

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

Note: See sections 5 and 6.

Permissible ingredients and requirements			
Column 1	Column 2	Column 3	Column 4
Item	Ingredient name	Purpose	Specific requirements
2860	KADSURA COCCINEA	A, H	
2861	KAEMPFERIA GALANGA	A, H	
2862	KALMIA LATIFOLIA	A, H	<p>Beta-arbutin is a mandatory component of <i>Kalmia latifolia</i>.</p> <p>When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.</p> <p>When for dermal application exclusively to the face:</p> <p>a) the concentration of beta-arbutin in the medicine must not be more than 7%;</p> <p>b) hydroquinone is a mandatory component; and</p> <p>c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p>
2863	KAOLIN	E	
2864	KELP DRY	A, H	<p>Iodine is a mandatory component of Kelp dry.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per</p>

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			maximum recommended daily dose.
2865	KELP POWDER	A, E, H	<p>Iodine is a mandatory component of Kelp powder.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2866	KERATIN	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
2867	KEROSENE	E, H	<p>Only for use as a homoeopathic ingredient.</p> <p>When used in liquid preparations, the concentration in the medicine must be no more than 25%.</p>
2868	KHAYA SENEGALENSIS	A, E	<p>The maximum daily dose of the medicine must not contain more than the equivalent of 1 g dry bark of Khaya senegalensis.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (LONGUSE) 'Not for prolonged use. May harm liver'; - (GEN2) 'If symptoms persist,

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			seek the advice of a healthcare professional’; - (CHILD3) ‘Use in children under 12 years is not recommended’; and - (7DAYS) ‘Do not use for more than 7 days’.
2869	KIDNEY BEAN	E	
2870	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2871	KIWI FRUIT	E	
2872	KNAUTIA ARVENSIS	A, H	
2873	KOREAN GINSENG ROOT DRY	A, H	
2874	KOREAN GINSENG ROOT POWDER	A, H	
2875	KRAMERIA IXIENA	A, H	
2876	KRAMERIA LAPPACEA	A, H	
2877	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ - (EXTERN) ‘For external use only’ - (UNDILU) ‘Not to be applied undiluted to the skin except on the advice of a health care practitioner’. When the dosage form is other

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			<p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.
2878	L-BORNEOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2879	L-BORNYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
2880	L-CARVONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2881	L-LIMONENE	E	<p>L-limonene must only be included in medicines when in combination with other</p>

			<p>permitted ingredients as a flavour proprietary excipient formulation or a fragrance proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing l-limonene must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing l-limonene must not be more than 1% of the total medicine.</p>
2882	L-LINALOOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
2883	L-MENTHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
2884	L-MENTHYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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2885	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%.
2886	LABDANUM ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2887	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%.
2888	LABDANUM OIL	A, E, H	
2889	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%.
2890	LACTALBUMIN	E	
2891	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

			<p>force or existing form time to time.</p> <p>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.</p>
2892	LACTITOL	E	
2893	LACTITOL MONOHYDRATE	E	
2894	LACTO-N-NEOTETRAOSE	A	<p>Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 20 August 2023.</p> <p>Lactose is a mandatory component of lacto-N-neotetraose.</p> <p>The route of administration for medicines that contain lacto-N-neotetraose must be limited to oral.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 1.5 g of lacto-N-neotetraose to individuals aged 4 years and older; and</p> <p>(b) 0.6 g of lacto-N-neotetraose to individuals aged up to 3 years (inclusive).</p> <p>The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is released for supply after 20 August 2023:</p> <p>(a) One of the following statements is required on the</p>

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			medicine label: (i) When the medicine is only for use in individuals aged 2 years and above: 'Not to be taken on the same day with other products containing lacto-N-neotetraose' (or words to that effect); or (ii) When the medicine is for use in children aged less than 2 years: 'Not to be taken on the same day with breastmilk or other products containing lacto-N-neotetraose' (or words to that effect).
2895	LACTO-N-TETRAOSE	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 24 January 2024. Lactose is a mandatory component of lacto-N-tetraose. The route of administration for medicines that contain lacto-N-tetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than 2 g of lacto-N-tetraose. Not permitted for use in children aged below 1 year. One of the following statements is required on the medicine label: a) When the medicine is only for use in individuals aged above 2 years: 'Not to be taken on the same day with other products containing lacto-N-tetraose' (or words to that

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			effect); or b) When the medicine is for use in children aged less than 2 years: 'Not to be taken on the same day with breastmilk or other products containing lacto-N-tetraose' (or words to that effect).
2896	LACTOBACILLUS ACIDOPHILUS	A	
2897	LACTOBACILLUS AMYLOVORUS	A	
2898	LACTOBACILLUS BREVIS	A	
2899	LACTOBACILLUS CASEI	A	
2900	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2901	LACTOBACILLUS CRISPATUS	A	
2902	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2903	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2904	LACTOBACILLUS FERMENTUM	A	
2905	LACTOBACILLUS GALLINARUM	A	
2906	LACTOBACILLUS GASSERI	A	
2907	LACTOBACILLUS HELVETICUS	A	
2908	LACTOBACILLUS JOHNSONII	A	
2909	LACTOBACILLUS KEFIRANOFACIENS	A	
2910	LACTOBACILLUS KEFIRGRANUM	A	
2911	LACTOBACILLUS KEFIRI	A	
2912	LACTOBACILLUS PARACASEI	A	
2913	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2914	LACTOBACILLUS PLANTARUM	A	
2915	LACTOBACILLUS REUTERI	A	
2916	LACTOBACILLUS RHAMNOSUS	A	
2917	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2918	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2919	LACTOBIONIC ACID	E	Only for use in topical

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			medicines for dermal application.
2920	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%.
2921	LACTOSE	E	
2922	LACTOSE MONOHYDRATE	E	
2923	LACTUCA SATIVA	A, H	
2924	LACTUCA VIROSA	A, H	
2925	LACTULOSE	E	
2926	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.
2927	LAGENARIA VULGARIS	A, H	
2928	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.
2929	LAMINARIA DIGITATA	A, E, H	Iodine is a mandatory component of Laminaria digitata. Only for external use when the

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			<p>concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2930	LAMINARIA JAPONICA	A, E, H	<p>Iodine is a mandatory component of Laminaria japonica.</p> <p>Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.</p> <p>Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.</p>
2931	LAMIUM ALBUM	A, H	
2932	LANETH-5	E	Only for use in topical medicines for dermal application.
2933	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2934	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2935	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2936	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.

