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**
2849	KADSURA COCCINEA	A, H	
2850	KAEMPFERIA GALANGA	A, H	
2851	KALMIA LATIFOLIA	A, H	Beta-arbutin is a mandatory component of Kalmia latifolia. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. 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%.
2852	KAOLIN	E	
2853	KELP DRY	A, H	Iodine is a mandatory component of Kelp dry. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less.

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			Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2854	KELP POWDER	A, E, H	Iodine is a mandatory component of Kelp powder. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2855	KERATIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
2856	KEROSENE	E, H	Only for use as a homoeopathic ingredient. When used in liquid preparations, the concentration in the medicine must be no more than 25%.
2857	KHAYA SENEGALENSIS	A, E	The maximum daily dose of the medicine must not contain more than the equivalent of 1 g dry bark of Khaya senegalensis. The following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (LONGUSE) ‘Not for prolonged use. May harm liver';

			- (GEN2) ‘If symptoms persist, seek the advice of a healthcare professional’; - (CHILD3) ‘Use in children under 12 years is not recommended’; and - (7DAYS) 'Do not use for more than 7 days'.
2858	KIDNEY BEAN	E	
2859	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2860	KIWI FRUIT	E	
2861	KNAUTIA ARVENSIS	A, H	
2862	KOREAN GINSENG ROOT DRY	A, H	
2863	KOREAN GINSENG ROOT POWDER	A, H	
2864	KRAMERIA IXINE	A, H	
2865	KRAMERIA LAPPACEA	A, H	
2866	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only' - (UNDILU) 'Not to be applied undiluted to the skin except on the

			advice of a health care practitioner'. When the dosage form is other than essential oil, the maximum concentration in topical medicines must be no more than 25% w/w and the medicine requires the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' - (EXTERN) 'For external use only'.
2867	L-BORNEOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2868	L-BORNYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used as in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
2869	L-CARVONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a

			medicine must be no more 1%.
2870	L-LIMONENE	E	L-limonene must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation or a fragrance proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing l-limonene must not be more than 5% of the total medicine. The total concentration of fragrance proprietary excipient formulations containing l-limonene must not be more than 1% of the total medicine.
2871	L-LINALOOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2872	L-MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2873	L-MENTHYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2874	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%.
2875	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%.
2876	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%.
2877	LABDANUM OIL	A, E, H	
2878	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%.
2879	LACTALBUMIN	E	

2880	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.
2881	LACTITOL	E	
2882	LACTITOL MONOHYDRATE	E	
2883	LACTO-N-NEOTETRAOSE	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 20 August 2023. 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).

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			The requirements specified in paragraph (a) below apply to a medicine that contains the ingredient that is released for supply after 20 August 2023: (a) One of the following statements is required on the medicine label: (i) When the medicine is only for use in individuals aged 2 years and above: ‘Not to be taken on the same day with other products containing lacto-N-neotetraose' (or words to that effect); or (ii) When the medicine is for use in children aged less than 2 years: ‘Not to be taken on the same day with breastmilk or other products containing lacto-N-neotetraose’ (or words to that effect).
2884	LACTO-N-TETRAOSE	A	Only to be used in a medicine where Glycom A/S (Client ID 76983), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 24 January 2024. Lactose is a mandatory component of lacto-N-tetraose. The route of administration for medicines that contain lacto-N-tetraose must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: 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 that 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'.
2885	LACTOBACILLUS ACIDOPHILUS	A	
2886	LACTOBACILLUS AMYLOVORUS	A	
2887	LACTOBACILLUS BREVIS	A	
2888	LACTOBACILLUS CASEI	A	
2889	LACTOBACILLUS CASEI SUBSP. BIOVAR CASEI	A	
2890	LACTOBACILLUS CRISPATUS	A	
2891	LACTOBACILLUS DELBRUECKII SSP BULGARICUS	A	
2892	LACTOBACILLUS DELBRUECKII SSP LACTIS	A	
2893	LACTOBACILLUS FERMENTUM	A	
2894	LACTOBACILLUS GALLINARUM	A	
2895	LACTOBACILLUS GASSERI	A	
2896	LACTOBACILLUS HELVETICUS	A	
2897	LACTOBACILLUS JOHNSONII	A	
2898	LACTOBACILLUS KEFIRANOFACIENS	A	
2899	LACTOBACILLUS KEFIRGRANUM	A	
2900	LACTOBACILLUS KEFIRI	A	

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2901	LACTOBACILLUS PARACASEI	A	
2902	LACTOBACILLUS PARACASEI SUBSP. PARACASEI	A	
2903	LACTOBACILLUS PLANTARUM	A	
2904	LACTOBACILLUS REUTERI	A	
2905	LACTOBACILLUS RHAMNOSUS	A	
2906	LACTOBACILLUS SALIVARIUS SSP SALICINIUS	A	
2907	LACTOBACILLUS SALIVARIUS SSP SALIVARIUS	A	
2908	LACTOBIONIC ACID	E	Only for use in topical medicines for dermal application.
2909	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%.
2910	LACTOSE	E	
2911	LACTOSE MONOHYDRATE	E	
2912	LACTUCA SATIVA	A, H	
2913	LACTUCA VIROSA	A, H	
2914	LACTULOSE	E	
2915	LACTULOSE SOLUTION	A	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing form time to time.
2916	LAGENARIA VULGARIS	A, H	
2917	LAMINARIA CLOUSTONI	A, E, H	Iodine is a mandatory component of Laminaria cloustoni. Only for external use when the concentration of iodine in the medicine (excluding salts

			derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2918	LAMINARIA DIGITATA	A, E, H	Iodine is a mandatory component of Laminaria digitata. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2919	LAMINARIA JAPONICA	A, E, H	Iodine is a mandatory component of Laminaria japonica. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
2920	LAMIUM ALBUM	A, H	
2921	LANETH-5	E	Only for use in topical medicines for dermal application.
2922	LANOLIN ALCOHOL	E	Only for use in topical medicines for dermal application.
2923	LANOLIN OIL	E	Only for use in topical medicines for dermal application.

