

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
2856	KADSURA COCCINEA	A, H	
2857	KAEMPFERIA GALANGA	A, H	
2858	KALMIA LATIFOLIA	A, H	<p>Beta-arbutin is a mandatory component of Kalmia latifolia.</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>
2859	KAOLIN	E	
2860	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.
2861	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>
2862	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>
2863	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>
2864	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';

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			<p>- (GEN2) 'If symptoms persist, seek the advice of a healthcare professional';</p> <p>- (CHILD3) 'Use in children under 12 years is not recommended'; and</p> <p>- (7DAYS) 'Do not use for more than 7 days'.</p>
2865	KIDNEY BEAN	E	
2866	KIRSCH	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>
2867	KIWI FRUIT	E	
2868	KNAUTIA ARVENSIS	A, H	
2869	KOREAN GINSENG ROOT DRY	A, H	
2870	KOREAN GINSENG ROOT POWDER	A, H	
2871	KRAMERIA IXINE	A, H	
2872	KRAMERIA LAPPACEA	A, H	
2873	KUNZEA AMBIGUA	A	<p>Only for use when the plant preparation is essential oil.</p> <p>Only for use when the route of administration is topical or inhalation.</p> <p>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:</p> <p>- (CHILD) 'Keep out of reach of children'</p> <p>- (EXTERN) 'For external use only'</p> <p>- (UNDILU) 'Not to be applied undiluted to the skin except on the advice of a health care practitioner'.</p>

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			<p>When the dosage form is other than essential oil, the maximum concentration in topical medicines must be no more than 25% w/w and the medicine requires the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.
2874	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>
2875	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>
2876	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>
2877	L-LIMONENE	E	<p>L-limonene must only be included in medicines when in</p>

			<p>combination with other 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>
2878	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>
2879	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>
2880	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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2881	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%.
2882	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%.
2883	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%.
2884	LABDANUM OIL	A, E, H	
2885	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%.
2886	LACTALBUMIN	E	
2887	LACTIC ACID	A, E, H	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in

			force or existing form time to time. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.
2888	LACTITOL	E	
2889	LACTITOL MONOHYDRATE	E	
2890	LACTO-N-NEOTETRAOSE	A	Lactose is a mandatory component of lacto-N-neotetraose. The route of administration for medicines that contain lacto-N-neotetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 1.5 g of lacto-N-neotetraose to individuals aged 4 years and older; and (b) 0.6 g of lacto-N-neotetraose to individuals aged up to 3 years (inclusive). One of the following statements (or words to the same effect) is required on the medicine label: (a) 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 (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-neotetraose'.
2891	LACTO-N-TETRAOSE	A	Lactose is a mandatory component of lacto-N-tetraose.

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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:

- a) 2 g of lacto-N-tetraose to individuals aged 1 year and older; and
- b) 0.6 g of lacto-N-tetraose to individuals aged more than 6 months to 11 months (inclusive); and
- c) 0.8 g of lacto-N-tetraose to individuals aged up to 6 months (inclusive).

One of the following statements (or words to the same effect) is required on the medicine label:

- a) 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-tetraose'; 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'.

2892	LACTOBACILLUS ACIDOPHILUS	A
2893	LACTOBACILLUS AMYLOVORUS	A
2894	LACTOBACILLUS BREVIS	A
2895	LACTOBACILLUS CASEI	A
2896	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A
2897	LACTOBACILLUS CRISPATUS	A
2898	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A
2899	LACTOBACILLUS DELBRUECKII SSP LACTIS	A
2900	LACTOBACILLUS FERMENTUM	A

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2901	LACTOBACILLUS GALLINARUM	A	
2902	LACTOBACILLUS GASSERI	A	
2903	LACTOBACILLUS HELVETICUS	A	
2904	LACTOBACILLUS JOHNSONII	A	
2905	LACTOBACILLUS KEFIRANOFACIENS	A	
2906	LACTOBACILLUS KEFIRGRANUM	A	
2907	LACTOBACILLUS KEFIRI	A	
2908	LACTOBACILLUS PARACASEI	A	
2909	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2910	LACTOBACILLUS PLANTARUM	A	
2911	LACTOBACILLUS REUTERI	A	
2912	LACTOBACILLUS RHAMNOSUS	A	
2913	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2914	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2915	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2916	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%.
2917	LACTOSE	E	
2918	LACTOSE MONOHYDRATE	E	
2919	LACTUCA SATIVA	A, H	
2920	LACTUCA VIROSA	A, H	
2921	LACTULOSE	E	
2922	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

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			British Pharmacopoeia, as in force or existing form time to time.
2923	LAGENARIA VULGARIS	A, H	
2924	LAMINARIA CLOUSTONI	A, E, H	<p>Iodine is a mandatory component of Laminaria cloustoni.</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>
2925	LAMINARIA DIGITATA	A, E, H	<p>Iodine is a mandatory component of Laminaria digitata.</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>
2926	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>
2927	LAMIUM ALBUM	A, H	

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2928	LANETH-5	E	Only for use in topical medicines for dermal application.
2929	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2930	LANOLIN OIL	E	Only for use in topical medicines for dermal application.
2931	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2932	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2933	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 Larix occidentalis or Larix laricina.</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 Larix arabinogalactan in oral medicines must not be more than 15 grams.</p> <p>The concentration of Larix arabinogalactan in topical medicines for dermal application must not exceed 5.0%.</p>
2934	LARIX DECIDUA	A, H	

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2935	LARIX KAEMPFERI	A, H	The maximum recommended daily dose must be no more than 1 mg of the equivalent dry herbal material of Larix kaempferi.
2936	LARREA TRIDENTATA	A, H	The following warning statement is required on the medicine label: (CHAP1) 'In rare cases, Larrea tridentata may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain or dark urine.'
2937	LATHYRUS SATIVUS	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lathyrus sativus. The medicine must not contain lathyrogenic amino acids.
2938	LAURAMINE OXIDE	E	
2939	LAUREL LEAF OIL	A, H	When the total concentration of bay oil in the medicine is more than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) the container must be fitted with a restricted flow insert; (c) the following warning statements are required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and (d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.