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2937	LARIX ARABINOGALACTAN	A, E	<p>The concentration of polysaccharides in the ingredient must be greater than or equal to 85%.</p> <p>The ingredient must be derived from <i>Larix occidentalis</i> or <i>Larix laricina</i>.</p> <p>Only for use in oral medicines or topical medicines for dermal application, and not to be included in topical products intended for use in the eye.</p> <p>The maximum recommended daily dose of <i>Larix arabinogalactan</i> in oral medicines must not be more than 15 grams.</p> <p>The concentration of <i>Larix arabinogalactan</i> in topical medicines for dermal application must not exceed 5.0%.</p>
2938	LARIX DECIDUA	A, H	
2939	LARIX KAEMPFERI	A, H	<p>The maximum recommended daily dose must be no more than 1 mg of the equivalent dry herbal material of <i>Larix kaempferi</i>.</p>
2940	LARREA TRIDENTATA	A, H	<p>The medicine requires the following warning statement on the medicine label:</p> <p>- (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'.</p>
2941	LATHYRUS SATIVUS	A, H	<p>The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of <i>Lathyrus sativus</i>.</p> <p>The medicine must not contain lathyrogenic amino acids.</p>

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2942	LAURAMINE OXIDE	E	
2943	LAUREL LEAF OIL	A, H	
2944	LAURETH-10	E	Only for use in topical medicines for dermal application.
2945	LAURETH-12	E	Only for use in topical medicines for dermal application.
2946	LAURETH-2	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.4%. Residual levels of ethylene oxide (and related substances) must be kept below the level of detection.
2947	LAURETH-23	E	Only for use in topical medicines for dermal application.
2948	LAURETH-3	E	Only for use in topical medicines for dermal application.
2949	LAURETH-4	E	Only for use in topical medicines for dermal application.
2950	LAURETH-7	E	Only for use in topical medicines for dermal application.
2951	LAURETH-8	E	
2952	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.

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2953	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%.
2954	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2955	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%.
2956	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 the medicine

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			label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'.
2957	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%.
2958	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2959	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%.
2960	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.

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2961	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%.
2962	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%.
2963	LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or damaged skin. The concentration in the medicine must be no more than 3.5%.
2964	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.
2965	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

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			exceed 1% in leave-on medicines and 3% in wash-on/wash-off medicines.
2966	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2967	LAURYL DIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2968	LAURYL DIMONIUM HYDROXYPROPYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.007%.
2969	LAURYL METICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2970	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 than 1%.
2971	LAVANDIN OIL ABRIAL	A, E, H	
2972	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%.

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2973	LAVANDULA ANGUSTIFOLIA	A, E, H	<p>Camphor is a mandatory component of Lavandula angustifolia.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p>
2974	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	<p>Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p>
2975	LAVANDULA X INTERMEDIA	A, E, H	<p>Camphor is a mandatory component of Lavandula x intermedia.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p>
2976	LAVENDER OIL	A, E, H	
2977	LAWSONIA INERMIS	A, H	
2978	LEAD	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The concentration in the medicine must be no more than 0.001%.</p>
2979	LEAD ACETATE	H	<p>Only for use as an active homoeopathic ingredient.</p>
2980	LEAF ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a</p>

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			flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2981	LECITHIN	A, E	
2982	LEDEBOURIELLA SESELOIDES	A, H	
2983	LEDUM PALUSTRE	A, H	Beta-arbutin is a mandatory component of <i>Ledum palustre</i> . When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for topical use other than dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001 mg of the equivalent dry herbal material of <i>Ledum palustre</i> .
2984	LEMNA MINOR	A, H	
2985	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.
2986	LEMON BALM LEAF DRY	A, H	
2987	LEMON BALM LEAF POWDER	A, E, H	

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2988	LEMON OIL	A, E, H	<p>When used internally, oxdrine is a mandatory component of lemon oil.</p> <p>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>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:</p> <p>a) steam distilled or rectified; or</p> <p>b) for internal use; or</p> <p>c) contains 0.05% or less of lemon oil; or</p> <p>d) for use in soaps or bath or shower gels that are washed off the skin.</p>
2989	LEMON OIL DISTILLED	A, E, H	<p>When used internally, oxdrine is a mandatory component of lemon oil distilled.</p> <p>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
2990	LEMON OIL TERPENELESS	A, E, H	<p>When used internally, oxdrine is a mandatory component of lemon oil terpeneless.</p> <p>The quantity of oxdrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
2991	LEMON OIL TERPENES AND TERPENOIDS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
2992	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.
2993	LEMONGRASS OIL	A, E, H	
2994	LENS CULINARIS	A, H	
2995	LENTIL	E	
2996	LENTINULA EDODES	A, E, H	
2997	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%.
2998	LEONURUS CARDIACA	A, E, H	
2999	LEONURUS SIBIRICUS	A, E, H	
3000	LEPIDIUM APETALUM	A, H	
3001	LEPIDIUM MEYENII	A	The route of administration for medicines that contain <i>Lepidium meyenii</i> must be limited to oral. The ingredient must consist of the dried tuber of <i>Lepidium meyenii</i> only. The maximum recommended daily dose of the medicine must not provide more than 3.5 g of <i>Lepidium meyenii</i> dried tuber (or its extract equivalent).
3002	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.

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3003	LEPTOSPERMUM SCOPARIUM OIL	A	<p>Only for use as an active ingredient when the route of administration is topical or oral application in a mouthwash preparation.</p> <p>If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL.</p> <p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken' <p>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:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or word to that effect) - (NTAKEN) 'Not to be taken'
3004	LESPEDEZA CAPITATA	A, H	
3005	LETTUCE	E	
3006	LEUCINE	A, E	
3007	LEUZEA UNIFLORUM	A, H	
3008	LEVISTICUM OFFICINALE	A, H	
3009	LEVOCARNITINE	A	
3010	LEVOCARNITINE FUMARATE	A	
3011	LEVOCARNITINE HYDROCHLORIDE	A	

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3012	LEVOCARNITINE MAGNESIUM CITRATE	A	
3013	LEVOCARNITINE TARTRATE	A	
3014	LEVOMEFOLATE CALCIUM	A	<p>Available for medicines intended for internal use only.</p> <p>Levomefolic acid is a mandatory component of levomefolate calcium.</p> <p>The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate calcium.</p> <p>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.</p>
3015	LEVOMEFOLATE GLUCOSAMINE	A	<p>Available for medicines intended for internal use only.</p> <p>Levomefolic acid is a mandatory component of levomefolate glucosamine.</p> <p>The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine.</p> <p>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.</p>
3016	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3017	LEVULINIC ACID	E	Permitted for use only in

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			<p>combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3018	LIGHT KAOLIN	E	
3019	LIGHT LIQUID PARAFFIN	A, E	<p>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.</p>
3020	LIGHT MAGNESIUM OXIDE	A, E, H	<p>Magnesium is a mandatory component of light magnesium oxide.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains</p>

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			<p>magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3021	LIGUSTICUM SINENSE	A, H	
3022	LIGUSTICUM STRIATUM	A, E, H	
3023	LIGUSTRUM LUCIDUM	A, H	
3024	LILIUM BROWNII	A, H	
3025	LILIUM CANDIDUM	A, E, H	
3026	LILIUM LANCIFOLIUM	A, H	
3027	LILIUM LONGIFLORUM	A, H	
3028	LIME FRUIT	E	
3029	LIME OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3030	LIME OIL COLDPRESSED	A, E, H	<p>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:</p> <p>a) for internal use; or</p> <p>b) contains 0.5% or less of lime oil coldpressed; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
3031	LIME OIL DISTILLED	A, E, H	<p>The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight'</p>

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			(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.
3032	LIME OIL TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3033	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%.
3034	LIME TREE FLOWER DRY	A, H	
3035	LIME TREE FLOWER POWDER	A, H	
3036	LIME, ESSENCE	E	
3037	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%.
3038	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.