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2924	LANOLIN WAX	E	Only for use in topical medicines for dermal application.
2925	LANTANA CAMARA	A, H	The maximum recommended daily dose must contain no more than 1mg of the equivalent dry herbal material of Lantana camara.
2926	LARIX ARABINOGALACTAN	A, E	The concentration of polysaccharides in the ingredient must be greater than or equal to 85%. The ingredient must be derived from Larix occidentalis or Larix larcinia. Only for use in oral medicines or topical medicines for dermal application, and not to be included in topical products intended for use in the eye. The maximum recommended daily dose of Larix arabinogalactan in oral medicines must not be more than 15 grams. The concentration of Larix arabinogalactan in topical medicines for dermal application must not exceed 5.0%.
2927	LARIX DECIDUA	A, H	
2928	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.
2929	LARREA TRIDENTATA	A, H	The requirement specified in paragraph (a) below applies to a medicine that contains the ingredient that is: - listed in the Register before 1 March 2023; and - released for supply before 1

			March 2024: (a) One of the following warning statements is required on the medicine label: (i) (CHAP) 'WARNING: Chaparral may harm the liver in some people - use only under supervision of a health care professional'; or (ii) (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.' The requirement specified in paragraph (b) below applies to a medicine that contains the ingredient that is: - listed in the Register on or after 1 March 2023; or - released for supply on or after 1 March 2024. (b) 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.'
2930	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.
2931	LAURAMINE OXIDE	E	
2932	LAUREL LEAF OIL	A, H	When the total concentration of bay oil in the medicine is more

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			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.
2933	LAURETH-10	E	Only for use in topical medicines for dermal application.
2934	LAURETH-12	E	Only for use in topical medicines for dermal application.
2935	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.
2936	LAURETH-23	E	Only for use in topical medicines for dermal application.
2937	LAURETH-3	E	Only for use in topical medicines for dermal application.
2938	LAURETH-4	E	Only for use in topical medicines for dermal application.

2939	LAURETH-7	E	Only for use in topical medicines for dermal application.
2940	LAURETH-8	E	
2941	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.
2942	LAURIL MACROGOL 400 DIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 5%.
2943	LAUROMACROGOL 400	E	Only for use in topical medicines for dermal application.
2944	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%.
2945	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);

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			- (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.
2946	LAURYL ALDEHYDE	E	Permitted for use only in combination with other permitted ingredients as a coating solution, flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
2947	LAURYL BETAINE	E	Only for use in topical medicines for dermal application.
2948	LAURYL GLUCOSIDE	E	Only for use as an excipient ingredient in topical medicines for dermal application and not to be included in topical medicines intended for use in the eye. The concentration in the medicine must be no more than 12%.
2949	LAURYL LACTATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 3%. Sponsors should consider the impact of excipients containing alpha hydroxy acids on the sensitivity of the skin to sunlight and should ensure the finished medicine is safe for its intended purpose.

2950	LAURYL PCA	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 1%.
2951	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%.
2952	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%.
2953	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.
2954	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.

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2955	LAURYL PYRROLIDONE	E	Only for use in topical medicines for dermal application.
2956	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED COLLAGEN	E	Only for use in topical medicines for dermal application.
2957	LAURYLDIMONIUM HYDROXYPROPYL HYDROLYSED SOY PROTEIN	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.007%.
2958	LAURYLMETICONE COPOLYOL	E	Only for use in topical medicines for dermal application.
2959	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%.
2960	LAVANDIN OIL ABRIAL	A, E, H	
2961	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%.
2962	LAVANDULA ANGUSTIFOLIA	A, E, H	Camphor is a mandatory component of Lavandula angustifolia. In solid and semi solid preparations, the concentration of camphor must be no more than

			12.5%. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%.
2963	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%.
2964	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%.
2965	LAVENDER OIL	A, E, H	
2966	LAWSONIA INERMIS	A, H	
2967	LEAD	H	Only for use as an active homoeopathic ingredient. The concentration in the medicine must be no more than 0.001%.
2968	LEAD ACETATE	H	Only for use as an active homoeopathic ingredient.
2969	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%.

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2970	LECITHIN	A, E	
2971	LEDEBOURIELLA SESELOIDES	A, H	
2972	LEDUM PALUSTRE	A, H	Beta-arbutin is a mandatory component of Ledum palustre. When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. When for topical use other than dermal application exclusively to the face, the concentration of beta-arbutin in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%. When the route of administration is other than topical, the maximum recommended daily dose must not contain more than 0.001 mg of the equivalent dry herbal material of Ledum palustre.
2973	LEMNA MINOR	A, H	
2974	LEMON	E	When used internally, oxedrine is a mandatory component of lemon. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2975	LEMON BALM LEAF DRY	A, H	
2976	LEMON BALM LEAF POWDER	A, E, H	
2977	LEMON OIL	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil. The quantity of oxedrine in the

			maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) steam distilled or rectified; or b) for internal use; or c) contains 0.05% or less of lemon oil; or d) for use in soaps or bath or shower gels that are washed off the skin.
2978	LEMON OIL DISTILLED	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil distilled. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2979	LEMON OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of lemon oil terpeneless. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2980	LEMON OIL TERPENES AND TERPENOIDS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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2981	LEMON PEEL DRIED	A, E, H	When used internally, oxedrine is a mandatory component of lemon peel dried. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
2982	LEMONGRASS OIL	A, E, H	
2983	LENS CULINARIS	A, H	
2984	LENTIL	E	
2985	LENTINULA EDODES	A, E, H	
2986	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%.
2987	LEONURUS CARDIACA	A, E, H	
2988	LEONURUS SIBIRICUS	A, E, H	
2989	LEPIDIUM APETALUM	A, H	
2990	LEPIDIUM MEYENII	A	The route of administration for medicines that contain Lepidium meyenii must be limited to oral. The ingredient must consist of the dried tuber of Lepidium meyenii only. The maximum recommended daily dose of the medicine must not provide more than 3.5 g of Lepidium meyenii dried tuber (or its extract equivalent).
2991	LEPTOSPERMUM PETERSONII	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more 5%.
2992	LEPTOSPERMUM SCOPARIUM OIL	A	Only for use as an active ingredient when the route of

			administration is topical or oral application in a mouthwash preparation. If the concentration is more than 25%, the nominal capacity of the container must be no more than 25mL. When the concentration is more than 25%, and the nominal capacity of the container less than 15mL, a restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children' (or word to that effect) - (NTAKEN) ‘Not to be taken’ When the concentration is more than 25%, the nominal capacity of the container is more than 15 mL but no more than 25 mL, a child resistant closure and restricted flow insert must be fitted on the container and requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children' (or word to that effect) - (NTAKEN) ‘Not to be taken’
2993	LESPEDEZA CAPITATA	A, H	
2994	LETTUCE	E	
2995	LEUCINE	A, E	
2996	LEUZEA UNIFLORA	A, H	
2997	LEVISTICUM OFFICINALE	A, H	
2998	LEVOCARNITINE	A	
2999	LEVOCARNITINE FUMARATE	A	
3000	LEVOCARNITINE HYDROCHLORIDE	A	
3001	LEVOCARNITINE MAGNESIUM CITRATE	A	
3002	LEVOCARNITINE TARTRATE	A	

