Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 6 July 2018

Includes amendments up to: F2018L01003

This compilation is in 6 volumes

Volume 1: section 1–3, Schedule 1, Parts 1 and 2 (items 1–729)
Volume 2: Schedule 1, Part 2 (items 730–2137)
Volume 3: Schedule 1, Part 2 (items 2138—2814)
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Each volume has its own contents

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018* that shows the text of the law as amended and in force on 6 July 2018 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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

(section 4)

Part 2 – 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
2815	KADSURA COCCINEA	A, H	
2816	KAEMPFERIA GALANGA	A, H	
2817	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 %.
2818	KAOLIN	E	
2819	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 2.5% or less. Only for internal use when the medicine contains less than 300

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
			micrograms of iodine per maximum recommended daily dose.
2820	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.
2821	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%.
2822	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%.
2823	KIDNEY BEAN	E	
2824	KIRSCH	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2825	KIWI FRUIT	E	
2826	KNAUTIA ARVENSIS	A, H	
2827	KOREAN GINSENG ROOT DRY	A, H	
2828	KOREAN GINSENG ROOT POWDER	A, H	
2829	KRAMERIA IXIENA	A, H	
2830	KRAMERIA LAPPACEA	A, H	
2831	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'.

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 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 following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.
2832	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%.
2833	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%.
2834	L-CARVONE	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2835	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%.
2836	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 5%.
2837	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

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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2838	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%.
2839	L-ROSE 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%.
2840	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

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 1%.
2841	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%.
2842	LABDANUM OIL	A, E, H	
2843	LABURNUM ANAGYROIDES	A, H	Sparteine is a mandatory component of Laburnum anagyroides. The concentration of sparteine in the medicine must be no more than 0.001%.
2844	LACTALBUMIN	E	
2845	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

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
			purpose.
2846	LACTITOL	E	The medicine requires the following warning statements on the medicine label: - (SUGOLS) 'Medicines containing lactitol may have a laxative effect or cause diarrhoea' (or words to that effect); - (LACT) 'Contains lactose' (or words to that effect); and - (COWMK) 'Derived from cows milk'.
2847	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'.
2848	LACTOBACILLUS ACIDOPHILUS	A	
2849	LACTOBACILLUS	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
	AMYLOVORUS		
2850	LACTOBACILLUS BREVIS	A	
2851	LACTOBACILLUS CASEI	A	
2852	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2853	LACTOBACILLUS CRISPATUS	A	
2854	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2855	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2856	LACTOBACILLUS FERMENTUM	A	
2857	LACTOBACILLUS GALLINARUM	A	
2858	LACTOBACILLUS GASSERI	A	
2859	LACTOBACILLUS HELVETICUS	A	
2860	LACTOBACILLUS JOHNSONII	A	
2861	LACTOBACILLUS KEFIRANOFACIENS	A	
2862	LACTOBACILLUS KEFIRGRANUM	A	
2863	LACTOBACILLUS KEFIRI	A	
2864	LACTOBACILLUS PARACASEI	A	
2865	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2866	LACTOBACILLUS PLANTARUM	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
2867	LACTOBACILLUS REUTERI	A	
2868	LACTOBACILLUS RHAMNOSUS	A	
2869	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2870	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2871	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2872	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%.
2873	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 name of sugar]’ if medicine contains one sugar OR ‘Contains sugars [or words to that effect]’ if medicine contains two or more sugars.

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 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]'.
2874	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 also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose monohydrate [or words to that effect]'.
2875	LACTUCA SATIVA	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
2876	LACTUCA VIROSA	A, H	
2877	LACTULOSE	E	
2878	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.
2879	LAGENARIA VULGARIS	A, H	
2880	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 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.
2881	LAMINARIA DIGITATA	A, E, H	Iodine is a mandatory component of Laminaria digitata. Only for external use when the concentration of iodine in the

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			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.
2882	LAMINARIA JAPONICA	A, E, H	Iodine is a mandatory component of Laminaria japonica. 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.
2883	LAMIUM ALBUM	A, H	
2884	LANETH-5	E	Only for use in topical medicines for dermal application.
2885	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2886	LANOLIN OIL	E	Only for use in topical medicines

