3590	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			application.
3591	OXACYCLOHEXADECEN-2-ONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3592	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3593	OXALIS ACETOSELLA	A, H	
3594	OXIDISED MAIZE STARCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3595	OXIDISED TAPIOCA STARCH	E	
3596	OXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to

Column 1	Column 2 Ingredient Name	Column 3 Purpose of the ingredient in the medicine	Column 4 Specific requirements(s) applying to the ingredient in Column 2
			be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%. When used in primary sunscreen products and listed in the Register on or after 1 January 2018, the medicine must have the following statements on the medicine 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). When used in primary sunscreen products and listed in the Register before 1 January 2018, the medicine requires the following statements on the medicine label if supplied after 1 July 2019: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear

Column 1	**Column 2** **Ingredient Name**	**Column 3** **Purpose of the ingredient in the medicine**	**Column 4** **Specific requirements(s) applying to the ingredient in Column 2**
			when exposed to the sun' (or words to this effect).
3597	OYSTER	E	
3598	OYSTER SHELL	A, E, H	