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2940	LAURETH-10	E	Only for use in topical medicines for dermal application.
2941	LAURETH-12	E	Only for use in topical medicines for dermal application.
2942	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.
2943	LAURETH-23	E	Only for use in topical medicines for dermal application.
2944	LAURETH-3	E	Only for use in topical medicines for dermal application.
2945	LAURETH-4	E	Only for use in topical medicines for dermal application.
2946	LAURETH-7	E	Only for use in topical medicines for dermal application.
2947	LAURETH-8	E	
2948	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.
2949	LAURIL MACROGOL 400 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
2950	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2951	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%.
2952	LAURUS NOBILIS	A, E, H	When the plant preparation is oil or distillate, and the concentration of bay oil or distillate in the medicine is greater than 25%: (a) the nominal capacity of the container must not be more than 25 mL; (b) the container must be fitted with a restricted flow insert; (c) the following warning statements are required on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; and (d) when the nominal capacity of the container is greater than 15 mL, the container must also be fitted with a child resistant closure.
2953	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a

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			<p>coating solution, 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>
2954	LAURYL BETAINE	E	<p>Only for use in topical medicines for dermal application.</p>
2955	LAURYL GLUCOSIDE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 12%.</p>
2956	LAURYL LACTATE	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 3%.</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>
2957	LAURYL PCA	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 1%.</p>

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2958	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%.
2959	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%.
2960	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.
2961	LAURYL POLYGLUCOSE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration must not exceed 1% in leave-on medicines and 3% in wash-on/wash-off medicines.
2962	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.

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2963	LAURYL DIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2964	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%.
2965	LAURYL METICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2966	LAVANDIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2967	LAVANDIN OIL ABRIAL	A, E, H	
2968	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%.
2969	LAVANDULA ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.

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			In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.
2970	LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia subsp. angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.
2971	LAVANDULA X INTERMEDIA	A, E, H	Camphor is a mandatory component of Lavandula x intermedia. In solid and semi solid preparations, the concentration of camphor must be no more than 12.5%.
2972	LAVENDER OIL	A, E, H	
2973	LAWSONIA INERMIS	A, H	
2974	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2975	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2976	LEAF ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total flavour concentration in a medicine must be no more than 5%.
2977	LECITHIN	A, E	

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2978	LEDEBOURIELLA SESELOIDES	A, H	
2979	LEDUM PALUSTRE	A, H	<p>Beta-arbutin is a mandatory component of Ledum palustre.</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 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%.</p> <p>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 Ledum palustre.</p>
2980	LEMNA MINOR	A, H	
2981	LEMON	E	<p>When used internally, oxedrine is a mandatory component of lemon.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
2982	LEMON BALM LEAF DRY	A, H	
2983	LEMON BALM LEAF POWDER	A, E, H	
2984	LEMON OIL	A, E, H	<p>When used internally, oxedrine is a mandatory component of lemon oil.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>

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			<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>
2985	LEMON OIL DISTILLED	A, E, H	<p>When used internally, oxedrine is a mandatory component of lemon oil distilled.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
2986	LEMON OIL TERPENELESS	A, E, H	<p>When used internally, oxedrine is a mandatory component of lemon oil terpeneless.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
2987	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 fragrance concentration in a medicine must be no more 1%.</p>
2988	LEMON PEEL DRIED	A, E, H	<p>When used internally, oxedrine is a mandatory component of lemon peel dried.</p> <p>The quantity of oxedrine in the maximum recommended daily</p>

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			dose must be no more than 30 milligrams.
2989	LEMONGRASS OIL	A, E, H	
2990	LENS CULINARIS	A, H	
2991	LENTIL	E	
2992	LENTINULA EDODES	A, E, H	
2993	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%.
2994	LEONURUS CARDIACA	A, E, H	
2995	LEONURUS SIBIRICUS	A, E, H	
2996	LEPIDIUM APETALUM	A, H	
2997	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).
2998	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2999	LEPTOSPERMUM SCOPARIUM OIL	A	Only for use as an active ingredient when the route of administration is oral application in a mouthwash, or topical. If the concentration is more than 25%, the nominal capacity of the container must not be more than 25 millilitres.

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When the concentration is more 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 and requires the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or word to that effect); and

- (NTAKEN) 'Not to be taken'.

When the concentration is more than 25%, and the nominal capacity of the container is more than 15 millilitres but not more than 25 millilitres, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or word to that effect); and

- (NTAKEN) 'Not to be taken'.

3000	LESPEDEZA CAPITATA	A, H	
3001	LETTUCE	E	
3002	LEUCINE	A, E	
3003	LEUZEA UNIFLORA	A, H	
3004	LEVISTICUM OFFICINALE	A, H	
3005	LEVOCARNITINE	A	
3006	LEVOCARNITINE FUMARATE	A	
3007	LEVOCARNITINE HYDROCHLORIDE	A	
3008	LEVOCARNITINE MAGNESIUM CITRATE	A	
3009	LEVOCARNITINE TARTRATE	A	
3010	LEVOMEFOLATE CALCIUM	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate calcium.

			<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>
3011	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>
3012	LEVOTHYROXINE SODIUM	H	<p>Only for use as an active homoeopathic ingredient.</p>
3013	LEVULINIC ACID	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>
3014	LIGHT KAOLIN	E	

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3015	LIGHT LIQUID PARAFFIN	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time.
3016	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 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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3017	LIGUSTICUM SINENSE	A, H	
3018	LIGUSTICUM STRIATUM	A, E, H	
3019	LIGUSTRUM LUCIDUM	A, H	
3020	LILIUM BROWNII	A, H	
3021	LILIUM CANDIDUM	A, E, H	
3022	LILIUM LANCIFOLIUM	A, H	
3023	LILIUM LONGIFLORUM	A, H	
3024	LIME FRUIT	E	
3025	LIME OIL	E	<p>Lime oil must only be included in medicines when in combination with other permitted ingredients as a flavour or a fragrance proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing lime oil must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing lime oil must not be more than 1% of the total medicine.</p> <p>When for other than internal use:</p> <p>(a) the concentration of lime oil in the medicine must not be more than 0.5%; or</p> <p>(b) the following warning statement (or words to the same effect) is required on the medicine label:</p> <p>- (SENS) 'Application to the skin may increase sensitivity to sunlight'.</p>
3026	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>

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			c) for use in soaps or bath or shower gels that are washed off the skin.
3027	LIME OIL DISTILLED	A, E, H	The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) contains 0.5% or less of lime oil distilled; or c) for use in soaps or bath or shower gels that are washed off the skin.
3028	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%.
3029	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%.
3030	LIME TREE FLOWER DRY	A, H	
3031	LIME TREE FLOWER POWDER	A, H	
3032	LIME, ESSENCE	E	
3033	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

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			medicine must be no more than 1%.
3034	LIMONENE	E	When for oral use, the quantity must be no more than 10 mg per maximum recommended daily dose.
3035	LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3036	LINALOOL OXIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3037	LINALYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3038	LINALYL ACETATE	E	Permitted for use only: (a) in topical medicines for dermal application; and