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			for dermal application.
2887	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2888	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2889	LARIX ARABINOGALACTAN	A, E	Only for use in oral medicines. The ingredient must be derived from Larix occidentalis or Larix larcinia. The maximum recommended daily dose must be no more than 15 grams. The concentration of polysaccharides in the medicine must be equal to or more than 85%.
2890	LARIX DECIDUA	A, H	
2891	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.
2892	LARREA TRIDENTATA	A, H	The medicine requires the following warning statement on the

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			medicine label: - (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.
2893	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.
2894	LAURAMINE OXIDE	E	
2895	LAUREL LEAF OIL	A, H	
2896	LAURETH-10	E	Only for use in topical medicines for dermal application.
2897	LAURETH-12	E	Only for use in topical medicines for dermal application.
2898	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

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
			kept below the level of detection.
2899	LAURETH-23	E	Only for use in topical medicines for dermal application.
2900	LAURETH-3	E	Only for use in topical medicines for dermal application.
2901	LAURETH-4	E	Only for use in topical medicines for dermal application.
2902	LAURETH-7	E	Only for use in topical medicines for dermal application.
2903	LAURETH-8	E	
2904	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.
2905	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%.

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2906	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2907	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%.
2908	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 than 25%, the medicine must include the following warning statements on

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 medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2909	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%.
2910	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2911	LAURYL GLUCOSIDE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 12%.

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
2912	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.
2913	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 1%.
2914	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%.
2915	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

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 3.5%.
2916	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%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2917	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.
2918	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2919	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2920	LAURYLDIMONIUM HYDROXYPROPYL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

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
	HYDROLYSED SOY PROTEIN		use in the eye. The concentration in the medicine must be no more than 0.007%.
2921	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2922	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%.
2923	LAVANDIN OIL ABRIAL	A, E, H	
2924	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%.
2925	LAVANDULA ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations,

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 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 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.

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
2926	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 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.

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**
2927	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 be no more than 25 millilitres.
2928	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

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 and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and

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
			- (NTAKEN) 'Not to be taken'. If the concentration of camphor is more than 2.5%, the nominal capacity of the container must be no more than 25 millilitres.
2929	LAWSONIA INERMIS	A, H	
2930	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2931	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2932	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%.
2933	LECITHIN	A, E	
2934	LEDEBOURIELLA SESELOIDES	A, H	
2935	LEDUM GROENLANDICUM	A, H	
2936	LEDUM PALUSTRE	A, H	Arbutin is a mandatory component of Ledum palustre.

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 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.
2937	LEMNA MINOR	A, H	
2938	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.
2939	LEMON BALM LEAF DRY	A, H	
2940	LEMON BALM LEAF POWDER	A, E, H	
2941	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)

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 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.
2942	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 milligrams.
2943	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.
2944	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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 flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2945	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.
2946	LEMONGRASS OIL	A, E, H	
2947	LENS CULINARIS	A, H	
2948	LENTIL	E	
2949	LENTINULA EDODES	A, E, H	
2950	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%.
2951	LEONURUS CARDIACA	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
2952	LEONURUS SIBIRICUS	A, E, H	
2953	LEPIDIUM APETALUM	A, H	
2954	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).
2955	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2956	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)

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
			- (NTAKEN) 'Not to be taken' When the concentration is more than 25%, the nominal capacity of the container is 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'
2957	LESPEDEZA CAPITATA	A, H	
2958	LETTUCE	E	
2959	LEUCINE	A, E	
2960	LEUZEA UNIFLORUM	A, H	
2961	LEVISTICUM OFFICINALE	A, H	
2962	LEVOCARNITINE	A	
2963	LEVOCARNITINE FUMARATE	A	
2964	LEVOCARNITINE HYDROCHLORIDE	A	
2965	LEVOCARNITINE MAGNESIUM CITRATE	A	
2966	LEVOCARNITINE TARTRATE	A	
2967	LEVOMEFOLATE CALCIUM	A	Available for medicines intended for internal use only.

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
			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)'.
2968	LEVOMEFOLATE GLUCOSAMINE	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate glucosamine. The maximum recommended daily

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
			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).'
2969	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
2970	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

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 5%.
2971	LIGHT KAOLIN	E	
2972	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.
2973	LIGHT MAGNESIUM OXIDE	A, E, H	
2974	LIGUSTICUM SINENSE	A, H	
2975	LIGUSTICUM STRIATUM	A, E, H	
2976	LIGUSTRUM LUCIDUM	A, H	
2977	LILIUM BROWNII	A, H	
2978	LILIUM CANDIDUM	A, E, H	
2979	LILIUM LANCIFOLIUM	A, H	
2980	LILIUM LONGIFLORUM	A, H	
2981	LIME FRUIT	E	
2982	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%.