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3003	LEVOMEFOLATE CALCIUM	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate calcium. The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate calcium. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
3004	LEVOMEFOLATE GLUCOSAMINE	A	Available for medicines intended for internal use only. Levomefolic acid is a mandatory component of levomefolate glucosamine. The maximum recommended daily dose must not provide more than 500 micrograms of levomefolic acid from levomefolate glucosamine. When the medicine contains a combination of folic acid, folinic acid or levomefolic acid, the medicine must not provide more than a combined total of 500 micrograms of folic acid, folinic acid and levomefolic acid per maximum recommended daily dose.
3005	LEVOTHYROXINE SODIUM	H	Only for use as an active homoeopathic ingredient.
3006	LEVULINIC ACID	E	Permitted for use only in

			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3007	LIGHT KAOLIN	E	
3008	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.
3009	LIGHT MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of light magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (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.
3010	LIGUSTICUM SINENSE	A, H	
3011	LIGUSTICUM STRIATUM	A, E, H	
3012	LIGUSTRUM LUCIDUM	A, H	
3013	LILIUM BROWNII	A, H	
3014	LILIUM CANDIDUM	A, E, H	
3015	LILIUM LANCIFOLIUM	A, H	
3016	LILIUM LONGIFLORUM	A, H	
3017	LIME FRUIT	E	
3018	LIME OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3019	LIME OIL COLDPRESSED	A, E, H	The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is: a) for internal use; or b) contains 0.5% or less of lime oil coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
3020	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.
3021	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%.
3022	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%.
3023	LIME TREE FLOWER DRY	A, H	
3024	LIME TREE FLOWER POWDER	A, H	
3025	LIME, ESSENCE	E	
3026	LIMES TERPENES	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3027	LIMONENE	E	When for oral use, the quantity

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			must be no more than 10 mg per maximum recommended daily dose.
3028	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%.
3029	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%.
3030	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%.
3031	LINALYL ACETATE	E	Permitted for use only: (a) in topical medicines for dermal application; and (b) in oral medicines in

			combination with other permitted ingredients as part of a flavour proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%.
3032	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%.
3033	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%.
3034	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%.
3035	LINALYL FORMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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3036	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%.
3037	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%.
3038	LINDERA STRYCHNIFOLIA	A, H	
3039	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%.
3040	LINOLEIC ACID	E	
3041	LINOLENIC ACID	E	
3042	LINSEED DRY	A, E, H	
3043	LINSEED OIL	A, E, H	
3044	LINSEED OIL FATTY ACIDS	E	Linseed oil fatty acids must only be included in medicines when in combination with other permitted ingredients as a 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.
3045	LINSEED POWDER	A, E, H	
3046	LINUM USITATISSIMUM	A, E, H	
3047	LIPASE	A	Lipase must only be derived from Rhizopus oryzae and must comply with the relevant compositional guideline.
3048	LIPPIA DULCIS	A, H	
3049	LIQUID GLUCOSE	E	
3050	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.
3051	LIQUIDAMBAR FORMOSANA	A, H	
3052	LIQUIDAMBAR ORIENTALIS	A, H	
3053	LIQUIDAMBAR STYRACIFLUA	A, E, H	
3054	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%.
3055	LIQUIDAMBAR TAIWANIANA	A, H	
3056	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%.

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3057	LIQUORICE DRY	A, E, H	
3058	LIQUORICE LIQUID EXTRACT	A, E, H	
3059	LIQUORICE POWDER	A, E, H	
3060	LITCHI CHINENSIS	A, H	
3061	LITHIUM CARBONATE	H	Only for use as an active homoeopathic ingredient.
3062	LITHOSPERMUM OFFICINALE	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material of Lithospermum officinale.
3063	LITSEA CUBEBA	A, E, H	
3064	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%.
3065	LOBARIA PULMONARIA	A, H	
3066	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.
3067	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.
3068	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.
3069	LOLIUM PERENNE	A, H	
3070	LOLIUM TEMULENTUM	A, H	
3071	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%.
3072	LONICERA CAPRIFOLIUM	A, E, H	
3073	LONICERA JAPONICA	A, E, H	
3074	LONICERA PERICLYMENUM	A, H	
3075	LOPHATHERUM GRACILE	A, H	
3076	LOQUAT	E	
3077	LORANTHUS PARASITICUS	A, H	
3078	LOROPETALUM CHINENSE	A, H	
3079	LOTUS CORNICULATUS	A, H	
3080	LOVAGE OIL	A, E, H	
3081	LOVAGE ROOT DRY	A, H	
3082	LOVAGE ROOT POWDER	A, H	
3083	LUDWIGIA PROSTRATA	A, H	
3084	LUFFA CYLINDRICA	A, H	
3085	LUFFA PURGANS	A, H	
3086	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.
3087	LYCHEE	E	
3088	LYCIUM BARBARUM	A, H	
3089	LYCIUM CHINENSE	A, E, H	
3090	LYCOPENE	A, E	
3091	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.
3092	LYCOPODIUM ANNOTINUM	A, H	
3093	LYCOPODIUM CLAVATUM	A, H	
3094	LYCOPODIUM COMPLANATUM	A, H	
3095	LYCOPUS EUROPAEUS	A, H	
3096	LYCOPUS LUCIDUS	A, H	
3097	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%.
3098	LYGODIUM JAPONICUM	A, H	
3099	LYSIMACHIA CHRISTINAE	A, H	
3100	LYSIMACHIA VULGARIS	A, H	
3101	LYSINE	A, E	
3102	LYSINE HYDROCHLORIDE	A, E	
3103	LYTHRUM HYSSOPIFOLIA	A, H	
3104	LYTHRUM SALICARIA	A, H	
3105	LYTHRUM VERTICILLATUM	A, H	
3106	MACADAMIA INTEGRIFOLIA	A, E	
3107	MACADAMIA NUT OIL	E	
3108	MACADAMIA TERNIFOLIA	A, E, H	
3109	MACE	E	Safrole is a mandatory component of Mace. When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%.
3110	MACE OIL	A, H	Safrole is a mandatory component of Mace oil.