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			(b) in oral medicines in combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3039	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%.
3040	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%.
3041	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%.
3042	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%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3043	LINALYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3044	LINALYL PROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3045	LINDERA STRYCHNIFOLIA	A, H	
3046	LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3047	LINOLEIC ACID	E	
3048	LINOLENIC ACID	E	
3049	LINSEED DRY	A, E, H	
3050	LINSEED OIL	A, E, H	
3051	LINSEED OIL FATTY ACIDS	E	Linseed oil fatty acids must only be included in medicines when in combination with other permitted ingredients as a

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			flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing linseed oil fatty acids must not be more than 5% of the total medicine.
3052	LINSEED POWDER	A, E, H	
3053	LINUM USITATISSIMUM	A, E, H	
3054	LIPASE	A	Permitted for use only when derived from <i>Rhizopus oryzae</i> and in medicines containing 20,000 lipase units (equivalent to 20,000 BP units) or less of lipase activity per dosage unit. Lipase must comply with the relevant compositional guideline.
3055	LIPPIA DULCIS	A, H	
3056	LIQUID GLUCOSE	E	
3057	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.
3058	LIQUIDAMBAR FORMOSANA	A, H	
3059	LIQUIDAMBAR ORIENTALIS	A, H	
3060	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3061	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%.
3062	LIQUIDAMBAR TAIWANIANA	A, H	

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3063	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%.
3064	LIQUORICE DRY	A, E, H	
3065	LIQUORICE LIQUID EXTRACT	A, E, H	
3066	LIQUORICE POWDER	A, E, H	
3067	LITCHI CHINENSIS	A, E, H	When used as an excipient, Litchi chinensis must only be included in medicines when the plant part is fruit, in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing Litchi chinensis must not be more than 5% of the total medicine.
3068	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3069	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3070	LITSEA CUBEBA	A, E, H	
3071	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%.

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3072	LOBARIA PULMONARIA	A, H	
3073	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.
3074	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.
3075	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.
3076	LOLIUM PERENNE	A, H	
3077	LOLIUM TEMULENTUM	A, H	
3078	LONGIFOLENE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total longifolene concentration in a medicine must be no more than 1%.
3079	LONICERA CAPRIFOLIUM	A, E, H	
3080	LONICERA JAPONICA	A, E, H	
3081	LONICERA PERICLYMENUM	A, H	
3082	LOPHATHERUM GRACILE	A, H	
3083	LOQUAT	E	
3084	LORANTHUS PARASITICUS	A, H	
3085	LOROPETALUM CHINENSE	A, H	
3086	LOTUS CORNICULATUS	A, H	
3087	LOVAGE OIL	A, E, H	
3088	LOVAGE ROOT DRY	A, H	
3089	LOVAGE ROOT POWDER	A, H	
3090	LUDWIGIA PROSTRATA	A, H	
3091	LUFFA CYLINDRICA	A, H	
3092	LUFFA PURGANS	A, H	

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3093	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.
3094	LYCHEE	E	
3095	LYCIUM BARBARUM	A, H	
3096	LYCIUM CHINENSE	A, E, H	
3097	LYCOPENE	A, E	
3098	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.
3099	LYCOPODIUM ANNOTINUM	A, H	
3100	LYCOPODIUM CLAVATUM	A, H	
3101	LYCOPODIUM COMPLANATUM	A, H	
3102	LYCOPUS EUROPAEUS	A, H	
3103	LYCOPUS LUCIDUS	A, H	
3104	LYCOPUS VIRGINICUS	A, H	Pulegone is a mandatory component of Lycopus virginicus. The concentration of pulegone in the medicine must be no more than 4%.
3105	LYGODIUM JAPONICUM	A, H	
3106	LYSIMACHIA CHRISTINAE	A, H	
3107	LYSIMACHIA VULGARIS	A, H	
3108	LYSINE	A, E	
3109	LYSINE HYDROCHLORIDE	A, E	
3110	LYTHRUM HYSSOPIFOLIA	A, H	
3111	LYTHRUM SALICARIA	A, H	
3112	LYTHRUM VERTICILLATUM	A, H	
3113	MACADAMIA INTEGRIFOLIA	A, E	
3114	MACADAMIA NUT OIL	E	
3115	MACADAMIA TERNIFOLIA	A, E, H	
3116	MACE	E	Safrole is a mandatory component of Mace.

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			<p>When used internally, the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When used topically, the concentration of safrole in the medicine must be no more than 1.0%.</p>
3117	MACE OIL	A, H	<p>Safrole is a mandatory component of Mace oil.</p> <p>When used internally, the concentration of safrole in the medicine must be no more than 0.1%.</p> <p>When used topically, the concentration of safrole in the medicine must be no more than 1.0%.</p> <p>When the concentration of mace oil in the preparation is more than 50% and the nominal capacity of the container is 25 mL or less, a restricted flow insert must be fitted on the container.</p>
3118	MACROCYSTIS PYRIFERA	A, E, H	<p>Iodine is a mandatory component of <i>Macrocystis pyrifera</i>.</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>
3119	MACROGOL 1000	E	
3120	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3121	MACROGOL 1500	E	

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3122	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%.
3123	MACROGOL 200	E	Only for use in topical medicines for dermal application.
3124	MACROGOL 20000	E	
3125	MACROGOL 300	E	
3126	MACROGOL 3000	E	
3127	MACROGOL 3350	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
3128	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3129	MACROGOL 400	E	
3130	MACROGOL 4000	E	
3131	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3132	MACROGOL 600	E	
3133	MACROGOL 6000	E	
3134	MACROGOL 600000	E	
3135	MACROGOL 800	E	
3136	MACROGOL 8000	E	
3137	MACROGOL 900	E	Only for use in topical medicines for dermal application and not to be

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			included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.95%.
3138	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3139	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3140	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.
3141	MAGNESIUM ASCORBATE	A, E, H	
3142	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3143	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3144	MAGNESIUM ASPARTATE	A, E, H	
3145	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3146	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3147	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3148	MAGNESIUM CHLORIDE 4.5-HYDRATE	A	Magnesium is a mandatory component of magnesium chloride 4.5-hydrate. 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

			<p>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>
3149	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</p>

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			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.
3150	MAGNESIUM CITRATE	A, E, H	
3151	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	
3152	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3153	MAGNESIUM DIGLUTAMATE	A, E, H	
3154	MAGNESIUM GLUCONATE	A, E, H	
3155	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3156	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3157	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.
3158	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

			<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>
3159	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>

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			<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>
3160	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3161	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3162	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3163	MAGNESIUM OROTATE	A, E, H	
3164	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3165	MAGNESIUM OXIDE	A, E, H	<p>Magnesium is a mandatory component of 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 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>
3166	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>