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%.
2983	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 c) for use in soaps or bath or shower gels that are washed off the skin.
2984	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.
2985	LIME OIL TERPENELESS	E	Permitted for use only in combination with other permitted

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**
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2986	LIME 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%.
2987	LIME TREE FLOWER DRY	A, H	
2988	LIME TREE FLOWER POWDER	A, H	
2989	LIME, ESSENCE	E	
2990	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%.
2991	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum 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**
2992	LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2993	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%.
2994	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%. 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%.
2995	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%.
2996	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%.
2997	LINALYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2998	LINALYL CINNAMATE	E	Permitted for use only in combination with other permitted

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
			ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2999	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%.
3000	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3001	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

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 in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3002	LINDERA STRYCHNIFOLIA	A, H	
3003	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 0.5%.
3004	LINOLEIC ACID	E	
3005	LINOLENIC ACID	E	
3006	LINSEED DRY	A, E, H	
3007	LINSEED OIL	A, E, H	
3008	LINSEED POWDER	A, E, H	
3009	LINUM USITATISSIMUM	A, E, H	
3010	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

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.
3011	LIPPIA DULCIS	A, H	
3012	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) 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).
3013	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.

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
3014	LIQUIDAMBAR FORMOSANA	A, H	
3015	LIQUIDAMBAR ORIENTALIS	A, H	
3016	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3017	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%.
3018	LIQUIDAMBAR TAIWANIANA	A, H	
3019	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%.
3020	LIQUORICE DRY	A, E, H	
3021	LIQUORICE LIQUID EXTRACT	A, E, H	
3022	LIQUORICE POWDER	A, E, H	
3023	LITCHI CHINENSIS	A, H	
3024	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.

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
3025	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3026	LITSEA CUBEBA	A, E, H	
3027	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%.
3028	LOBARIA PULMONARIA	A, H	
3029	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.
3030	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.
3031	LOBELIA POWDER	A, H	The concentration 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 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3032	LOLIUM PERENNE	A, H	
3033	LOLIUM TEMULENTUM	A, H	
3034	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%.
3035	LONICERA CAPRIFOLIUM	A, E, H	
3036	LONICERA JAPONICA	A, E, H	
3037	LONICERA PERICLYMENUM	A, H	
3038	LOPHATHERUM GRACILE	A, H	
3039	LOQUAT	E	
3040	LORANTHUS PARASITICUS	A, H	
3041	LOROPETALUM CHINENSIS	A, H	
3042	LOTUS CORNICULATUS	A, H	
3043	LOVAGE OIL	A, E, H	
3044	LOVAGE ROOT DRY	A, H	
3045	LOVAGE ROOT POWDER	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
3046	LUDWIGIA PROSTRATA	A, H	
3047	LUFFA CYLINDRICA	A, H	
3048	LUFFA PURGANS	A, H	
3049	LUTEIN	A, E, H	When used as an excipient, permitted for use as a colour for oral and topical use.
3050	LYCHEE	E	
3051	LYCIUM BARBARUM	A, H	
3052	LYCIUM CHINENSE	A, E, H	
3053	LYCOPENE	A, E	
3054	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 of steroidal alkaloids calculated as solanine.
3055	LYCOPODIUM ANNOTINUM	A, H	
3056	LYCOPODIUM CLAVATUM	A, H	
3057	LYCOPODIUM COMPLANATUM	A, H	
3058	LYCOPUS EUROPAEUS	A, H	
3059	LYCOPUS LUCIDUS	A, H	
3060	LYCOPUS VIRGINICUS	A, H	Pulegone is a mandatory component of Lycopus virginicus.

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 pulegone in the medicine must be no more than 4%.
3061	LYGODIUM JAPONICUM	A, H	
3062	LYSIMACHIA CHRISTINAE	A, H	
3063	LYSIMACHIA VULGARIS	A, H	
3064	LYSINE	A, E	
3065	LYSINE HYDROCHLORIDE	A, E	
3066	LYTHRUM HYSSOPIFOLIA	A, H	
3067	LYTHRUM SALICARIA	A, H	
3068	LYTHRUM VERTICILLATUM	A, H	
3069	MACADAMIA INTEGRIFOLIA	A, E	
3070	MACADAMIA NUT	E	
3071	MACADAMIA NUT OIL	E	
3072	MACADAMIA TERNIFOLIA	A, E, H	
3073	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%.