			When used internally, the concentration of safrole in the medicine must be no more than 0.1%. When used topically, the concentration of safrole in the medicine must be no more than 1.0%. When the concentration of mace oil in the preparation is more than 50% and the nominal capacity of the container is 25 mL or less, a restricted flow insert must be fitted on the container.
3111	MACROCYSTIS PYRIFERA	A, E, H	Iodine is a mandatory component of Macrocystis pyrifera. Only for external use when the concentration of iodine in the medicine (excluding salts derivatives or iodophors) is 2.5% or less. Only for internal use when the medicine contains less than 300 micrograms of iodine per maximum recommended daily dose.
3112	MACROGOL 1000	E	
3113	MACROGOL 1450	E	Only for use in topical medicines for dermal application.
3114	MACROGOL 1500	E	
3115	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%.
3116	MACROGOL 200	E	Only for use in topical medicines for dermal application.

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3117	MACROGOL 20000	E	
3118	MACROGOL 300	E	
3119	MACROGOL 3000	E	
3120	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.
3121	MACROGOL 40	E	Only for use in topical medicines for dermal application.
3122	MACROGOL 400	E	
3123	MACROGOL 4000	E	
3124	MACROGOL 45000	E	Only for use in topical medicines for dermal application.
3125	MACROGOL 600	E	
3126	MACROGOL 6000	E	
3127	MACROGOL 600000	E	
3128	MACROGOL 800	E	
3129	MACROGOL 8000	E	
3130	MACROGOL 900	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.95%.
3131	MACROGOL POLY(VINYL ALCOHOL) GRAFTED POLYMER	E	Only for use in oral medicines. The concentration in the medicine must be no more than 5%.
3132	MACROPIPER EXCELSUM VAR EXCELSUM	A, H	
3133	MAGNESIUM AMINO ACID	A, E, H	Only for use in oral medicines.

	CHELATE		The concentration of magnesium must be no more than 25% of the magnesium amino acid chelate.
3134	MAGNESIUM ASCORBATE	A, E, H	
3135	MAGNESIUM ASCORBATE MONOHYDRATE	A, E, H	
3136	MAGNESIUM ASCORBYL PHOSPHATE	E	Only for use in topical medicines for dermal application.
3137	MAGNESIUM ASPARTATE	A, E, H	
3138	MAGNESIUM ASPARTATE DIHYDRATE	A, E, H	
3139	MAGNESIUM ASPARTATE TETRAHYDRATE	A, E, H	
3140	MAGNESIUM CARBONATE HYDRATE	A, E, H	
3141	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 from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium,

			which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3142	MAGNESIUM CHLORIDE HEXAHYDRATE	A, E, H	Magnesium is a mandatory component of magnesium chloride hexahydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3143	MAGNESIUM CITRATE	A, E, H	
3144	MAGNESIUM CITRATE NONAHYDRATE	A, E, H	

3145	MAGNESIUM CITRATE TETRADECAHYDRATE	A, E, H	
3146	MAGNESIUM DIGLUTAMATE	A, E, H	
3147	MAGNESIUM GLUCONATE	A, E, H	
3148	MAGNESIUM GLYCEROPHOSPHATE	A, E, H	
3149	MAGNESIUM GLYCINATE	A	Only for use in oral medicines.
3150	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.
3151	MAGNESIUM HYDROGEN PHOSPHATE	H	Magnesium is a mandatory component of magnesium hydrogen phosphate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label:

			- (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3152	MAGNESIUM HYDROXIDE	A, E	When used as an active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia, as in force or existing from time to time. Magnesium is a mandatory component of magnesium hydroxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect

			or cause 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.
3153	MAGNESIUM LYSINATE	A	Only for use in oral medicines.
3154	MAGNESIUM METHIONINATE	A	Only for use in oral medicines.
3155	MAGNESIUM NITRATE	E	Only for use in topical medicines for dermal application.
3156	MAGNESIUM OROTATE	A, E, H	
3157	MAGNESIUM OROTATE DIHYDRATE	A, E, H	
3158	MAGNESIUM OXIDE	A, E, H	Magnesium is a mandatory component of magnesium oxide. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (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.
3159	MAGNESIUM PHOSPHATE PENTAHYDRATE	A, E, H	Magnesium is a mandatory component of magnesium phosphate pentahydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3160	MAGNESIUM PHOSPHATE TRIBASIC	A, E, H	Magnesium is a mandatory component of magnesium phosphate tribasic. The percentage of magnesium

			from magnesium phosphate tribasic should be calculated based on the molecular weight of magnesium phosphate tribasic. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3161	MAGNESIUM PYRUVATE	A	Only for use in oral medicines. The maximum recommended daily dose must be no more than 7 grams.
3162	MAGNESIUM STEARATE	E	
3163	MAGNESIUM SULFATE DIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5g.

			Magnesium is a mandatory component of magnesium sulfate dihydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3164	MAGNESIUM SULFATE HEPTAHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. Magnesium is a mandatory component of magnesium sulfate heptahydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or

			related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause diarrhoea' (or words to that effect). When the route of administration is oral, the medicine must not be directed for use in infants younger than 12 months of age.
3165	MAGNESIUM SULFATE MONOHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. Magnesium is a mandatory component of magnesium sulfate monohydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts;

			(ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3166	MAGNESIUM SULFATE TRIHYDRATE	A, E, H	When used internally, the maximum recommended daily dose must not be more than 1.5 g. Magnesium is a mandatory component of magnesium sulfate trihydrate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts;

			the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.
3167	MAGNESIUM TRISILICATE	E	Magnesium is a mandatory component of magnesium trisilicate. When used in a medicine: (a) with an oral route of administration; (b) not indicated for laxative (or related) use; and (c) where the maximum recommended daily dose for: (i) children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium from inorganic magnesium salts; (ii) children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium from inorganic magnesium salts; or (iii) individuals aged 9 years or older provides 350 mg or more total magnesium from inorganic magnesium salts; the following warning statement is required on the medicine label: - (LAX6) 'Contains magnesium, which may have a laxative effect or cause 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.