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3039	LINALOOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3040	LINALOOL OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3041	LINALYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3042	LINALYL ACETATE	E	<p>Permitted for use only:</p> <p>(a) in topical medicines for dermal application; and</p> <p>(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary</p>

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			excipient formulation in a medicine must be no more than 5%.
3043	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%.
3044	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%.
3045	LINALYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3046	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%.
3047	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3048	LINALYL PROPIONATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3049	LINDERA STRYCHNIFOLIA	A, H	
3050	LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
3051	LINOLEIC ACID	E	
3052	LINOLENIC ACID	E	
3053	LINSEED DRY	A, E, H	
3054	LINSEED OIL	A, E, H	
3055	LINSEED OIL FATTY ACIDS	E	<p>Linseed oil fatty acids must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing linseed oil fatty acids must not be more than 5% of the total medicine.</p>

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3056	LINSEED POWDER	A, E, H	
3057	LINUM USITATISSIMUM	A, E, H	
3058	LIPASE	A	Lipase must only be derived from <i>Rhizopus oryzae</i> and must comply with the relevant compositional guideline.
3059	LIPPIA DULCIS	A, H	
3060	LIQUID GLUCOSE	E	
3061	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.
3062	LIQUIDAMBAR FORMOSANA	A, H	
3063	LIQUIDAMBAR ORIENTALIS	A, H	
3064	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3065	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%.
3066	LIQUIDAMBAR TAIWANIANA	A, H	
3067	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%.
3068	LIQUORICE DRY	A, E, H	
3069	LIQUORICE LIQUID EXTRACT	A, E, H	
3070	LIQUORICE POWDER	A, E, H	

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3071	LITCHI CHINENSIS	A, H	
3072	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3073	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3074	LITSEA CUBEBA	A, E, H	
3075	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%.
3076	LOBARIA PULMONARIA	A, H	
3077	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.
3078	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.
3079	LOBELIA POWDER	A, H	The concentration in the medicine must be no more than 0.001% or 10mg/kg or 10ml/L or 10 ppm unless the medicine is administered by inhalation.
3080	LOLIUM PERENNE	A, H	
3081	LOLIUM TEMULENTUM	A, H	
3082	LONGIFOLENE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total longifolene concentration in a medicine must be no more than 1%.
3083	LONICERA CAPRIFOLIUM	A, E, H	
3084	LONICERA JAPONICA	A, E, H	
3085	LONICERA PERICLYMENUM	A, H	
3086	LOPHATHERUM GRACILE	A, H	
3087	LOQUAT	E	
3088	LORANTHUS PARASITICUS	A, H	
3089	LOROPETALUM CHINENSIS	A, H	
3090	LOTUS CORNICULATUS	A, H	
3091	LOVAGE OIL	A, E, H	
3092	LOVAGE ROOT DRY	A, H	
3093	LOVAGE ROOT POWDER	A, H	
3094	LUDWIGIA PROSTRATA	A, H	
3095	LUFFA CYLINDRICA	A, H	
3096	LUFFA PURGANS	A, H	
3097	LUTEIN	A, E, H	When used as an excipient, permitted for use only as a colour in medicines limited to topical and oral routes of administration.
3098	LYCHEE	E	
3099	LYCIUM BARBARUM	A, H	
3100	LYCIUM CHINENSE	A, E, H	
3101	LYCOPENE	A, E	
3102	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.
3103	LYCOPODIUM ANNOTINUM	A, H	
3104	LYCOPODIUM CLAVATUM	A, H	
3105	LYCOPODIUM COMPLANATUM	A, H	

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3106	LYCOPUS EUROPAEUS	A, H	
3107	LYCOPUS LUCIDUS	A, H	
3108	LYCOPUS VIRGINICUS	A, H	Pulegone is a mandatory component of <i>Lycopus virginicus</i> . The concentration of pulegone in the medicine must be no more than 4%.
3109	LYGODIUM JAPONICUM	A, H	
3110	LYSIMACHIA CHRISTINAE	A, H	
3111	LYSIMACHIA VULGARIS	A, H	
3112	LYSINE	A, E	
3113	LYSINE HYDROCHLORIDE	A, E	
3114	LYTHRUM HYSSOPIFOLIA	A, H	
3115	LYTHRUM SALICARIA	A, H	
3116	LYTHRUM VERTICILLATUM	A, H	
3117	MACADAMIA INTEGRIFOLIA	A, E	
3118	MACADAMIA NUT	E	
3119	MACADAMIA NUT OIL	E	
3120	MACADAMIA TERNIFOLIA	A, E, H	
3121	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%.
3122	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

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			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.
3123	MACROCYSTIS PYRIFERA	A, E, H	Iodine is a mandatory component of <i>Macrocystis pyrifera</i> . 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.
3124	MACROGOL 1000	E	
3125	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3126	MACROGOL 1500	E	
3127	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%.
3128	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3129	MACROGOL 20000	E	
3130	MACROGOL 300	E	
3131	MACROGOL 3000	E	
3132	MACROGOL 3350	A, E	When used as an active ingredient, can only be supplied as an un compounded medicine substance packed for

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			retail sale, and must comply with an un compounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
3133	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3134	MACROGOL 400	E	
3135	MACROGOL 4000	E	
3136	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3137	MACROGOL 600	E	
3138	MACROGOL 6000	E	
3139	MACROGOL 600000	E	
3140	MACROGOL 800	E	
3141	MACROGOL 8000	E	
3142	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%.
3143	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3144	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3145	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.
3146	MAGNESIUM ASCORBATE	A, E, H	

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3147	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3148	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3149	MAGNESIUM ASPARTATE	A, E, H	
3150	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3151	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3152	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3153	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	<p>Magnesium is a mandatory component of magnesium chloride 4.5-hydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the</p>

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			medicine must not be directed for use in infants younger than 12 months of age.
3154	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	<p>Magnesium is a mandatory component of magnesium chloride hexahydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3155	MAGNESIUM CITRATE	A, E, H	
3156	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3157	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	

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3158	MAGNESIUM DIGLUTAMATE	A, E, H	
3159	MAGNESIUM GLUCONATE	A, E, H	
3160	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3161	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3162	MAGNESIUM GLYCINATE DIHYDRATE	A	Only for use in oral medicines. Magnesium is a mandatory component of Magnesium glycinate dihydrate. The percentage of Magnesium from Magnesium glycinate dihydrate should be calculated based on the molecular weight of Magnesium glycinate dihydrate.
3163	MAGNESIUM HYDROGEN PHOSPHATE	H	Magnesium is a mandatory component of magnesium hydrogen phosphate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause

			<p>diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3164	MAGNESIUM HYDROXIDE	A, E	<p>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.</p> <p>Magnesium is a mandatory component of magnesium hydroxide.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause</p>

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			diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3165	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3166	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3167	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3168	MAGNESIUM OROTATE	A, E, H	
3169	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3170	MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label:

			<p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3171	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	<p>Magnesium is a mandatory component of magnesium phosphate pentahydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>