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
3074	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 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.
3075	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.
3076	MACROGOL 1000	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
3077	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3078	MACROGOL 1500	E	
3079	MACROGOL 1500 CASTOR OIL	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%.
3080	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3081	MACROGOL 20000	E	
3082	MACROGOL 300	E	
3083	MACROGOL 3000	E	
3084	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.
3085	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
3086	MACROGOL 400	E	
3087	MACROGOL 4000	E	
3088	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3089	MACROGOL 600	E	
3090	MACROGOL 6000	E	
3091	MACROGOL 600000	E	
3092	MACROGOL 800	E	
3093	MACROGOL 8000	E	
3094	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%.
3095	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3096	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3097	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.

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
3098	MAGNESIUM ASCORBATE	A, E, H	
3099	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3100	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3101	MAGNESIUM ASPARTATE	A, E, H	
3102	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3103	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3104	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3105	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	
3106	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	
3107	MAGNESIUM CITRATE	A, E, H	
3108	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3109	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3110	MAGNESIUM DIGLUTAMATE	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
3111	MAGNESIUM GLUCONATE	A, E, H	
3112	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3113	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3114	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 more than 12.2% of the Magnesium glycinate dihydrate in the formulation. These figures incorporate a 5% variance to allow for rounding in calculations.
3115	MAGNESIUM HYDROGEN PHOSPHATE	H	
3116	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

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
			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)]' - (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'.
3117	MAGNESIUM LYSINATE	A	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
3118	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3119	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3120	MAGNESIUM OROTATE	A, E, H	
3121	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3122	MAGNESIUM OXIDE	A, E, H	
3123	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	
3124	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.
3125	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3126	MAGNESIUM STEARATE	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
3127	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3128	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3129	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3130	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must be no more than 1.5g.
3131	MAGNESIUM TRISILICATE	E	
3132	MAGNOLIA GLAUCA	A, H	
3133	MAGNOLIA LILIFLORA	A, H	
3134	MAGNOLIA OBOVATA	A, H	
3135	MAGNOLIA OFFICINALIS	A, E, H	
3136	MAGNOLIA SALICIFOLIA	A, H	
3137	MAIZE	E	
3138	MAIZE BRAN	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
3139	MAIZE OIL	A, E, H	
3140	MAIZE STARCH	A, E, H	
3141	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3142	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.
3143	MALPIGHIA GLABRA	A, E, H	
3144	MALT EXTRACT	E	
3145	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 effect]'.
3146	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

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 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).
3147	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 to that effect).
3148	MALTOL	E	
3149	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%.
3150	MALTOSE	E	When the medicine is for oral ingestion and the total amount of 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
			sugars (monosaccharides and disaccharides such as glucose, honey, invert sugar, lactose, maltose, and sucrose) is more than 100mg in the maximum daily dose, then the medicine requires the following warning statement on the medicine label: - (SUGARS) 'Contains [insert name of sugar]' if medicine contains one sugar OR 'Contains sugars' (or words to that effect) if medicine contains two or more sugars. If one of the sugars is lactose then the medicine also requires the following warning statement on the medicine label: - (LACT) 'Contains lactose' (or words to that effect).
3151	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3152	MALUS PUMILA	A, E, H	
3153	MALUS SYLVESTRIS	A, H	
3154	MALVA MOSCHATA	A, H	
3155	MALVA SYLVESTRIS	A, E, H	
3156	MALVA VERTICILLATA	A, H	
3157	MANDARIN	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
3158	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 medicine must be no more 1%.
3159	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.
3160	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%.
3161	MANDARIN RESIDUE	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3162	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%.
3163	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 must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.