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3168	MAGNOLIA GLAUCA	A, H	
3169	MAGNOLIA LILIFLORA	A, H	
3170	MAGNOLIA OBOVATA	A, H	
3171	MAGNOLIA OFFICINALIS	A, E, H	
3172	MAGNOLIA SALICIFOLIA	A, H	
3173	MAIZE OIL	A, E, H	
3174	MAIZE STARCH	A, E, H	
3175	MALACHITE GREEN	E	Permitted for use only as a colour for topical use.
3176	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.
3177	MALPIGHIA GLABRA	A, E, H	
3178	MALT EXTRACT	E	
3179	MALTITOL	E	
3180	MALTITOL SOLUTION	E	
3181	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.
3182	MALTOL	E	
3183	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%.
3184	MALTOSE	E	
3185	MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.

3186	MALUS SYLVESTRIS	A, H	
3187	MALVA MOSCHATA	A, H	
3188	MALVA SYLVESTRIS	A, E, H	
3189	MALVA VERTICILLATA	A, H	
3190	MANDARIN	E	
3191	MANDARIN OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3192	MANDARIN OIL COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of mandarin oil coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3193	MANDARIN OIL TERPENES	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3194	MANDARIN RESIDUE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total

			flavour concentration in a medicine must be no more than 5%.
3195	MANDRAGORA OFFICINARUM	A, H	Atropine, hyoscine and hyoscyamine are mandatory components of Mandragora officinarum. The concentration in the medicine must be no more than 10 mg/kg or 10 mL/L or 0.001%. The concentration of atropine in the medicine must be no more than 100 micrograms/kg or 100 micrograms/L or 0.00001%. The concentration of hyoscine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%. The concentration of hyoscyamine in the medicine must be no more than 300 micrograms/kg or 300 micrograms/L or 0.00003%.
3196	MANGANESE	H	Only for use as an active homoeopathic ingredient.
3197	MANGANESE (II) DIASPARTATE	A, H	Only for use in oral medicines.
3198	MANGANESE (II) GLYCINATE	A, H	Only for use in oral medicines.
3199	MANGANESE ACETATE TETRAHYDRATE	H	Only for use as an active homoeopathic ingredient.
3200	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.
3201	MANGANESE CHLORIDE TETRAHYDRATE	A, E, H	
3202	MANGANESE DIASPARTATE	A, E, H	Only for use in oral medicines.

3203	MANGANESE GLUCONATE	A, E, H	
3204	MANGANESE GLYCEROPHOSPHATE	A, E, H	
3205	MANGANESE OXIDE	A, E, H	
3206	MANGANESE SULFATE MONOHYDRATE	A, E, H	
3207	MANGANESE SULFATE TETRAHYDRATE	A, E, H	
3208	MANGIFERA INDICA	A, E, H	
3209	MANGO	E, H	
3210	MANIHOT ESCULENTA	A, H	
3211	MANNITOL	E	
3212	MARANTA ARUNDINACEA	A, H	
3213	MARINE SPONGE	H	Only for use as an active homoeopathic ingredient.
3214	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).
3215	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).
3216	MARRUBIUM VULGARE	A, E, H	

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3217	MARSDENIA CUNDURANGO	A, H	
3218	MARSHMALLOW ROOT DRY	A, H	
3219	MARSHMALLOW ROOT POWDER	A, H	
3220	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%.
3221	MASTIC	A, H	
3222	MATE ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3223	MATRICARIA CHAMOMILLA	A, E, H	
3224	MATRICARIA FLOWER DRY	A, E, H	
3225	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: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application i) the concentration of methyl salicylate in the medicine must not be more than 25% ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight.' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following

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			warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3226	MECOBALAMIN	A	Only for use in oral medicines.
3227	MEDICAGO SATIVA	A, E, H	The level of l-canavanine must be no more than that of the dried leaf. When fresh leaf extract is used and the extraction ratio is between 34:1 and 46:1, the quantity of l-canavanine in the extract must not be more than that in the fresh leaf.
3228	MEDIUM CHAIN TRIGLYCERIDES	E	
3229	MELALEUCA ALTERNIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca alternifolia. In liquid preparations when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is 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.

3230	MELALEUCA CAJUPUTI	A, E, H	Cineole is a mandatory component of Melaleuca cajuputi. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3231	MELALEUCA CITRINA	A, H	
3232	MELALEUCA DISSITIFLORA	A, H	Cineole is a mandatory component of Melaleuca dissitiflora. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on

			the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3233	MELALEUCA ERICIFOLIA	A, E, H	Cineole is a mandatory component of Melaleuca ericifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3234	MELALEUCA LINARIIFOLIA	A, H	Cineole is a mandatory component

			of Melaleuca linariifolia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3235	MELALEUCA OIL	A, E, H	Cineole and cajuput oil are a mandatory components of Melaleuca Oil. When the plant preparation is oil and the concentration in the medicine is more than 25%, the nominal capacity of the container must be no more than 25 mL and the medicine requires the following warning statements on the medicine label: - (CHILD) ‘Keep out of reach of children’ (or word to that effect) - (NTAKEN) ‘Not to be taken’. When the nominal capacity of the container is 15 mL or less, then a restricted flow insert must be

			fitted on the container. Where the nominal capacity of the container is more than 15 mL but less than or equal to 25 mL, then a child resistant closure and restricted flow insert must be fitted on the container.
3236	MELALEUCA QUINQUENERVIA	A, E, H	Cineole is a mandatory component of Melaleuca quinquenervia. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25%: a) the nominal capacity of the container must be no more than 25 millilitres; b) a restricted flow insert must be fitted on the container; and c) the container must include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In liquid preparations, when the concentration of cineole OR the concentration of oil or distillate in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres the medicine must also have a child resistant closure.
3237	MELICOPE PTELEIFOLIA	A, H	
3238	MELILOTUS OFFICINALIS	A, E, H	Coumarin is a mandatory component of Melilotus officinalis. The concentration of coumarin in the medicine must be no more than 0.001%.