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3172	MAGNESIUM PHOSPHATE TRIBASIC	A, E, H	<p>Magnesium is a mandatory component of magnesium phosphate tribasic.</p> <p>The percentage of magnesium from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate tribasic.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3173	MAGNESIUM PYRUVATE	A	<p>Only for use in oral medicines.</p> <p>The maximum recommended daily dose must be no more</p>

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			than 7 grams.
3174	MAGNESIUM STEARATE	E	
3175	MAGNESIUM SULFATE DIHYDRATE	A, E, H	<p>When used internally, the maximum recommended daily dose must not be more than 1.5g.</p> <p>Magnesium is a mandatory component of magnesium sulfate dihydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3176	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily

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			<p>dose must not be more than 1.5 g.</p> <p>Magnesium is a mandatory component of magnesium sulfate heptahydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3177	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	<p>When used internally, the maximum recommended daily dose must not be more than 1.5 g.</p> <p>Magnesium is a mandatory component of magnesium sulfate monohydrate.</p> <p>When used in a medicine:</p>

			<p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p> <p>(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;</p> <p>the following warning statement is required on the medicine label:</p> <p>- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).</p> <p>When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.</p>
3178	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	<p>When used internally, the maximum recommended daily dose must not be more than 1.5 g.</p> <p>Magnesium is a mandatory component of magnesium sulfate trihydrate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p>

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(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;

(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or

(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;

the following warning statement is required on the medicine label:

- (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect).

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

3179	MAGNESIUM TRISILICATE	E	<p>Magnesium is a mandatory component of magnesium trisilicate.</p> <p>When used in a medicine:</p> <p>(a) with an oral route of administration;</p> <p>(b) not indicated for laxative (or related) use; and</p> <p>(c) where the maximum recommended daily dose for:</p> <p>(i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;</p> <p>(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or</p>
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			(iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3180	MAGNOLIA GLAUCA	A, H	
3181	MAGNOLIA LILIFLORA	A, H	
3182	MAGNOLIA OBOVATA	A, H	
3183	MAGNOLIA OFFICINALIS	A, E, H	
3184	MAGNOLIA SALICIFOLIA	A, H	
3185	MAIZE	E	
3186	MAIZE BRAN	E	
3187	MAIZE OIL	A, E, H	
3188	MAIZE STARCH	A, E, H	
3189	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3190	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.
3191	MALPIGHIA GLABRA	A, E, H	
3192	MALT EXTRACT	E	
3193	MALTITOL	E	
3194	MALTITOL SOLUTION	E	
3195	MALTODEXTRIN	E	Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains

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			such as wheat, barley, rye and oats.
3196	MALTOL	E	
3197	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%.
3198	MALTOSE	E	
3199	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3200	MALUS SYLVESTRIS	A, H	
3201	MALVA MOSCHATA	A, H	
3202	MALVA SYLVESTRIS	A, E, H	
3203	MALVA VERTICILLATA	A, H	
3204	MANDARIN	E	
3205	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%.
3206	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.
3207	MANDARIN OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3208	MANDARIN RESIDUE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3209	MANDARINAL 32048	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3210	MANDRAGORA OFFICINARUM	A, H	<p>Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum.</p> <p>The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%.</p> <p>The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%.</p> <p>The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.</p> <p>The concentration of hyoscyamine in the medicine must be no more than 300</p>

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			micrograms/kg or 300 micrograms/L or 0.00003%.
3211	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3212	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3213	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3214	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3215	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.
3216	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3217	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3218	MANGANESE GLUCONATE	A, E, H	
3219	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3220	MANGANESE OXIDE	A, E, H	
3221	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3222	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3223	MANGIFERA INDICA	A, E, H	
3224	MANGO	E, H	
3225	MANIHOT ESCULENTA	A, H	
3226	MANNITOL	E	
3227	MARANTA ARUNDINACEA	A, H	
3228	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3229	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

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			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).
3230	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).
3231	MARRUBIUM VULGARE	A, E, H	
3232	MARSDENIA CUNDURANGO	A, H	
3233	MARSHMALLOW ROOT DRY	A, H	
3234	MARSHMALLOW ROOT POWDER	A, H	
3235	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%.
3236	MASTIC	A, H	
3237	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

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			medicine must be no more 1%.
3238	MATRICARIA CHAMOMILLA	A, E, H	
3239	MATRICARIA FLOWER DRY	A, E, H	
3240	MEADOWSWEET HERB DRY	A, H	<p>Methyl salicylate is a mandatory component of meadowsweet herb dry.</p> <p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> - 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. <p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (METSAL) 'Contains methyl salicylate' (or words to that effect). <p>When for use in topical medicines for dermal application</p> <p>i) the concentration of methyl</p>

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			<p>salicylate in the medicine must not be more than 25%</p> <p>ii) the following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (IRRIT) 'If irritation develops, discontinue use'.
3241	MECOBALAMIN (CO-METHYLCOBALAMIN)	A	Only for use in oral medicines.
3242	MEDICAGO SATIVA	A, E, H	<p>The level of l-canavanine must be no more than that of the dried leaf.</p> <p>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.</p>
3243	MEDIUM CHAIN TRIGLYCERIDES	E	
3244	MELALEUCA ALTERNIFOLIA	A, E, H	<p>Cineole is a mandatory component of Melaleuca alternifolia.</p> <p>In liquid preparations when the</p>

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			<p>concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p>
3245	MELALEUCA CAJUPUTI	A, E, H	<p>Cineole is a mandatory component of Melaleuca cajuputi.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p>

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			- (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.
3246	MELALEUCA CITRINA	A, H	
3247	MELALEUCA DISSITIFLORA	A, H	Cineole is a mandatory component of Melaleuca dissitiflora. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3248	MELALEUCA ERICIFOLIA	A, E, H	Cineole is a mandatory

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			<p>component of Melaleuca ericifolia.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p>
3249	MELALEUCA LINARIIFOLIA	A, H	<p>Cineole is a mandatory component of Melaleuca linariifolia.</p> <p>In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p>

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			<p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p>
3250	MELALEUCA OIL	A, E, H	<p>Cineole and cajuput oil are a mandatory components of Melaleuca Oil.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect)</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be fitted on the container.</p> <p>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.</p>
3251	MELALEUCA QUINQUENERVIA	A, E, H	<p>Cineole is a mandatory component of Melaleuca quinquenervia.</p> <p>In liquid preparations, when</p>

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			<p>the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%:</p> <p>a) the nominal capacity of the container must be no more than 25 millilitres;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the container must include the following warning statements on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p>
3252	MELICOPE PTELEIFOLIA	A, H	
3253	MELILOTUS OFFICINALIS	A, E, H	<p>Coumarin is a mandatory component of Melilotus officinalis.</p> <p>The concentration of coumarin in the medicine must be no more than 0.001%.</p>
3254	MELISSA OFFICINALIS	A, E, H	
3255	MELON	E	
3256	MENADIONE SODIUM BISULFITE	E	
3257	MENAQUINONE 7	A	<p>For oral use only.</p> <p>The medicine must not provide more than 180 micrograms per maximum daily dose in adults, 90 micrograms per maximum daily dose in children between</p>