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
3164	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3165	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3166	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3167	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3168	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.
3169	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3170	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3171	MANGANESE GLUCONATE	A, E, H	
3172	MANGANESE GLYCEROPHOSPHATE	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
3173	MANGANESE OXIDE	A, E, H	
3174	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3175	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3176	MANGIFERA INDICA	A, E, H	
3177	MANGO	E, H	
3178	MANIHOT ESCULENTA	A, H	
3179	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 effect).
3180	MARANTA ARUNDINACEA	A, H	
3181	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3182	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

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
			and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3183	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 effect).
3184	MARRUBIUM VULGARE	A, E, H	
3185	MARSDENIA CUNDURANGO	A, H	
3186	MARSHMALLOW ROOT DRY	A, H	
3187	MARSHMALLOW ROOT POWDER	A, H	
3188	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%.
3189	MASTIC	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
3190	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 medicine must be no more 1%.
3191	MATRICARIA CHAMOMILLA	A, E, H	
3192	MATRICARIA FLOWER DRY	A, E, H	
3193	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:

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 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 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

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
			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).
3194	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3195	MEDICAGO SATIVA	A, E, H	The level of l-canavanine must be no more than that of the 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.
3196	MEDIUM CHAIN TRIGLYCERIDES	E	
3197	MELALEUCA ALTERNIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca alternifolia.

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 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.
3198	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

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 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.
3199	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

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
			millilitres the medicine must also have a child resistant closure.
3200	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.
3201	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

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 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.
3202	MELALEUCA OIL	A, E, H	Cineole and cajuput oil are a mandatory components of 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

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
			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.
3203	MELALEUCA QUINQUENERVIA	A, E, H	Cineole is a mandatory component of Melaleuca quinquenervia. 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.
3204	MELICOPE PTELEIFOLIA	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
3205	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%.
3206	MELISSA OFFICINALIS	A, E, H	
3207	MELON	E	
3208	MENADIONE SODIUM BISULFITE	E	
3209	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.
3210	MENISPERMUM CANADENSE	A, H	
3211	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

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
			- 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 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.
3212	MENTHA ARVENSIS	A, E, H	When the ingredient is included in a medicine that is listed in the Register:

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
			- 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: - (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

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
			daily dose must not contain more than 1 gram of menthol.
3213	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 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:

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
			(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.
3214	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

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); - 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 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 recommended daily dose must not contain 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 1 gram of menthol.
3215	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 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;

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
			- (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 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 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:

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
			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 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.
3217	MENTHA SPICATA	A, E, H	When the ingredient is included in a medicine that is listed in the Register:

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
			- 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 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

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
			daily dose must not contain more than 1 gram of menthol.
3218	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 sensitive skin, test this product on a small area of skin before applying it to 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
			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 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 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

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**
			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.
3220	MENTHADIENYL 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%.
3221	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%.

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
3222	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%.
3223	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 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

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
			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). b) When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3224	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%.
3225	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%.
3226	MENTHONE THIOL FRACTION	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3227	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3228	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%.
3229	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%.
3230	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

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
			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).
3231	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%.

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
3232	MENTHYL LACTATE	E	
3233	MENYANTHES TRIFOLIATA	A, H	
3234	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3235	MERCURY	H	Only for use as an active homoeopathic ingredient.
3236	MESPILUS GERMANICA	A, H	
3237	METACRESOL	E	Only for use in topical medicines for dermal application.
3238	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3239	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%.
3240	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%.
3241	METHIONINE	A, 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
3242	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3243	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%.
3244	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%.
3245	METHYL ACETATE	E	The residual solvent limit is 50 mg per recommended daily dose. The concentration 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 0.5%.
3246	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%.
3247	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3248	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%.
3249	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

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%.
3250	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3251	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%.
3252	METHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3253	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%.

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
3254	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%.
3255	METHYL CEDRYL 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 1%.
3256	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%.
3257	METHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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 flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3258	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%.
3259	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%.
3260	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

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 1%.
3261	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%.
3262	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%.
3263	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%.
3264	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3265	METHYL ETHYL KETONE	E	The residual solvent limit is 50 mg per maximum recommended daily dose. The concentration 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 0.5%.
3266	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%.
3267	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 5%.
3268	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.

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
3269	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3270	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%.
3271	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3272	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3273	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3274	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3275	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%.

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%.
3276	METHYL HEPTYL 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%.
3277	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%.
3278	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
3279	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3280	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3281	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.
3282	METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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
3283	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%.
3284	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%.
3285	METHYL 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%.
3286	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%.