3239	MELISSA OFFICINALIS	A, E, H	
3240	MELON	E	
3241	MENADIONE SODIUM BISULFITE	E	
3242	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.
3243	MENISPERMUM CANADENSE	A, H	
3244	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 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.
3245	MENTHA ARVENSIS	A, E, H	Menthol is a mandatory component of Mentha arvensis. 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 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.
3246	MENTHA ARVENSIS LEAF OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation or fragrance proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must be no more than 5%. The total fragrance proprietary excipient formulation in a medicine must be no more 1%. Menthol is a mandatory component of Mentha arvensis leaf oil. 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

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			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.
3247	MENTHA ARVENSIS OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total flavour proprietary excipient formulation in a medicine must not be more than 5%. Menthol is a mandatory component of Mentha arvensis oil. 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

			statements 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.
3248	MENTHA HAPLOCALYX	A, E, H	Menthol is a mandatory component of Mentha haplocalyx. 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 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.
3249	MENTHA PULEGIUM	A, H	D-pulegone, menthol and volatile oil components (of Mentha pulegium) are mandatory components of Mentha pulegium. When the nominal capacity of the container is more than 15 millilitres, the concentration of d-pulegone in the medicine must be no more than 4%. When the concentration of d-pulegone in the preparation is more than 4% and the nominal capacity of the container is 15 millilitres or less, the medicine must have a child resistant closure and restricted flow insert fitted on the container.

	The medicine requires the following warning statements on the medicine label: - (NTAKEN) 'Not to be taken'; - (CHILD) 'Keep out of reach of children' (or words to that effect). When the medicine is for topical use for dermal application: a) the maximum recommended daily dose must not contain more than 150 mg of Mentha pulegium oil or distillate; b) the medicine must not be intended for use in the eye or on damaged skin; c) the medicine must not deliver more than 25% total menthol when administered according to the directions for use; d) the following warning statement is required on the medicine label: - (EYE) Avoid contact with eyes (or words to that effect). e) if the medicine delivers more than 1% total menthol when administered according to the directions for use, the following warning statements are required on the medicine label: - (SKTEST) If you have sensitive skin, test this product on a small area of skin before applying it to a large area; - (IRRIT) If irritation develops, discontinue use. f) if the medicine delivers more than 5% total menthol when administered according to the directions for use, the following warning statement is required on the medicine label: – (MENTH) Contains a high concentration of menthol, which

			can cause severe skin irritation. When the medicine is for internal use: a) the maximum recommended daily dose must not contain more than 50 mg of Mentha pulegium oil or distillate; b) the maximum recommended daily dose must not contain more than 1 gram of menthol.
3250	MENTHA SPICATA	A, E, H	Menthol is a mandatory component of Mentha spicata. 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 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.
3251	MENTHA X CARDIACA	A, E, H	Menthol is a mandatory component of Mentha x cardiaca. 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 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.
3252	MENTHA X PIPERITA	A, E, H	Menthol is a mandatory component of Mentha x piperita. 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 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.
3253	MENTHADIENYL ACETATE	E	Menthadienyl acetate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing menthadienyl acetate must not be more than 5% of the total medicine.
3254	MENTHANYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3255	MENTHOFURAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3256	MENTHOL	A, E	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

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			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.
3257	MENTHONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3258	MENTHONE GLYCERINE ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour.

			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3259	MENTHONE THIOL FRACTION	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3260	MENTHOXYPROPANEDIOL	E	For oral use only. The concentration in the medicine must be no more than 0.04%.
3261	MENTHYL 2-HYDROXYETHYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3262	MENTHYL 2-HYDROXYPROPYL CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3263	MENTHYL ANTHRANILATE	A	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the label:

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			- (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).
3264	MENTHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3265	MENTHYL LACTATE	E	
3266	MENYANTHES TRIFOLIATA	A, H	
3267	MERCURIC CHLORIDE	H	Only for use as an active homoeopathic ingredient. Mercury is a mandatory component of mercuric chloride. The total concentration of mercury in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3268	MERCURY	H	Only for use as an active homoeopathic ingredient. The total concentration of mercury in the medicine must not be more than 1 mg/kg or 1 mg/L or 0.0001%.
3269	METACRESOL	E	Only for use in topical medicines for dermal application.
3270	METHACRYLIC ACID COPOLYMER	E	Only for use in oral medicines.
3271	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%.
3272	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%.
3273	METHIONINE	A, E	
3274	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%.
3275	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%.
3276	METHYL 2-OCTYNOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

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3277	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%.
3278	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%.
3279	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%.
3280	METHYL ACETYL RICINOLEATE	E	Only for use in topical medicines for dermal application.
3281	METHYL ANISATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3282	METHYL ANTHRANILATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than

			5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3283	METHYL BENZOATE	E	Only for use in topical medicines for dermal application.
3284	METHYL BUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3285	METHYL CAPROATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3286	METHYL CAPRYLATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3287	METHYL CARBITOL	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.

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3288	METHYL CEDRYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3289	METHYL CHAVICOL	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The ingredient is not to be included in medicines intended for oral use. The quantity of methyl chavicol in a medicine must be no more than 0.01%. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3290	METHYL CINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3291	METHYL CIS-5-OCTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

3292	METHYL CYCLOPENTENOLONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3293	METHYL CYCLOPENTYLIDENEACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3294	METHYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3295	METHYL DIHYDROABIETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3296	METHYL DIISOPROPYL PROPIONAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

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3297	METHYL ETHER	E	Only for use in topical medicines for dermal application.
3298	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%.
3299	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%.
3300	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%.
3301	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.
3302	METHYL GLUCETH-20	E	Only for use in topical medicines for dermal application.

3303	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%.
3304	METHYL GLUCETH-20 SESQUIHYDRATE	E	Only for use in topical medicines for dermal application.
3305	METHYL GLUCOSE DIOLEATE	E	Only for use in topical medicines for dermal application.
3306	METHYL GLUCOSE SESQUIOLEATE	E	Only for use in topical medicines for dermal application.
3307	METHYL GLUCOSE SESQUISTEARATE	E	Only for use in topical medicines for dermal application.
3308	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%.
3309	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%.
3310	METHYL HEPTYL KETONE	E	Permitted for use only in combination with other permitted

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			ingredients 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%.
3311	METHYL HEXYL CARBINOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3312	METHYL HEXYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3313	METHYL HYDROGENATED ROSINATE	E	Only for use in topical medicines for dermal application.
3314	METHYL HYDROJASMONATE	E	Only for use in topical medicines for dermal application.
3315	METHYL HYDROXYBENZOATE	E	
3316	METHYL IONONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3317	METHYL ISOBUTYL KETONE	E	The residual solvent limit is 50 mg per maximum daily dose. The concentration in the medicine must be no more than 0.5%.
3318	METHYL ISOEUGENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3319	METHYL ISOVALERATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3320	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%.
3321	METHYL LAURATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used as a flavour the total

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			flavour concentration in a medicine must be no more than 5%.
3322	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%.
3323	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%.
3324	METHYL MAGNESIUM CHLORIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3325	METHYL METHACRYLATE CROSSPOLYMER	E	Methyl methacrylate is a mandatory component of methyl methacrylate crosspolymer. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. When the concentration of methyl methacrylate crosspolymer is greater than 1%, the medicine must not be intended for use on damaged skin. The total concentration of methyl methacrylate crosspolymer in the medicine must not be more than 4.85%.