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			10-18 years, and 45 micrograms per maximum daily dose in children less than 10 years of age.
3258	MENISPERMUM CANADENSE	A, H	
3259	MENTHA AQUATICA	A, H	<p>Menthol is a mandatory component of Mentha aquatica. When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for</p>

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			internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3260	MENTHA ARVENSIS	A, E, H	<p>Menthol is a mandatory component of <i>Mentha arvensis</i>. When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must</p>

			not contain more than 1 gram of menthol.
3261	MENTHA ARVENSIS LEAF OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more 1%.</p> <p>Menthol is a mandatory component of Mentha arvensis leaf oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops,</p>

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			<p>discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3262	MENTHA ARVENSIS OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total flavour proprietary excipient formulation in a medicine must not be more than 5%.</p> <p>Menthol is a mandatory component of <i>Mentha arvensis</i> oil.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statements is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the</p>

			<p>following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (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. <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> – (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3263	MENTHA HAPLOCALYX	A, E, H	<p>Menthol is a mandatory component of Mentha haplocalyx.</p> <p>When the medicine is for topical use for dermal application:</p> <ul style="list-style-type: none"> (i) the medicine must not be intended for use in the eye or on damaged skin; (ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; (iii) the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the

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			<p>following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (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. <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3264	MENTHA PULEGIUM	A, H	<p>D-pulegone, menthol and volatile oil components (of <i>Mentha pulegium</i>) are mandatory components of <i>Mentha pulegium</i>.</p> <p>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%.</p> <p>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.</p> <p>The medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (NTAKEN) 'Not to be taken'; - (CHILD) 'Keep out of reach of children' (or words to that

effect).

When the medicine is for
topical use for dermal
application:

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 medicine must not
deliver more than 25% total
menthol when administered
according to the directions for
use;

d) the following warning
statement is required on the
medicine label:

- (EYE) Avoid contact with
eyes (or words to that effect).

e) if the medicine delivers
more than 1% total menthol
when administered according
to the directions for use, 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.

f) if the medicine delivers more
than 5% total menthol when
administered according to the
directions for use, the
following warning statement is
required on the medicine label:

- (MENTH) Contains a high
concentration of menthol,
which can cause severe skin
irritation.

When the medicine is for
internal use:

a) the maximum recommended
daily dose must not contain

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			<p>more than 50 mg of Mentha pulegium oil or distillate;</p> <p>b) the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3265	MENTHA SPICATA	A, E, H	<p>Menthol is a mandatory component of Mentha spicata.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for</p>

			internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3266	MENTHA X CARDIACA	A, E, H	<p>Menthol is a mandatory component of Mentha x cardiaca.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for</p>

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			internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.
3267	MENTHA X PIPERITA	A, E, H	<p>Menthol is a mandatory component of Mentha x piperita.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p> <p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum</p>

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			recommended daily dose must not contain more than 1 gram of menthol.
3268	MENTHADIENYL ACETATE	E	<p>Menthadienyl acetate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation.</p> <p>The total concentration of the flavour proprietary excipient formulation containing menthadienyl acetate must not be more than 5% of the total medicine.</p>
3269	MENTHANYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3270	MENTHOFURAN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3271	MENTHOL	A, E	<p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the</p>

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			<p>medicine label:</p> <ul style="list-style-type: none"> - (EYE) Avoid contact with eyes (or words to that effect). (iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: <ul style="list-style-type: none"> - (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. (v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: <ul style="list-style-type: none"> - (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation. <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3272	MENTHONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3273	MENTHONE GLYCERINE ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p>

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3274	MENTHONE THIOL FRACTION	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3275	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3276	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%.
3277	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%.
3278	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 not be more than 5%. When used in primary sunscreen products, the

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			following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3279	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%.
3280	MENTHYL LACTATE	E	
3281	MENYANTHES TRIFOLIATA	A, H	
3282	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient.
3283	MERCURY	H	Only for use as an active homoeopathic ingredient.
3284	METACRESOL	E	Only for use in topical medicines for dermal application.
3285	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3286	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%.
3287	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

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			medicine must be no more than 1%.
3288	METHIONINE	A, E	
3289	METHYL 2,6,6-TRIMETHYLCYCLOHEX-2-ENE-1-CARBOXYLATE	E	<p>Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.</p>
3290	METHYL 2-METHYLBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3291	METHYL 2-OCTYNOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3292	METHYL 3,6-DIMETHYLRESORCYLATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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3293	METHYL ACETATE	E	The residual solvent limit is 50 mg per recommended daily dose. The concentration in the medicine must be no more than 0.5%.
3294	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%.
3295	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3296	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%.
3297	METHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3298	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.

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3299	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%.
3300	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%.
3301	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 than 1%.
3302	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%.
3303	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

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			1%.
3304	METHYL CHAVICOL	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The ingredient is not to be included in medicines intended for oral use.</p> <p>The quantity of methyl chavicol in a medicine must be no more than 0.01%.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3305	METHYL CINNAMATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3306	METHYL CIS-5-OCTENOATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3307	METHYL CYCLOPENTENOLONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more 1%.
3308	METHYL CYCLOPENTYLIDENEACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3309	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%.
3310	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%.
3311	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%.
3312	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3313	METHYL ETHYL KETONE	E	The residual solvent limit is 50 mg per maximum recommended daily dose. The concentration in the

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			medicine must be no more than 0.5%.
3314	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 than 1%.
3315	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%.
3316	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.
3317	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.
3318	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

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				1%.
3319	METHYL GLUCETH-20 SESQUIHYDRATE	E		Only for use in topical medicines for dermal application.
3320	METHYL GLUCOSE DIOLEATE	E		Only for use in topical medicines for dermal application.
3321	METHYL GLUCOSE SESQUIOLEATE	E		Only for use in topical medicines for dermal application.
3322	METHYL GLUCOSE SESQUISTEARATE	E		Only for use in topical medicines for dermal application.
3323	METHYL HEPTANOATE	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 not be more than 5%.
3324	METHYL HEPTENONE	E		Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3325	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

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3326	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%.
3327	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%.
3328	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3329	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3330	METHYL HYDROXYBENZOATE	E	
3331	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%.

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3332	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%.
3333	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%.
3334	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%.
3335	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%.
3336	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%.
3337	METHYL LINOLEATE	E	Permitted for use only in combination with other

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			permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3338	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%.
3339	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%.
3340	METHYL METHACRYLATE	E	
3341	METHYL METHACRYLATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be intended for use on damaged skin. The concentration in the medicine must not be more than 4.85%.
3342	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

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			1%.
3343	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%.
3344	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%.
3345	METHYL NONYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3346	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%.
3347	METHYL OCTIN CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a

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			flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3348	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3349	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%.
3350	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%.
3351	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%.
3352	METHYL PHENYLACETATE	E	Permitted for use only in combination with other

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			<p>permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3353	METHYL PHENYLCARBINYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3354	METHYL ROSINATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3355	METHYL SALICYLATE	A, E	<p>Not to be included in medicines for use in the eye or on damaged skin.</p> <p>When used internally, the concentration in the medicine must not be more than 0.001%.</p> <p>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.</p> <p>When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray,</p>

the medicine does not require child resistant packaging if:

- the delivery device is engaged into the container in such a way that prevents it from being readily removed;

- direct suction through the delivery device results in delivery of no more than one dosage unit; and

- actuation of the spray device is ergonomically difficult for young children to accomplish.