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
3287	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%.
3288	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%.
3289	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%.
3290	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%.
3291	METHYL METHACRYLATE	E	
3292	METHYL METHACRYLATE	E	Only for use in topical medicines for dermal application and not to 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
	CROSSPOLYMER		included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3293	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%.
3294	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%.
3295	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 1%.
3296	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

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 in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3297	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%.
3298	METHYL OCTIN CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3299	METHYL PALMITATE	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%.
3300	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%.
3301	METHYL PHENYL CARBINYL-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%.
3302	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%.
3303	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%.

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%.
3304	METHYL PHENYLCARBINYL 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%.
3305	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%.
3306	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 packaging.

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 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 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).
3307	METHYL STEARATE	E	
3308	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%.
3309	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal application and not to 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
			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3310	METHYL-3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3311	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%.
3312	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%.
3313	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

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 1%.
3314	METHYLCELLULOSE	A, E	
3315	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%.
3316	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%.
3317	METHYLDIBROMO GLUTARONITRILE	E	Only for use in topical medicines for dermal application.
3318	METHYLENE BIS-BENZOTRIAZOLYL TETRAMETHYLBUTYLPHENOL	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

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 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).
3319	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

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
			total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3320	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%.
3321	METHYLPROPANEDIOL	E	Only for use in topical medicines for dermal 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%.
3322	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%.
3323	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	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
3324	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 than 0.5%.
3325	MICROCALICIUM ARENARIUM	A, H	
3326	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%.
3327	MICROCOS PANICULATA	A, H	
3328	MICROCRYSTALLINE CELLULOSE	E	
3329	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'.
3330	MILK FAT	E	Permitted for use only in combination with other permitted

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**
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3331	MILK THISTLE FRUIT DRY	A, H	
3332	MILK THISTLE FRUIT POWDER	A, H	
3333	MILLET	E	
3334	MILLETTIA DIELSIANA	A, H	
3335	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%.
3336	MIMULUS GUTTATUS	A, H	
3337	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 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 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 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.
3338	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

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 5%.
3339	MITCHELLA REPENS	A, H	
3340	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3341	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3342	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%.
3343	MODIFIED FOOD STARCH	E	
3344	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%.
3345	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

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
			maximum recommended daily dose must be no more than 62.5 micrograms.
3346	MOLYBDENUM TRIOXIDE	A	Molybdenum is a mandatory component of Molybdenum trioxide. The maximum daily dose of molybdenum from 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.
3347	MOMORDICA BALSAMINA	A, H	
3348	MOMORDICA CHARANTIA	A, H	
3349	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.
3350	MONARDA DIDYMA	A, H	
3351	MONO- AND DI- GLYCERIDES	E	
3352	MONOBASIC AMMONIUM PHOSPHATE	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
3353	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3354	MONOBASIC POTASSIUM PHOSPHATE	A, E, H	When used in a solid medicine containing this ingredient, 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 medicine containing this ingredient, the pH of the medicine must be no more than 11.5.
3355	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).'
3356	MONOBASIC SODIUM PHOSPHATE DIHYDRATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution

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 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).
3357	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3358	MONOPHOSPHOTHIAMINE	A	
3359	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3360	MONOPOTASSIUM GLUTAMATE	A, E	
3361	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

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
			label: - (SODIUM) 'The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).'
3362	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3363	MONSTERA DELICIOSA	A, H	
3364	MONTAN WAX	E	
3365	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%..
3366	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).
3367	MORINDA OFFICINALIS	A, H	
3368	MORINGA OLEIFERA	A, H	
3369	MORUS ALBA	A, H	
3370	MORUS BOMBYCIS	A, H	
3371	MORUS NIGRA	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
3372	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%.
3373	MOTHERWORT HERB DRY	A, H	
3374	MOTHERWORT HERB POWDER	A, H	
3375	MUCUNA PRURIENS	A, H	Levodopa (of Mucuna pruriens) is a mandatory component of Mucuna pruriens. The concentration of Levodopa (of Mucuna pruriens) in the medicine must be no more than 1mg/kg or 1mg/L or 0.1%.
3376	MULBERRY	E	
3377	MUNG BEAN	E	
3378	MURRAYA KOENIGII	A, H	
3379	MURRAYA PANICULATA	A, H	
3380	MUSA X PARADISIACA	A, H	
3381	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3382	MUSK TIBETENE	E	Permitted for use only in combination with other permitted ingredients as 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 fragrance the total fragrance concentration in a medicine must be no more than 1%.
3383	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3384	MUSKS	H	Only for use as an active homoeopathic ingredient.
3385	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%.
3386	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%.
3387	MUSTARD SEED OIL	E	Allyl isothiocyanate is a mandatory component of mustard seed oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients