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			<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>
3167	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>
3168	MAGNESIUM PYRUVATE	A	<p>Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.</p>
3169	MAGNESIUM STEARATE	E	
3170	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>

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			<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>
3171	MAGNESIUM SULFATE HEPTAHYDRATE	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 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>
3172	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</p>

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			<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>
3173	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> <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>

3174	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> <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>
3175	MAGNOLIA GLAUCA	A, H	
3176	MAGNOLIA LILIFLORA	A, H	
3177	MAGNOLIA OBOVATA	A, H	
3178	MAGNOLIA OFFICINALIS	A, E, H	
3179	MAGNOLIA SALICIFOLIA	A, H	
3180	MAIZE OIL	A, E, H	
3181	MAIZE STARCH	A, E, H	

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3182	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3183	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.
3184	MALPIGHIA GLABRA	A, E, H	
3185	MALT EXTRACT	E	
3186	MALTITOL	E	
3187	MALTITOL SOLUTION	E	
3188	MALTODEXTRIN	E	Gluten is a mandatory component of Maltodextrin where the ingredient is derived from gluten containing grains such as wheat, barley, rye and oats.
3189	MALTOL	E	
3190	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%.
3191	MALTOSE	E	
3192	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
3193	MALUS SYLVESTRIS	A, H	
3194	MALVA MOSCHATA	A, H	
3195	MALVA SYLVESTRIS	A, E, H	
3196	MALVA VERTICILLATA	A, H	
3197	MANDARIN	E	
3198	MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance.

			<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>
3199	MANDARIN OIL COLDPRESSED	A, E, H	<p>When used internally, oxedrine is a mandatory component of mandarin oil coldpressed.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
3200	MANDARIN OIL TERPENES	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>
3201	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>
3202	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</p>

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			or 100 micrograms/L or 0.00001%.
			The concentration of hyoscyne in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
			The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
3203	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3204	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3205	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3206	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3207	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.
3208	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3209	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.
3210	MANGANESE GLUCONATE	A, E, H	
3211	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3212	MANGANESE OXIDE	A, E, H	
3213	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3214	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3215	MANGIFERA INDICA	A, E, H	
3216	MANGO	E, H	
3217	MANIHOT ESCULENTA	A, H	
3218	MANNITOL	E	

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3219	MARANTA ARUNDINACEA	A, H	
3220	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3221	MARJORAM OIL SPANISH	A, E, H	When the concentration in the preparation is more than 50%, the nominal capacity of the container must be no more than 50 mL, the medicine must have a restricted flow insert fitted to the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3222	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).
3223	MARRUBIUM VULGARE	A, E, H	
3224	MARSDENIA CUNDURANGO	A, H	
3225	MARSHMALLOW ROOT DRY	A, H	
3226	MARSHMALLOW ROOT POWDER	A, H	
3227	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%.
3228	MASTIC	A, H	
3229	MATE ABSOLUTE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3230	MATRICARIA CHAMOMILLA	A, E, H	
3231	MATRICARIA FLOWER DRY	A, E, H	
3232	MEADOWSWEET HERB DRY	A, H	Methyl salicylate is a mandatory component of meadowsweet herb dry. Not to be included in medicines for use in the eye or on damaged skin. When used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being 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:

			<p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>When for use in topical medicines for dermal application</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%</p> <p>ii) the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged 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>
3233	MECOBALAMIN	A	Only for use in oral medicines.
3234	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>

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3235	MEDIUM CHAIN TRIGLYCERIDES	E	
3236	MELALEUCA ALTERNIFOLIA	A, E, H	<p>Cineole is a mandatory component of Melaleuca alternifolia.</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>
3237	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> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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>
3238	MELALEUCA CITRINA	A, H	
3239	MELALEUCA DISSITIFLORA	A, H	<p>Cineole is a mandatory component of Melaleuca dissitiflora.</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> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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</p>

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			<p>container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.</p>
3240	MELALEUCA ERICIFOLIA	A, E, H	<p>Cineole is a mandatory 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>
3241	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> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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>
3242	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> <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 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</p>

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			closure and restricted flow insert must be fitted on the container.
3243	MELALEUCA QUINQUENERVIA	A, E, H	<p>Cineole is a mandatory component of Melaleuca quinquenervia.</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>
3244	MELICOPE PTELEIFOLIA	A, H	
3245	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>
3246	MELISSA OFFICINALIS	A, E, H	
3247	MELON	E	

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3248	MENADIONE SODIUM BISULFITE	E	
3249	MENAQUINONE 7	A	For oral use only. The medicine must not provide more than 180 micrograms per maximum daily dose in adults, 90 micrograms per maximum daily dose in children between 10-18 years, and 45 micrograms per maximum daily dose in children less than 10 years of age.
3250	MENISPERMUM CANADENSE	A, H	
3251	MENTHA AQUATICA	A, H	Menthol is a mandatory component of Mentha aquatica. When the medicine is for topical use for dermal application: (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: - (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: - (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

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			<p>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>
3252	MENTHA ARVENSIS	A, E, H	<p>Menthol is a mandatory component of <i>Mentha arvensis</i>.</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</p>

			<p>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>
3253	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</p>

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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.

(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:

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

When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

3254	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 Mentha arvensis oil.</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;
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			<p>(iii) the following warning statements is required on the medicine label:</p> <ul style="list-style-type: none"> - (EYE) Avoid contact with eyes (or words to that effect). <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> <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>
3255	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;

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

- (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:

- (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:

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

When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

3256	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</p>
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must have a child resistant closure and restricted flow insert fitted on the container.

The medicine requires the following warning statements on the medicine label:

- (NTAKEN) 'Not to be taken';
- (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:

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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:</p> <p>a) the maximum recommended daily dose must not contain 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>
3257	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</p>

			<p>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>
3258	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</p>

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			<p>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>
3259	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</p>

			<p>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>
3260	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>
3261	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>
3262	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>
3263	MENTHOL	A, E	<p>When the medicine is for topical use for dermal application:</p>

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

When the medicine is for internal use, the maximum recommended daily dose must not contain more than 1 gram of menthol.