The following warning statement is required on the medicine label:

- (METSAL) 'Contains methyl salicylate' (or words to that effect).

When for use in topical medicines for dermal application:

i) the concentration of methyl salicylate in the medicine must not be more than 25%;

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);

- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';

- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);

- (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect);

iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:

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			- (IRRIT) 'If irritation develops, discontinue use'.
3356	METHYL STEARATE	E	
3357	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%.
3358	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3359	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%.
3360	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%.
3361	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

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			5%.
3362	METHYLBENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3363	METHYLCELLULOSE	A, E	
3364	METHYLCHLOROISOTHIAZOLI NONE	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%.
3365	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%.
3366	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 not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective

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			clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3367	METHYLISOTHIAZOLINONE	E	<p>Only for use in topical medicines for dermal application that are rinsed off the skin.</p> <p>The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.</p>
3368	METHYLMERCAPTAN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3369	METHYLPROPANEDIOL	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 10%.</p>
3370	METHYLSILANOL/SILICATE CROSSPOLYMER	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
3371	METHYLSTYRENE/VINYLTOLU ENE COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p>
3372	MICA	E	<p>Only for use when the route of</p>

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			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%.
3373	MICROCALICIUM ARENARIUM	A, H	
3374	MICROCOCCLUS 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%.
3375	MICROCOS PANICULATA	A, H	
3376	MICROCRYSTALLINE CELLULOSE	E	
3377	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'.
3378	MILK FAT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3379	MILK THISTLE FRUIT DRY	A, H	
3380	MILK THISTLE FRUIT POWDER	A, H	
3381	MILLET	E	
3382	MILLETTIA DIELSIANA	A, H	

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3383	MIMOSA ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3384	MIMULUS GUTTATUS	A, H	
3385	MINT OIL DEMENTHOLISED	A, E, H	<p>Menthol is a mandatory component of mint oil dementholised.</p> <p>When the medicine is for topical use for dermal application:</p> <p>(i) the medicine must not be intended for use in the eye or on damaged skin;</p> <p>(ii) the medicine must not deliver more than 25% total menthol when administered according to the directions for use;</p> <p>(iii) the following warning statement is required on the medicine label:</p> <p>- (EYE) Avoid contact with eyes (or words to that effect).</p> <p>(iv) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label:</p> <p>- (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area;</p> <p>- (IRRIT) If irritation develops, discontinue use.</p> <p>(v) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label:</p>

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			<p>– (MENTH) Contains a high concentration of menthol, which can cause severe skin irritation.</p> <p>When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.</p>
3386	MINTLACTONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3387	MITCHELLA REPENS	A, H	
3388	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3389	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3390	MIXED TERPENES	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3391	MODIFIED FOOD STARCH	E	
3392	MOLASSES	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3393	MOLYBDENUM	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>When Molybdenum is sourced from Molybdenum trioxide</p>

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			then the maximum daily dose must be no more than 125 micrograms. When Molybdenum is sourced from yeast - high molybdenum then the maximum recommended daily dose must be no more than 62.5 micrograms.
3394	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.
3395	MOMORDICA BALSAMINA	A, H	
3396	MOMORDICA CHARANTIA	A, H	
3397	MOMORDICA COCHINCHINENSIS	A, H	
3398	MONARDA DIDYMA	A, H	
3399	MONO- AND DI- GLYCERIDES	E	
3400	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3401	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3402	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.

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3403	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.
3404	MONOBASIC SODIUM PHOSPHATE DIHYDRATE	E	When used in a solid preparation, the pH of a 10 g/L aqueous solution must not be more than 11.5. When used in a liquid or a semi-solid preparation, the pH of the preparation must not exceed 11.5.
3405	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3406	MONOMENTHYL SUCCINATE	E	Monomenthyl succinate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing monomenthyl succinate must not be more than 5% of the total medicine.
3407	MONOPHOSPHOTHIAMINE	A	
3408	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3409	MONOPOTASSIUM GLUTAMATE	A, E	
3410	MONOSODIUM DIHYDROGEN CITRATE	E	
3411	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	

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3412	MONSTERA DELICIOSA	A, H	
3413	MONTAN WAX	E	
3414	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%..
3415	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).
3416	MORINDA OFFICINALIS	A, H	
3417	MORINGA OLEIFERA	A, H	
3418	MORUS ALBA	A, H	
3419	MORUS BOMBYCIS	A, H	
3420	MORUS NIGRA	A, E, H	
3421	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%.
3422	MOTHERWORT HERB DRY	A, H	
3423	MOTHERWORT HERB POWDER	A, H	
3424	MUCUNA PRURIENS	A	Levodopa is a mandatory component of Mucuna pruriens. The concentration of levodopa in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
3425	MULBERRY	E	
3426	MUNG BEAN	E	
3427	MURRAYA KOENIGII	A, H	
3428	MURRAYA PANICULATA	A, H	

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3429	MUSA X PARADISIACA	A, H	
3430	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3431	MUSK TIBETENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3432	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3433	MUSKS	H	Only for use as an active homoeopathic ingredient.
3434	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%.
3435	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%.
3436	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

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			ingredients in the product must be no more than 10 mg/kg or 10 mg/L or 0.001%.
3437	MYOSOTIS ARVENSIS	A, H	
3438	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%.
3439	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%.
3440	MYRICA CERIFERA	A, E, H	
3441	MYRISTIC ACID	E	
3442	MYRISTIC ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3443	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%.

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			<p>When for topical use then the concentration of safrole in the medicine must be no more than 1%.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children' (or word to that effect).</p>
3444	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3445	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3446	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3447	MYROXYLON BALSAMUM	A, E, H	
3448	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3449	MYRRH	A, H	
3450	MYRRH OIL	A, E, H	
3451	MYRRH RESIN	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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3452	MYRRHIS ODORATA	A, H	
3453	MYRSINE AFRICANA	A, H	
3454	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%.
3455	MYRTENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3456	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%.
3457	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%.
3458	MYRTUS COMMUNIS	A, E, H	
3459	N,N'-BIS(SALICYLIDENE)PROPYLENEDIAMINE	E	N,N'-Bis(salicylidene)propylenediamine must only be included in medicines when in combination with other permitted ingredients as a proprietary excipient

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			formulation in medicines with a dermal route of administration for topical application.
3460	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%.
3461	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%.
3462	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%.
3463	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%.