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 product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3388	MYOSOTIS ARVENSIS	A, H	
3389	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%.
3390	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%.
3391	MYRICA CERIFERA	A, E, H	
3392	MYRISTIC ACID	E	
3393	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

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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3394	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 following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect).
3395	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3396	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3397	MYRISTYL MYRISTATE	E	Only for use 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.
3398	MYROXYLON BALSAMUM	A, E, H	
3399	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3400	MYRRH	A, H	
3401	MYRRH OIL	A, E, H	
3402	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3403	MYRRHIS ODORATA	A, H	
3404	MYRSINE AFRICANA	A, H	
3405	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%.
3406	MYRTENYL ACETATE	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3407	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%.
3408	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%.
3409	MYRTUS COMMUNIS	A, E, H	
3410	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**
3411	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%.
3412	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%.
3413	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 medicine must be no more 1%.
3414	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.

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
3415	NARDOSTACHYS CHINENSIS	A, H	
3416	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%.
3417	NASTURTIUM OFFICINALE	A, E, H	
3418	NATURAL CHERRY FLAVOUR	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3419	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 of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents

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
			per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.
3420	NAUCLEA OFFICINALIS	A, H	
3421	NELUMBO NUCIFERA	A, H	
3422	NELUMBO NUCIFERA FLOWER WAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

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
			use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3423	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%
3424	NEOMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3425	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%.
3426	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

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 5%.
3427	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 medicine must be no more than 5%.
3428	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3429	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3430	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%.
3431	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%.
3432	NERIUM OLEANDER	A, H	The concentration of equivalent dry Nerium oleander in the product

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 1mg/Kg or 1mg/L or 0.0001%.
3433	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%.
3434	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%.
3435	NEROLIDOL	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%.
3436	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%.
3437	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3438	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%.

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
3439	NICKEL	H	Only for use as an active homoeopathic ingredient.
3440	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3441	NICOTINAMIDE	A, E, H	
3442	NICOTINAMIDE ASCORBATE	A, E	
3443	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3444	NIGELLA DAMASCENA	A, H	
3445	NIGELLA SATIVA	A, E, H	
3446	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3447	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

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%.
3448	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%.
3449	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%.
3450	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).

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	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%.
3452	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3453	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%.
3454	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%.
3455	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration 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 25%.
3456	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%.
3457	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%.
3458	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%.
3459	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%.

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
3460	NOTOPTERYGIUM FORBESII	A, H	
3461	NOTOPTERYGIUM INCISIUM	A, H	
3462	NUPHAR JAPONICA	A, H	
3463	NUPHAR LUTEA	A, H	
3464	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%.
3465	NUTMEG OIL	A, E, H	Safrole is a mandatory component of Nutmeg oil. 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

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
			label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3466	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 1%.
3467	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%.
3468	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%.

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
3469	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 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

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 required on the medicine label: - (METSAL) ‘Contains methyl salicylate’ (or words to that effect); and 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).
3470	NYLON	E	Only for use in topical medicines for dermal application.
3471	NYLON 6/12	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
3472	NYLON-12	E	Only for use in topical medicines for dermal application.
3473	NYMPHAEA ALBA	A, E, H	
3474	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.
3475	NYMPHAEA ODORATA	A, H	
3476	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 medicine must be no more than 5%.
3477	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%.

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**
3478	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%.
3479	OAT	E, H	Only for use as a homoeopathic ingredient. Gluten is a mandatory component of Oat 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 warning statement: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3480	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

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 requires the following warning statement on the medicine label: - (GLUTEN) 'Contains [insert name of ingredient]' (or words to that effect).
3481	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 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).
3482	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%.
3483	OCIMENYL ACETATE	E	Permitted for use only in

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
			combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3484	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

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%, 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 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 not be greater than 25%.
3485	OCIMUM KILIMANDSCHARICUM	A, H	Camphor is a mandatory component of Ocimum

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
			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 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.
3486	OCIMUM MINIMUM	A, H	
3487	OCIMUM TENUIFLORUM	A, H	When the plant part is oil or distillate, eugenol is a mandatory

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
			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 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%.
3488	OCOTEA ODORIFERA	A, H	Safrole is a mandatory component of Ocotea odorifera.