			The total concentration of methyl methacrylate as residual monomer in the medicine must not be more than 1%.
3326	METHYL METHOXY PYRAZINE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3327	METHYL MYRISTATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3328	METHYL NAPHTHYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3329	METHYL NONYL KETONE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3330	METHYL NONYLENATE	E	Permitted for use only in combination with other permitted

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			ingredients 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%.
3331	METHYL OCTIN CARBONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3332	METHYL PALMITATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3333	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%.
3334	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%.
3335	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%.
3336	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%.
3337	METHYL PHENYLCARBINYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3338	METHYL ROSINATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3339	METHYL SALICYLATE	A, E	Not to be included in medicines

	for use in the eye or on damaged skin. When used internally, the concentration in the medicine must not be more than 0.001%. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging. When the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish. The following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that effect). When for use in topical medicines for dermal application: i) the concentration of methyl salicylate in the medicine must not be more than 25%; ii) the following warning statements are required on the medicine label: - (PREGNT2) 'Do not use if pregnant or likely to become pregnant' (or words to that effect); - (CHILD4) 'Do not use [this

			product/insert name of product] in children 6 years of age or less'; - (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect); - (AVOID) 'Avoid prolonged exposure in the sun' (or words to that effect); iii) if the concentration of methyl salicylate in the medicine is greater than 1%, the following warning statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3340	METHYL STEARATE	E	
3341	METHYL THIOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3342	METHYL TRIMETICONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3343	METHYL-3-METHYLTHIOPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3344	METHYL-BETA-METHYL THIOLPROPIONATE	E	Permitted for use only in combination with other permitted ingredients as a flavour.

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			If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3345	METHYL-PARA-TERT-BUTYL PHENYLACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3346	METHYLBENZYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3347	METHYLCELLULOSE	A, E	
3348	METHYLCHLOROISOTHIAZOLINONE	E	Only for use in topical medicines for dermal application that are rinsed off the skin. The total concentration of methylchloroisothiazolinone and methylisothiazolinone in the medicine must be no more than 0.0015%.
3349	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%.
3350	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).
3351	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%.
3352	METHYLMERCAPTAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3353	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%.
3354	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.

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			The concentration in the medicine must be no more than 0.1%.
3355	METHYLSTYRENE/VINYLTOLUENE COPOLYMER	E	Only for use in topical medicines for dermal application.
3356	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%.
3357	MICROCALICIUM ARENARIUM	A, H	
3358	MICROCOCCUS LUTEUS LYSATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.005%.
3359	MICROCOS PANICULATA	A, H	
3360	MICROCRYSTALLINE CELLULOSE	E	
3361	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'.
3362	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%.
3363	MILK THISTLE FRUIT DRY	A, H	
3364	MILK THISTLE FRUIT POWDER	A, H	
3365	MILLET	E	
3366	MILLETTIA DIELSIANA	A, H	
3367	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%.
3368	MIMULUS GUTTATUS	A, H	
3369	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: (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,

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			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.
3370	MINTLACTONE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3371	MITCHELLA REPENS	A, H	
3372	MIXED (HIGH-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3373	MIXED (LOW-ALPHA TYPE) TOCOPHEROLS CONCENTRATE	A, E	
3374	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%.
3375	MODIFIED FOOD STARCH	E	
3376	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%.
3377	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.
3378	MOLYBDENUM TRIOXIDE	A	Molybdenum is a mandatory component of Molybdenum trioxide. The maximum daily dose of molybdenum from Molybdenum trioxide must be no more than 125 micrograms. The percentage of molybdenum from molybdenum trioxide should be calculated based on the molecular weight of molybdenum trioxide.
3379	MOMORDICA BALSAMINA	A, H	
3380	MOMORDICA CHARANTIA	A, H	
3381	MOMORDICA COCHINCHINENSIS	A, H	
3382	MONARDA DIDYMA	A, H	
3383	MONO- AND DI- GLYCERIDES	E	
3384	MONOBASIC AMMONIUM PHOSPHATE	E	Only for use in topical medicines for dermal application.
3385	MONOBASIC CALCIUM PHOSPHATE	A, E, H	
3386	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.

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			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.
3387	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.
3388	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.
3389	MONOETHANOLAMINE	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 5%.
3390	MONOMENTHYL GLUTARATE	E	Monomenthyl glutarate must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing monomenthyl glutarate must not be more than 5% of the total medicine. The maximum recommended daily dose of the medicine must not provide more than 1.8mg of monomenthyl glutarate.
3391	MONOMENTHYL SUCCINATE	E	Monomenthyl succinate must only be included in medicines when in combination with other permitted

			ingredients as a flavour proprietary excipient formulation. The total concentration of the flavour proprietary excipient formulation containing monomenthyl succinate must not be more than 5% of the total medicine.
3392	MONOPHOSPHOTHIAMINE	A	
3393	MONOPHOSPHOTHIAMINE DIHYDRATE	A	
3394	MONOPOTASSIUM GLUTAMATE	A, E	
3395	MONOSODIUM DIHYDROGEN CITRATE	E	
3396	MONOSODIUM GLUTAMATE MONOHYDRATE	A, E	
3397	MONSTERA DELICIOSA	A, H	
3398	MONTAN WAX	E	
3399	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%..
3400	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).
3401	MORINDA OFFICINALIS	A, H	
3402	MORINGA OLEIFERA	A, H	
3403	MORUS ALBA	A, H	
3404	MORUS BOMBYCIS	A, H	
3405	MORUS NIGRA	A, E, H	
3406	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

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			medicine must be no more than 1%.
3407	MOTHERWORT HERB DRY	A, H	
3408	MOTHERWORT HERB POWDER	A, H	
3409	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%.
3410	MULBERRY	E	
3411	MUNG BEAN	E	
3412	MURRAYA KOENIGII	A, H	
3413	MURRAYA PANICULATA	A, H	
3414	MUSA X PARADISIACA	A, H	
3415	MUSK KETONE	E	Only for use in topical medicines for dermal application.
3416	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%.
3417	MUSK XYLOL	E	Only for use in topical medicines for dermal application.
3418	MUSKS	H	Only for use as an active homoeopathic ingredient.
3419	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%.