3264	MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a
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			<p>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>
3265	MENTHONE GLYCERINE ACETAL	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>
3266	MENTHONE THIOL FRACTION	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>
3267	MENTHOXYPROPANEDIOL	E	<p>For oral use only.</p> <p>The concentration in the medicine must be no more than 0.04%.</p>
3268	MENTHYL 2-HYDROXYETHYL CARBONATE	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>
3269	MENTHYL 2-HYDROXYPROPYL CARBONATE	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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3270	MENTHYL ANTHRANILATE	A	<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 not be more than 5%.</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).
3271	MENTHYL ISOVALERATE	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>
3272	MENTHYL LACTATE	E	
3273	MENYANTHES TRIFOLIATA	A, H	
3274	MERCURIC CHLORIDE	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Mercury is a mandatory component of mercuric chloride.</p> <p>The total concentration of mercury in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.</p>
3275	MERCURY	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>The total concentration of mercury in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.</p>

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3276	METACRESOL	E	Only for use in topical medicines for dermal application.
3277	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3278	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%.
3279	METHICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
3280	METHIONINE	A, E	
3281	METHYL 2,6,6-TRIMETHYLCYCLOHEX-2-ENE-1-CARBOXYLATE	E	Only for use in medicines in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must not be more than 1%.
3282	METHYL 2-METHYLBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3283	METHYL 2-OCTYNOATE	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3284	METHYL 3,6-DIMETHYLRESORCYLATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3285	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%.
3286	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%.
3287	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3288	METHYL ACRYLATE, METHYL METHACRYLATE AND METHACRYLIC ACID COPOLYMER DISPERSION (30 PER CENT)	E	Methyl methacrylate is a mandatory component of methyl acrylate, methyl methacrylate and methacrylic acid copolymer dispersion (30 per cent).

			<p>The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.</p> <p>The route of administration for medicines that contain methyl acrylate, methyl methacrylate and methacrylic acid copolymer dispersion (30 per cent) must be limited to oral use.</p> <p>Methyl acrylate, methyl methacrylate and methacrylic acid copolymer dispersion (30 per cent) is not permitted for use in children under the age of 4 years.</p> <p>The maximum recommended daily dose of the medicine must not provide more than:</p> <p>(a) 667 milligrams of methyl acrylate, methyl methacrylate and methacrylic acid copolymer dispersion (30 per cent) to individuals aged 4 to 17 years (inclusive); and</p> <p>(b) 2.33 grams of methyl acrylate, methyl methacrylate and methacrylic acid copolymer dispersion (30 per cent) to individuals aged 18 years and above.</p>
3289	METHYL ANISATE	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>
3290	METHYL ANTHRANILATE	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</p>

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			<p>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 BENZOATE	E	<p>Only for use in topical medicines for dermal application.</p>
3292	METHYL 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>
3293	METHYL CAPROATE	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>
3294	METHYL CAPRYLATE	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>
3295	METHYL CARBITOL	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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3296	METHYL CEDRYL KETONE	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>
3297	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>
3298	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>
3299	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>

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3300	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 fragrance concentration in a medicine must be no more 1%.</p>
3301	METHYL CYCLOPENTYLIDENEACETATE	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>
3302	METHYL DI-TERT-BUTYL-4- HYDROXYHYDROCINNAMATE	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>
3303	METHYL DIHYDROABIETATE	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>
3304	METHYL DIISOPROPYL PROPIONAMIDE	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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3305	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3306	METHYL ETHYL KETONE	E	The residual solvent limit is 50 mg per maximum recommended daily dose. The concentration in the medicine must be no more than 0.5%.
3307	METHYL EUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3308	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%.
3309	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.
3310	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.

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3311	METHYL GLUCETH-20 BENZOATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3312	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3313	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3314	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3315	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3316	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%.
3317	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%.

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3318	METHYL HEPTYL KETONE	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>
3319	METHYL HEXYL CARBINOL	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>
3320	METHYL HEXYL KETONE	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>
3321	METHYL HYDROGENATED ROSINATE	E	<p>Only for use in topical medicines for dermal application.</p>
3322	METHYL HYDROJASMONATE	E	<p>The route(s) of administration for medicines that contain methyl hydrojasmonate must be limited to:</p> <p>(a) topical for dermal use; and (b) oral.</p> <p>When used in oral medicines: (a) methyl hydrojasmonate must only be included in</p>

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			<p>medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation; and</p> <p>(b) the total concentration of flavour proprietary excipient formulations containing methyl hydrojasmonate must not be more than 5% of the total medicine.</p>
3323	METHYL HYDROXYBENZOATE	E	
3324	METHYL IONONE	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>
3325	METHYL ISOBUTYL KETONE	E	<p>The residual solvent limit is 50 mg per maximum daily dose.</p> <p>The concentration in the medicine must be no more than 0.5%.</p>
3326	METHYL ISOEUGENOL	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>
3327	METHYL ISOVALERATE	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%.
3328	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%.
3329	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%.
3330	METHYL LINOLEATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3331	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%.
3332	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

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			medicine must be no more than 5%.
3333	METHYL METHACRYLATE CROSSPOLYMER	E	<p>Methyl methacrylate is a mandatory component of methyl methacrylate crosspolymer.</p> <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>When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be intended for use on damaged skin.</p> <p>The total concentration of methyl methacrylate crosspolymer in the medicine must not be more than 4.85%.</p> <p>The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.</p>
3334	METHYL METHOXY PYRAZINE	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>
3335	METHYL MYRISTATE	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>
3336	METHYL NAPHTHYL KETONE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3337	METHYL NONYL KETONE	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>
3338	METHYL NONYLENATE	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>
3339	METHYL OCTIN CARBONATE	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>
3340	METHYL PALMITATE	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</p>

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			medicine must be no more than 1%.
3341	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%.
3342	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%.
3343	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%.
3344	METHYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3345	METHYL PHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

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			<p>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>
3346	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>
3347	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, 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>

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			<p>- (METSAL) 'Contains methyl salicylate' (or words to that effect).</p> <p>When for use in topical medicines for dermal application:</p> <p>i) the concentration of methyl salicylate in the medicine must not be more than 25%;</p> <p>ii) the following warning statements are required on the medicine label:</p> <p>- (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect);</p> <p>- (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less';</p> <p>- (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect);</p> <p>- (AVOID) 'Avoid prolonged 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>
3348	METHYL STEARATE	E	
3349	METHYL THIOBUTYRATE	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>
3350	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal

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			<p>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>
3351	METHYL-3-METHYLTHIOPROPIONATE	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>
3352	METHYL-BETA-METHYLTHIOLPROPIONATE	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>
3353	METHYL-PARA-TERT-BUTYL PHENYLACETATE	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>
3354	METHYLBENZYL 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>
3355	METHYLCELLULOSE	A, E	
3356	METHYLCHLOROISOTHIAZOLI NONE	E	<p>Only for use in topical medicines for dermal application that are rinsed off the skin.</p>

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			The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3357	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%.
3358	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 clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3359	METHYLISOTHIAZOLINONE	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%.
3360	METHYLMERCAPTAN	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3361	METHYLPROPANEDIOL	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 10%.
3362	METHYLSILANOL/SILICATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3363	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3364	MICA	E	Only for use when the route of administration is oral, dental or topical. The concentration in oral medicines must be no more than 2.5%. The concentration in dental toothpastes must be no more than 0.5%.
3365	MICROCALICIUM ARENARIUM	A, H	
3366	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.