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%.
3489	OCTACOSANOL	E	
3490	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%.
3491	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3492	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%.

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
3493	OCTAHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3494	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%.
3495	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%.
3496	OCTANOHYDROXAMIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for

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
			use in the eye. The concentration in the medicine must be no more than 0.5%.
3497	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%.
3498	OCTENE-1	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%.
3499	OCTHILINONE	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**
3500	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 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**
3501	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3502	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 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3503	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3504	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%.
3505	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3506	OCTYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens 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
			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 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).
3507	OCTYL PALMITATE	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**
3508	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 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 STEARATE	E	Only for use in topical medicines for dermal application.
3510	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).
3511	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3512	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.
3513	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

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 12%.
3514	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3515	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3516	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%.
3517	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%.
3518	OENANTHE AQUATICA	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg 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
			the equivalent dry herbal material.
3519	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3520	OENOTHERA BIENNIS	A, E, H	
3521	OENOTHERA STRICTA	A, H	
3522	OKOUBAKA AUBREVILLEI	A, H	
3523	OLDENLANDIA DIFFUSA	A, E, H	
3524	OLEA EUROPAEA	A, E, H	
3525	OLEIC ACID	E	
3526	OLETH-10	E	Only for use in topical medicines for dermal application.
3527	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 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%.

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
3528	OLETH-20	E	Only for use in topical medicines for dermal application.
3529	OLETH-3	E	Only for use in topical medicines for dermal application.
3530	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%.
3531	OLETH-5	E	Only for use in topical medicines for dermal application.
3532	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3533	OLIBANUM OIL	A, E, H	
3534	OLIGOFRUCTOSE	A, E	
3535	OLIVE	E	
3536	OLIVE OIL	A, E, H	
3537	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statement 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
			- (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'
3538	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 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).
3539	ONION	E	
3540	ONION OIL	A, H	
3541	ONONIS SPINOSA	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
3542	ONOPORDUM ACANTHIUM	A, H	
3543	ONOSMODIUM VIRGINIANUM	A, H	
3544	OPHIOPOGON JAPONICUS	A, H	
3545	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 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%.
3546	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%.
3547	OPUNTIA FICUS-INDICA	A, H	
3548	ORANGE	E	
3549	ORANGE FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3550	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.
3551	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%.
3552	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 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%.
3553	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.
3554	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 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

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.
3555	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.
3556	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

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%.
3557	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.
3558	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 fragrance concentration in a medicine must be no more 1%.
3559	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.
3560	ORANGE PEEL	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3561	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.
3562	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%.
3563	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3564	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

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
			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 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).
3565	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%.
3566	ORIGANUM OIL SPANISH	A, E, H	
3567	ORIGANUM VULGARE	A, E, H	
3568	ORNITHINE	A, E	
3569	ORNITHINE ASPARTATE	A, 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
3570	ORNITHINE MONOHYDROCHLORIDE	A, E	
3571	ORNITHOGALUM UMBELLATUM	A, H	
3572	OROSTACHYS FIMBRIATA	A, H	
3573	OROXYLUM INDICUM	A, H	
3574	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%.
3575	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%.
3576	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%.
3577	ORRIS ROOT OIL	A, E, H	
3578	ORRIS ROOT RESIN	E	Permitted for use only in combination with other permitted

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
			ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3579	ORTHO-CYMEN-5-OL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.1%.
3580	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%.
3581	ORTHOSIPHON ARISTATUS	A, H	
3582	ORYZA SATIVA	A, E, H	
3583	ORYZANOL	E	
3584	OSBECKIA CHINENSIS	A, H	
3585	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or 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 flavour the total flavour concentration in a medicine must be no more than 5%.
3586	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%.
3587	OTTELIA ALISMOIDES	A, H	
3588	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%.
3589	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3590	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%.

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
3591	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3592	OXALIS ACETOSELLA	A, H	
3593	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%.
3594	OXIDISED TAPIOCA STARCH	E	
3595	OXYBENZONE	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 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
			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).
3596	OYSTER	E	
3597	OYSTER SHELL	A, E, H	