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3464	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3465	NARDOSTACHYS CHINENSIS	A, H	
3466	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%.
3467	NASTURTIUM OFFICINALE	A, E, H	
3468	NATURAL FISH OIL	A, E	When therapeutic indications for this product are made against Vitamin A or colexcalciferol (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 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

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			<p>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.</p> <p>- (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.'</p> <p>When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.</p>
3469	NAUCLEA OFFICINALIS	A, H	
3470	NELUMBO NUCIFERA	A, H	
3471	NELUMBO NUCIFERA FLOWER WAX	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.1%.</p>
3472	NEOHESPERIDIN-DIHYDROCHALCONE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 0.1%</p>
3473	NEOMENTHOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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3474	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%.
3475	NEOPENTYL GLYCOL DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3476	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 not be more than 8.1%. When the concentration of neopentyl glycol dioctanoate is greater than 5%, the medicine must not be intended for use on damaged skin.
3477	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3478	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3479	NEPETA CATARIA	A, H	Pulegone is a mandatory component of <i>Nepeta cataria</i> and must be declared in the application. The concentration of pulegone in the medicine must be no more than 4%.

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3480	NERAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3481	NERIUM OLEANDER	A, H	<p>The concentration of equivalent dry Nerium oleander in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.</p>
3482	NEROL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3483	NEROL OXIDE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3484	NEROLIDOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p>

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3485	NERONE	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3486	NERYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3487	NERYL-ISO-BUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3488	NICKEL	H	Only for use as an active homoeopathic ingredient.
3489	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3490	NICOTINAMIDE	A, E, H	

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3491	NICOTINAMIDE ASCORBATE	A, E	
3492	NICOTINAMIDE RIBOSIDE CHLORIDE	A	<p>Ribose is a mandatory component of nicotinamide riboside chloride.</p> <p>Only permitted for use in medicines limited to oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 300 mg of nicotinamide riboside chloride.</p> <p>The following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (NTAKEN12) 'Not to be taken by children under 12 years old.'</p> <p>When the maximum recommended daily dose of the medicine provides greater than 230 mg of nicotinamide riboside chloride, the following warning statement is required on the medicine label:</p> <p>- (PREG) 'Not recommended for use during pregnancy or lactation'.</p>
3493	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3494	NIGELLA DAMASCENA	A, H	
3495	NIGELLA SATIVA	A, E, H	
3496	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3497	NONADIENOL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than</p>

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			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3498	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%.
3499	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%.
3500	NONFAT DRY MILK	E, H	
3501	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%.
3502	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3503	NONOXINOL 12	E	For use in hand scrub formulations for healthcare professionals only. Only for use in topical

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			<p>medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 5%.</p>
3504	NONOXINOL 5	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3505	NONOXINOL 9	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 25%.</p>
3506	NONYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3507	NOOTKATONE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3508	NOPYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total</p>

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			fragrance concentration in a medicine must be no more than 1%.
3509	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%.
3510	NOTOPTERYGIUM FORBESII	A, H	
3511	NOTOPTERYGIUM INCISIUM	A, H	
3512	NUPHAR JAPONICA	A, H	
3513	NUPHAR LUTEA	A, H	
3514	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%.
3515	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

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			on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3516	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%.
3517	NUX VOMICA DRY	A, H	Strychnine (of <i>Strychnos</i> 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%.
3518	NUX VOMICA POWDER	H	Only for use as an active homoeopathic ingredient. Strychnine (of <i>Strychnos</i> 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%.
3519	NYCTANTHES ARBOR-TRISTIS	A, H	When the plant part is leaf: a) methyl salicylate is a mandatory component of <i>Nyctanthes arbor-tristis</i> ; 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 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:

i) the concentration of methyl salicylate in the medicine must not be more than 25%

ii) the following warning statements are required on the medicine label:

- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);
- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';
- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);
- (AVOID) 'Avoid prolonged

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			<p>exposure in the sun' (or words to that effect);</p> <p>iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label:</p> <p>- (IRRIT) 'If irritation develops, discontinue use'.</p>
3520	NYLON	E	Only for use in topical medicines for dermal application.
3521	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3522	NYLON-12	E	Only for use in topical medicines for dermal application.
3523	NYMPHAEA ALBA	A, E, H	
3524	NYMPHAEA CAERULEA	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine to be no more than 0.3%.</p> <p>Only for use in liquid extracts where the plant part is the flower and the solvent in 100% water.</p>
3525	NYMPHAEA ODORATA	A, H	
3526	OAK CHIPS EXTRACT	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>

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3527	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%.
3528	OAT	E, H	Only for use as an active homoeopathic or excipient ingredient. Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal.
3529	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3530	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.
3531	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%.
3532	OCIMENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

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			<p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3533	OCIMUM BASILICUM	A, E, H	<p>When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are mandatory components of Ocimum basilicum.</p> <p>The concentration of methyleugenol in the medicine must not exceed 1%.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none">- (CHILD) 'Keep out of reach of children' (or words to that effect). When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the 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'. <p>When the concentration of</p>

			<p>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.</p> <p>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.</p> <p>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%.</p>
3534	OCIMUM KILIMANDSCHARICUM	A, H	<p>Camphor is a mandatory component of Ocimum kilimandscharicum.</p> <p>In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.</p> <p>In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.</p> <p>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:</p>

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			<p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p>
3535	OCIMUM MINIMUM	A, H	
3536	OCIMUM TENUIFLORUM	A, H	<p>When the plant part is oil or distillate, eugenol is a mandatory component of <i>Ocimum tenuiflorum</i>.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect); and</p> <p>- (NTAKEN) 'Not to be taken'.</p> <p>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.</p> <p>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</p>

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			<p>fitted on the container.</p> <p>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%.</p>
3537	OCOTEA ODORIFERA	A, H	<p>Safrole is a mandatory component of <i>Ocotea odorifera</i>.</p> <p>When for internal use then the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole in the medicine must be no more than 1%.</p>
3538	OCTACOSANOL	E	
3539	OCTADECANAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3540	OCTADECENE/MA COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p>
3541	OCTAHYDRO-4,7-METHANO-3AH-INDENE-3A-CARBOXYLIC ACID, ETHYL ESTER	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>

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3542	OCTAHYDROCOUMARIN	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.</p>
3543	OCTAN-1-OL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3544	OCTANAL DIMETHYL ACETAL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3545	OCTANOHYDROXAMIC ACID	E	<p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
3546	OCTANOIC ACID	A, E	<p>When for topical use, the concentration in the medicine must be no more than 2% (w/w).</p> <p>When for excipient use, permitted for use only in</p>

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			<p>combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation.</p> <p>When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.</p> <p>When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3547	OCTENE-1	E	<p>Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation.</p> <p>The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.</p>
3548	OCTOCRYLENE	A	<p>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.</p> <p>The concentration in the medicine must not be more than 10%.</p> <p>When used in primary sunscreen products, the following warning statements are required on the label:</p> <ul style="list-style-type: none"> - (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).
3549	OCTOXINOL 10	E	<p>Only for use in topical medicines for dermal</p>

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			application.
3550	OCTYL ACETATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3551	OCTYL CROTONATE	E	<p>Octyl crotonate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation.</p> <p>The total concentration of the fragrance proprietary excipient formulation containing octyl crotonate must not be more than 1% of the total medicine.</p>
3552	OCTYL HYDROXYSTEARATE	E	<p>Only for use in topical medicines for dermal application.</p>
3553	OCTYL ISOBUTYRATE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3554	OCTYL ISONONANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
3555	OCTYL METHOXYCINNAMATE	A	<p>Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines</p>

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			intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3556	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3557	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 not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3558	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3559	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	Only for use in topical medicines for dermal application.