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			The concentration in the medicine must be no more than 0.005%.
3367	MICROCOS PANICULATA	A, H	
3368	MICROCRYSTALLINE CELLULOSE	E	
3369	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'.
3370	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%.
3371	MILK THISTLE FRUIT DRY	A, H	
3372	MILK THISTLE FRUIT POWDER	A, H	
3373	MILLET	E	
3374	MILLETTIA DIELSIANA	A, H	
3375	MIMOSA ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3376	MIMULUS GUTTATUS	A, H	
3377	MINT OIL DEMENTHOLISED	A, E, H	Menthol is a mandatory component of mint oil dementholised. When the medicine is for topical use for dermal application:

			<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 not contain more than 1 gram of menthol.</p>
3378	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</p>

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			medicine must be no more than 5%.
3379	MITCHELLA REPENS	A, H	
3380	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3381	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3382	MIXED TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3383	MODIFIED FOOD STARCH	E	
3384	MOLASSES	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3385	MOLYBDENUM	H	Only for use as an active homoeopathic ingredient. When Molybdenum is sourced from Molybdenum trioxide then the maximum daily dose must be no more than 125 micrograms. When Molybdenum is sourced from yeast - high molybdenum then the maximum recommended daily dose must be no more than 62.5 micrograms.
3386	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.

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			The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide.
3387	MOMORDICA BALSAMINA	A, H	
3388	MOMORDICA CHARANTIA	A, H	
3389	MOMORDICA COCHINCHINENSIS	A, H	
3390	MONARDA DIDYMA	A, H	
3391	MONO- AND DI- GLYCERIDES	E	
3392	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3393	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3394	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.
3395	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.
3396	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.

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3397	MONOETHANOLAMINE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The concentration in the medicine must be no more than 5%.</p>
3398	MONOMENTHYL GLUTARATE	E	<p>Monomethyl glutarate 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 monomethyl glutarate must not be more than 5% of the total medicine.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 1.8mg of monomethyl glutarate.</p>
3399	MONOMENTHYL SUCCINATE	E	<p>Monomethyl succinate 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 monomethyl succinate must not be more than 5% of the total medicine.</p>
3400	MONOPHOSPHOTHIAMINE	A	
3401	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3402	MONOPOTASSIUM GLUTAMATE	A, E	
3403	MONOSODIUM DIHYDROGEN CITRATE	E	
3404	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	

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3405	MONSTERA DELICIOSA	A, H	
3406	MONTAN WAX	E	
3407	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%..
3408	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).
3409	MORINDA OFFICINALIS	A, H	
3410	MORINGA OLEIFERA	A, H	
3411	MORUS ALBA	A, H	
3412	MORUS BOMBYCIS	A, H	
3413	MORUS NIGRA	A, E, H	
3414	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%.
3415	MOTHERWORT HERB DRY	A, H	
3416	MOTHERWORT HERB POWDER	A, H	
3417	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%.
3418	MULBERRY	E	
3419	MUNG BEAN	E	
3420	MURRAYA KOENIGII	A, H	
3421	MURRAYA PANICULATA	A, H	
3422	MUSA X PARADISIACA	A, H	

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3423	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3424	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%.
3425	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3426	MUSKS	H	Only for use as an active homoeopathic ingredient.
3427	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%.
3428	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%.
3429	MUSTARD SEED OIL	E	Allyl isothiocyanate is a mandatory component of mustard seed oil when the plant part is seed. The concentration of allyl isothiocyanate from all ingredients in the product must

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			be no more than 10 mg/kg or 10 mg/L or 0.001%.
3430	MYOSOTIS ARVENSIS	A, H	
3431	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%.
3432	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%.
3433	MYRICA CERIFERA	A, E, H	
3434	MYRISTIC ACID	E	
3435	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%.
3436	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 saffrole 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>
3437	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3438	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3439	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.
3440	MYROXYLON BALSAMUM	A, E, H	
3441	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3442	MYRRH	A, H	
3443	MYRRH OIL	A, E, H	
3444	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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3445	MYRRHIS ODORATA	A, H	
3446	MYRSINE AFRICANA	A, H	
3447	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%.
3448	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%.
3449	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%.
3450	MYRTUS COMMUNIS	A, E, H	
3451	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 formulation in medicines with a dermal route of administration for topical application.
3452	N-(2-(PYRIDIN-2-YL)ETHYL)-P-MENTHANE-3-CARBOXAMIDE	E	N-(2-(pyridin-2-yl)ethyl)-p-menthane-3-carboxamide must only be included in medicines when in combination with other permitted ingredients as a

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			<p>flavour proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing N-(2-(pyridin-2-yl)ethyl)-p-menthane-3-carboxamide must not be more than 5% of the total medicine.</p> <p>The maximum recommended daily dose of the medicine must not provide more than 90 micrograms of N-(2-(pyridin-2-yl)ethyl)-p-menthane-3-carboxamide.</p>
3453	N-BUTYL SULFIDE	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>
3454	N-GLUCONYL ETHANOLAMINE	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>
3455	N-HEXYL 2-BUTENOATE	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>
3456	N-NONYL ALCOHOL	E	<p>Permitted for use only in combination with other</p>

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			permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3457	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3458	NARDOSTACHYS CHINENSIS	A, H	
3459	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%.
3460	NASTURTIUM OFFICINALE	A, E, H	
3461	NATURAL FISH OIL	A, E	When therapeutic indications for this product are made against Vitamin A or colecalciferol (Vitamin D), they are mandatory components of natural fish oil. When for use in topical medicines, the concentration of Vitamin A in the medicine must be no more than 1%. When for internal use, the maximum daily dose must be no more than 3000 micrograms of Retinol Equivalents. When preparations for internal use in adults contain more than 33 micrograms of retinol equivalents per dosage unit in divided preparations or per gram of an undivided preparation, the medicine requires the following warning statements on the medicine label:

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			<p>- (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.</p> <p>- (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use.</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>
3462	NAUCLEA OFFICINALIS	A, H	
3463	NELUMBO NUCIFERA	A, H	
3464	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>
3465	NEOHESPERIDIN-DIHYDROCHALCONE	E	<p>The routes of administration for medicines that contain neohesperidin-dihydrochalcone must be limited to:</p> <p>(a) topical for dermal application; and</p> <p>(b) oral.</p>

			<p>When used in topical medicines for dermal application:</p> <p>(a) neohesperidin-dihydrochalcone must not be included in medicines intended for use in the eye or on damaged skin; and</p> <p>(b) the concentration of neohesperidin-dihydrochalcone in the medicine must not be more than 0.1%.</p> <p>When used in oral medicines:</p> <p>(a) the concentration in the medicine must not be more than 0.1%; and</p> <p>(b) the following warning statement (or words to that effect) is required on the medicine label:</p> <p>- (NTAKEN3) 'Not to be taken by children under 3 years old'.</p>
3466	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>
3467	NEOPENTYL GLYCOL DIHEPTANOATE	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 25%.</p>
3468	NEOPENTYL GLYCOL DIISOSTEARATE	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>

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			The concentration in the medicine must be no more than 5%.
3469	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.
3470	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3471	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3472	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%.
3473	NERAL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3474	NERIUM OLEANDER	A, H	The concentration of equivalent dry Nerium oleander in the product must be no more than 1mg/Kg or 1mg/L or 0.0001%.

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3475	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>
3476	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>
3477	NEROLIDOL	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>
3478	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</p>

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			medicine must be no more than 1%.
3479	NERYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3480	NERYL-ISO-BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3481	NICKEL	H	Only for use as an active homoeopathic ingredient.
3482	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3483	NICOTINAMIDE	A, E, H	
3484	NICOTINAMIDE ASCORBATE	A, E	
3485	NICOTINAMIDE RIBOSIDE CHLORIDE	A	Ribose is a mandatory component of nicotinamide riboside chloride. Only permitted for use in medicines limited to oral routes of administration. The maximum recommended daily dose of the medicine must not provide more than 300 mg of nicotinamide riboside chloride. The following warning statement (or words to the same effect) is required on the medicine label:

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			<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>
3486	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3487	NIGELLA DAMASCENA	A, H	
3488	NIGELLA SATIVA	A, E, H	
3489	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3490	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 5%.</p> <p>If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.</p>
3491	NONANAL	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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3492	NONANOIC ACID	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>
3493	NONFAT DRY MILK	E, H	
3494	NONIVAMIDE	E	<p>Nonivamide must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation.</p> <p>The ingredient is not to be included in medicines intended for use in the eye.</p> <p>The total concentration of flavour proprietary excipient formulations containing nonivamide must not be more than 5% of the total medicine.</p> <p>The total concentration of fragrance proprietary excipient formulations containing nonivamide must not be more than 1% of the total medicine.</p>
3495	NONOXINOL 10	E	<p>Only for use in topical medicines for dermal application.</p>
3496	NONOXINOL 12	E	<p>For use in hand scrub formulations for healthcare professionals only.</p> <p>Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye.</p>

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			The concentration in the medicine must be no more than 5%.
3497	NONOXINOL 5	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3498	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3499	NONYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3500	NOOTKATONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3501	NOPYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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3502	NORDIHYDROGUAIARETIC 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 0.3%.</p>
3503	NOTOPTERYGIUM FORBESII	A, H	
3504	NOTOPTERYGIUM INCISIUM	A, H	
3505	NUPHAR JAPONICA	A, H	
3506	NUPHAR LUTEA	A, H	
3507	NUTMEG DRY	A, E, H	<p>Safrole is a mandatory component of Nutmeg Dry.</p> <p>When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%.</p> <p>When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.</p>
3508	NUTMEG OIL	A, E, H	<p>Safrole is a mandatory component of Nutmeg oil.</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> <p>When the concentration of Nutmeg oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label:</p> <p>- (CHILD) 'Keep out of reach of children' (or words to that effect).</p>

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3509	NUTMEG POWDER	A, E, H	<p>Safrole is a mandatory component of Nutmeg powder.</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>
3510	NUX VOMICA DRY	A, H	<p>Strychnine (of <i>Strychnos</i> spp.) is a mandatory component of Nux Vomica Dry.</p> <p>The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.</p>
3511	NUX VOMICA POWDER	H	<p>Only for use as an active homoeopathic ingredient.</p> <p>Strychnine (of <i>Strychnos</i> spp.) is a mandatory component of Nux vomica powder.</p> <p>The concentration in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.</p>
3512	NYCTANTHES ARBOR-TRISTIS	A, H	<p>When the plant part is leaf:</p> <ul style="list-style-type: none"> 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 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

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			statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3513	NYLON	E	Only for use in topical medicines for dermal application.
3514	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3515	NYLON-12	E	Only for use in topical medicines for dermal application.
3516	NYMPHAEA ALBA	A, E, H	
3517	NYMPHAEA CAERULEA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine to be no more than 0.3%. Only for use in liquid extracts where the plant part is the flower and the solvent in 100% water.
3518	NYMPHAEA ODORATA	A, H	
3519	OAK CHIPS EXTRACT	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3520	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

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			<p>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>
3521	OAT	E, H	<p>Only for use as an active homoeopathic or excipient ingredient.</p> <p>Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal.</p>
3522	OAT BRAN	E	<p>Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.</p>
3523	OATMEAL COLLOIDAL	A, E	<p>Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other than topical and mucosal.</p>
3524	OCIMENE	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>
3525	OCIMENYL 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>

3526	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 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</p>
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			<p>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>
3527	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 not be more than 12.5%.</p> <p>In liquid preparations, the nominal capacity of the container must not be more than 25 millilitres.</p> <p>In liquid preparations other than essential oils or distillates, the concentration of camphor must not be more than 2.5%.</p> <p>In essential oil or distillate preparations, if the concentration of camphor is more than 2.5% but less than or equal to 10%, and the nominal capacity of the container is less than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:</p> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); - (NTAKEN) 'Not to be taken'; <p>and</p>

- (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist' (or words to that effect).

In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is less than 15 millilitres, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);

- (NTAKEN) 'Not to be taken';
and

- (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist' (or words to that effect).

In essential oil 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 have a restricted flow insert and child resistant closure fitted on the container and include the following warning statements on the medicine label:

- (CHILD) 'Keep out of reach of children' (or words to that effect);

- (NTAKEN) 'Not to be taken';
and

- (BABY4) 'Do not apply to infants under 12 months of age except on the advice of a

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			doctor or pharmacist' (or words to that effect).
3528	OCIMUM MINIMUM	A, H	
3529	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> <ul style="list-style-type: none"> - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. <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 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>
3530	OCOTEA ODORIFERA	A, H	Safrole is a mandatory component of <i>Ocotea odorifera</i> .