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			The medicine requires the following warning statement on the medicine label: - (OBCARB) 'Contains octylbicycloheptenedicarboximide' (or words to that effect).
3560	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3561	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.
3562	OCTYLDODECYL CITRATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 12%.
3563	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.
3564	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%.

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3565	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%.
3566	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%.
3567	OENANTHE AQUATICA	H	Only for use as an active homoeopathic ingredient. The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3568	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3569	OENOTHERA BIENNIS	A, E, H	
3570	OENOTHERA STRICTA	A, H	
3571	OKOUBAKA AUBREVILLEI	A, H	
3572	OLDENLANDIA DIFFUSA	A, E, H	
3573	OLEA EUROPAEA	A, E, H	
3574	OLEIC ACID	E	
3575	OLETH-10	E	Only for use in topical medicines for dermal application.
3576	OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide

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			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%.
3577	OLETH-20	E	Only for use in topical medicines for dermal application.
3578	OLETH-3	E	Only for use in topical medicines for dermal application.
3579	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%.
3580	OLETH-5	E	Only for use in topical medicines for dermal application.
3581	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3582	OLIBANUM OIL	A, E, H	
3583	OLIVE	E	
3584	OLIVE OIL	A, E, H	
3585	OMEGA-3 FISH OIL PHYTOSTEROL ESTERS	A	The medicine requires the following warning statement on the medicine label: - (PREGNT) 'Not recommended for use by pregnant and lactating women (or words to that effect).'

3586	OMEGA-3-ACID ETHYL ESTERS 60	A	<p>Docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid are mandatory components of omega-3-acid ethyl esters 60.</p> <p>Only permitted for use in medicines that are for oral routes of administration.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 3750 milligrams of docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid combined.</p> <p>The following warning statements are required on the medicine label:</p> <ul style="list-style-type: none"> - (PREGNT) 'Not recommended for use by pregnant and lactating women' (or words to that effect); - (ACOAG) 'Individuals taking anticoagulants should seek medical advice before taking this product' (or words to that effect); - (CHILD3) 'Use in children under 12 years is not recommended'; - (FOOD) 'To be taken with food' (or words to that effect).
3587	OMEGA-3-ACID ETHYL ESTERS 90	A	<p>Only for use in oral medicines.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <ul style="list-style-type: none"> a) 4000 mg of omega-3-acid ethyl esters 90; and b) 3750 mg EPA, DHA and DPA combined, when used alone or in combination with other sources of omega-3 fatty acids. <p>The following warning statements (or words to the</p>

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			<p>same effect) are required on the medicine label:</p> <ul style="list-style-type: none"> - (ACOAG) 'Individuals taking anticoagulants should seek medical advice before taking this product.' - (FOOD) 'To be taken with food.' - (PREG) 'Not recommended for use during pregnancy or lactation.' - (CHILD3) 'Use in children under 12 years is not recommended.'
3588	ONION	E	
3589	ONION OIL	A, H	
3590	ONONIS SPINOSA	A, E, H	
3591	ONOPORDUM ACANTHIUM	A, H	
3592	ONOSMODIUM VIRGINIANUM	A, H	
3593	OPHIOPOGON JAPONICUS	A, H	
3594	OPOPANAX CHIRONIUM	A, E, H	<p>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.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3595	OPOPANAX OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>

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3596	OPUNTIA FICUS-INDICA	A, H	
3597	ORANGE	E	
3598	ORANGE FLOWER ABSOLUTE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3599	ORANGE FLOWER OIL	A, E, H	<p>When used internally, oxedrine is a mandatory component of orange flower oil.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
3600	ORANGE JUICE	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p>
3601	ORANGE JUICE OIL	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavour the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3602	ORANGE OIL	A, E, H	<p>When used internally, oxedrine is a mandatory component of orange oil.</p>

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			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3603	ORANGE OIL BITTER	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.</p> <p>If used in a flavor, the total flavour concentration in a medicine must be no more than 5%.</p> <p>If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%.</p> <p>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:</p> <ul style="list-style-type: none"> a) for internal use; b) in preparations containing 1.4% or less of orange oil bitter; c) for use in soaps or bath or shower gels that are washed off the skin.
3604	ORANGE OIL BITTER COLDPRESSED	A, E, H	<p>When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p> <p>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:</p> <ul style="list-style-type: none"> 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

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			shower gels that are washed off the skin.
3605	ORANGE OIL COLD PRESSED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3606	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.
3607	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%.
3608	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.
3609	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3610	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.
3611	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%.
3612	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3613	ORIGANUM MAJORANA	A, H	Beta-arbutin is a mandatory component of Origanum majorana. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%.

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			<p>When for use other than oral or dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.</p> <p>When the plant preparation is oil or distillate, and the concentration of <i>Origanum majorana</i> oil or distillate within the medicine is more than 50%:</p> <p>a) the nominal capacity of the container must not be more than 50 mL;</p> <p>b) a restricted flow insert must be fitted on the container; and</p> <p>c) the following warning statement is required on the label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>
3614	ORIGANUM OIL	E	<p>Permitted for use only in combination with other ingredients as a fragrance.</p> <p>If used as a fragrance the total concentration in the medicine must be no more than 1%.</p>
3615	ORIGANUM OIL SPANISH	A, E, H	
3616	ORIGANUM VULGARE	A, E, H	
3617	ORNITHINE	A, E	
3618	ORNITHINE ASPARTATE	A, E	
3619	ORNITHINE MONOHYDROCHLORIDE	A, E	
3620	ORNITHOGALUM UMBELLATUM	A, H	
3621	OROSTACHYS FIMBRIATA	A, H	
3622	OROXYLUM INDICUM	A, H	
3623	ORRIS	E	<p>Permitted for use only in combination with other permitted ingredients as a flavour.</p> <p>If used in a flavour the total flavour concentration in a</p>

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			medicine must be no more than 5%.
3624	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%.
3625	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%.
3626	ORRIS ROOT OIL	A, E, H	
3627	ORRIS ROOT RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3628	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%.
3629	ORTHOSIPHON ARISTATUS	A, H	
3630	ORYZA SATIVA	A, E, H	
3631	ORYZANOL	E	

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3632	OSBECKIA CHINENSIS	A, H	
3633	OSMANTHUS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3634	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%.
3635	OTTELIA ALISMOIDES	A, H	
3636	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%.
3637	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3638	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%.
3639	OXALIC ACID	H	Only for use as an active homoeopathic ingredient.
3640	OXALIS ACETOSELLA	A, H	

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3641	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%.
3642	OXIDISED TAPIOCA STARCH	E	
3643	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 not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3644	OYSTER	E	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2022; or - released for supply on or after 1 March 2023. (a) The following warning statement is required on the medicine label: - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
3645	OYSTER SHELL	A, E, H	The requirement specified in paragraph (a) below applies to

a medicine that contains the ingredient that is:

- listed in the Register on or after 1 March 2022; or
- released for supply on or after 1 March 2023.

(a) The following warning statement is required on the medicine label:

- (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
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