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			<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>
3531	OCTACOSANOL	E	
3532	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>
3533	OCTADECENE/MA COPOLYMER	E	<p>Only for use in topical medicines for dermal application.</p>
3534	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>
3535	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>
3536	OCTAN-1-OL	E	<p>Permitted for use only in combination with other</p>

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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>
3537	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>
3538	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>
3539	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 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</p>

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			excipient formulation in a medicine must be no more than 1%.
3540	OCTENE-1	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3541	OCTOCRYLENE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must 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).
3542	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3543	OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3544	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>
3545	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.
3546	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>
3547	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3548	OCTYL METHOXYCINNAMATE	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> <p>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and</p>

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			- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3549	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3550	OCTYL SALICYLATE	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 5%.</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).
3551	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3552	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	<p>Only for use in topical medicines for dermal application.</p> <p>The total concentration of octylbicycloheptenedicarboximide in the medicine must not be more than 10%.</p>
3553	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3554	OCTYLDODECETH-25	E	Only for use in topical medicines for dermal

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			<p>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> <p>Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.</p>
3555	OCTYLDODECYL CITRATE 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 12%.</p>
3556	OCTYLDODECYL NEOPENTANOATE	E	<p>Only for use in topical medicines for dermal application.</p>
3557	OCTYLDODECYL STEARATE	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 2%.</p>
3558	OCTYLDODECYL XYLOSIDE	E	<p>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.</p> <p>The concentration in the medicine must be no more than 1.5%.</p>
3559	OENANTHATE	E	<p>Permitted for use only in combination with other permitted ingredients as a fragrance.</p>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3560	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.
3561	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3562	OENOTHERA BIENNIS	A, E, H	
3563	OENOTHERA STRICTA	A, H	
3564	OKOUBAKA AUBREVILLEI	A, H	
3565	OLDENLANDIA DIFFUSA	A, E, H	
3566	OLEA EUROPAEA	A, E, H	
3567	OLEIC ACID	E	
3568	OLETH-10	E	Only for use in topical medicines for dermal application.
3569	OLETH-2	E	Only for use in topical medicines for dermal application. Dioxane and Ethylene oxide are mandatory components of Oleth-2. The concentration of Dioxane in the medicine must be no more than 10 mg/kg or 10 mg/L or 0.001%. The concentration of Ethylene oxide in the medicine must be no more than 1 mg/kg or 1 mg/L or 0.0001%.
3570	OLETH-20	E	Only for use in topical medicines for dermal application.

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3571	OLETH-3	E	Only for use in topical medicines for dermal application.
3572	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%.
3573	OLETH-5	E	Only for use in topical medicines for dermal application.
3574	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3575	OLIBANUM OIL	A, E, H	
3576	OLIVE OIL	A, E, H	
3577	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).'
3578	OMEGA-3-ACID ETHYL ESTERS 60	A	Docosahexaenoic acid, docosapentaenoic acid and eicosapentaenoic acid are mandatory components of omega-3-acid ethyl esters 60. Only permitted for use in medicines that are for oral routes of administration. 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>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).
3579	OMEGA-3-ACID ETHYL ESTERS 90	A	<p>Only for use in oral medicines. 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 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.'
3580	ONION	E	

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3581	ONION OIL	A, H	
3582	ONONIS SPINOSA	A, E, H	
3583	ONOPORDUM ACANTHIUM	A, H	
3584	ONOSMODIUM VIRGINIANUM	A, H	
3585	OPHIOPOGON JAPONICUS	A, H	
3586	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>
3587	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>
3588	OPUNTIA FICUS-INDICA	A, H	
3589	ORANGE	E	
3590	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>

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3591	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>
3592	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>
3593	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>
3594	ORANGE OIL	A, E, H	<p>When used internally, oxedrine is a mandatory component of orange oil.</p> <p>The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.</p>
3595	ORANGE OIL BITTER	E	<p>Orange oil bitter must only be included in medicines when in combination with other permitted ingredients as a flavour or fragrance proprietary excipient formulation.</p> <p>The total concentration of flavour proprietary excipient formulations containing orange oil bitter must not be more than 5% of the total medicine.</p>

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			<p>The total concentration of fragrance proprietary excipient formulations containing orange oil bitter must not be more than 1% of the total medicine.</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) for internal use;</p> <p>b) in preparations containing 1.4% or less of orange oil bitter; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
3596	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> <p>a) for internal use; or</p> <p>b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or</p> <p>c) for use in soaps or bath or shower gels that are washed off the skin.</p>
3597	ORANGE OIL COLD PRESSED	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>

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			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3598	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.
3599	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%.
3600	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.
3601	ORANGE PEEL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3602	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.

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3603	ORANGE PEEL OIL SWEET TERPENELESS	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>
3604	ORANGE ROUGHY OIL	E	<p>Only for use in topical medicines for dermal application.</p>
3605	ORIGANUM MAJORANA	A, H	<p>Beta-arbutin is a mandatory component of Origanum majorana.</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> <p>When the plant preparation is oil or distillate, and the concentration of Origanum majorana oil or distillate within the medicine is more than 50%:</p>

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			<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>
3606	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>
3607	ORIGANUM OIL SPANISH	A, E, H	
3608	ORIGANUM VULGARE	A, E, H	
3609	ORNITHINE	A, E	
3610	ORNITHINE ASPARTATE	A, E	
3611	ORNITHINE MONOHYDROCHLORIDE	A, E	
3612	ORNITHOGALUM UMBELLATUM	A, H	
3613	OROSTACHYS FIMBRIATA	A, H	
3614	OROXYLUM INDICUM	A, H	
3615	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 medicine must be no more than 5%.</p>
3616	ORRIS CONCRETE	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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3617	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%.
3618	ORRIS ROOT OIL	A, E, H	
3619	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%.
3620	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%.
3621	ORTHOSIPHON ARISTATUS	A, H	
3622	ORYZA SATIVA	A, E, H	
3623	ORYZANOL	E	
3624	OSBECKIA CHINENSIS	A, H	
3625	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%.
3626	OSMANTHUS FRAGRANS	E	Permitted for use only in combination with other

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			permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3627	OTTELIA ALISMOIDES	A, H	
3628	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%.
3629	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3630	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%.
3631	OXALIC ACID	H	Only for use as an active homoeopathic ingredient. The total concentration of oxalic acid in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.
3632	OXALIS ACETOSELLA	A, H	
3633	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%.

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3634	OXIDISED TAPIOCA STARCH	E	
3635	OXYBENZONE	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).
3636	OYSTER	E	<p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.
3637	OYSTER SHELL	A, E, H	<p>The following warning statement is required on the medicine label:</p> <ul style="list-style-type: none"> - (MOLLUSC) 'Contains mollusc' or 'Contains mollusc products'.