3420	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%.
3421	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 be no more than 10 mg/kg or 10 mg/L or 0.001%.
3422	MYOSOTIS ARVENSIS	A, H	
3423	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%.
3424	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%.
3425	MYRICA CERIFERA	A, E, H	
3426	MYRISTIC ACID	E	

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3427	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%.
3428	MYRISTICA FRAGRANS	A, E, H	Safrole is a mandatory component of Myristica fragrans. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the plant preparation is oil or distillate and the concentration in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 millilitres, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect).
3429	MYRISTYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3430	MYRISTYL LACTATE	E	Only for use in topical medicines for dermal application.
3431	MYRISTYL MYRISTATE	E	Only for use in topical medicines for dermal application.

3432	MYROXYLON BALSAMUM	A, E, H	
3433	MYROXYLON BALSAMUM VAR. PEREIRAE	A, H	
3434	MYRRH	A, H	
3435	MYRRH OIL	A, E, H	
3436	MYRRH RESIN	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3437	MYRRHIS ODORATA	A, H	
3438	MYRSINE AFRICANA	A, H	
3439	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%.
3440	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%.
3441	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%.

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3442	MYRTUS COMMUNIS	A, E, H	
3443	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.
3444	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 flavour proprietary excipient formulation. 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. 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.
3445	N-BUTYL SULFIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3446	N-GLUCONYL ETHANOLAMINE	E	Permitted for use only in

			combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3447	N-HEXYL 2-BUTENOATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3448	N-NONYL ALCOHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3449	NAPHTHALENE	H	Only for use as an active homoeopathic ingredient.
3450	NARDOSTACHYS CHINENSIS	A, H	
3451	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%.
3452	NASTURTIUM OFFICINALE	A, E, H	
3453	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: - (VITA2) 'WARNING: If you are pregnant - or considering becoming pregnant - do not take vitamin A supplements without consulting your doctor or pharmacist [or words to that effect].' NOTE: Position this warning at the beginning of the directions for use. - (VITA4) 'WARNING - When taken in excess of 3000 micrograms retinol equivalents - vitamin A can cause birth defects.' NOTE: Position this warning at the beginning of the directions for use. - (VITA3) 'The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.' When for internal use, the maximum recommended daily dose must be no more than 25 micrograms of Vitamin D.

3454	NAUCLEA OFFICINALIS	A, H	
3455	NELUMBO NUCIFERA	A, H	
3456	NELUMBO NUCIFERA FLOWER WAX	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%.
3457	NEOHESPERIDIN-DIHYDROCHALCONE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 0.1%
3458	NEOMENTHOL	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3459	NEOPENTYL GLYCOL DIHEPTANOATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 25%.
3460	NEOPENTYL GLYCOL DIISOSTEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3461	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.
3462	NEOPENTYL GLYCOL DIOCTANOATE/DIDECANOATE	E	Only for use in topical medicines for dermal application.
3463	NEOPICRORHIZA SCROPHULARIIFLORA	A, H	
3464	NEPETA CATARIA	A, H	Pulegone is a mandatory component of Nepeta cataria and must be declared in the application. The concentration of pulegone in the medicine must be no more than 4%.
3465	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%.
3466	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%.
3467	NEROL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.

			If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3468	NEROL OXIDE	E	Permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3469	NEROLIDOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3470	NERONE	E	Permitted for use only in combination with other permitted ingredients as part of a fragrance proprietary excipient formulation. The total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3471	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

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			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3472	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%.
3473	NICKEL	H	Only for use as an active homoeopathic ingredient.
3474	NICOTIANA TABACUM	H	Only for use as an active homoeopathic ingredient.
3475	NICOTINAMIDE	A, E, H	
3476	NICOTINAMIDE ASCORBATE	A, E	
3477	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: - (NTAKEN12) 'Not to be taken by children under 12 years old.' 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: - (PREG) 'Not recommended for use during pregnancy or lactation'.
3478	NICOTINIC ACID	A, E	The medicine must contain no more than 100 mg of nicotinic acid per dosage unit.
3479	NIGELLA DAMASCENA	A, H	
3480	NIGELLA SATIVA	A, E, H	
3481	NITRIC ACID	E, H	The concentration of nitric acid in the medicine must be no more than 0.5%.
3482	NONADIENOL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3483	NONANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3484	NONANOIC ACID	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3485	NONFAT DRY MILK	E, H	
3486	NONIVAMIDE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3487	NONOXINOL 10	E	Only for use in topical medicines for dermal application.
3488	NONOXINOL 12	E	For use in hand scrub formulations for healthcare professionals only. Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%.
3489	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%.
3490	NONOXINOL 9	E	Only for use in topical medicines for dermal application. The concentration in the medicine must be no more than 25%.
3491	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%.
3492	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%.
3493	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%.
3494	NORDIHYDROGUAIARETIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.3%.
3495	NOTOPTERYGIUM FORBESII	A, H	
3496	NOTOPTERYGIUM INCISIUM	A, H	
3497	NUPHAR JAPONICA	A, H	
3498	NUPHAR LUTEA	A, H	
3499	NUTMEG DRY	A, E, H	Safrole is a mandatory component of Nutmeg Dry. When for internal use then the concentration of safrole from all ingredients in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole from all ingredients in the medicine must be no more than 1%.

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3500	NUTMEG OIL	A, E, H	Safrole is a mandatory component of Nutmeg oil. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%. When the concentration of Nutmeg oil in the medicine is more than 50%, the nominal capacity of the container must be no more than 25 mL, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3501	NUTMEG POWDER	A, E, H	Safrole is a mandatory component of Nutmeg powder. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3502	NUX VOMICA DRY	A, H	Strychnine (of Strychnos spp.) is a mandatory component of Nux Vomica Dry. The concentration of in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3503	NUX VOMICA POWDER	H	Only for use as an active homoeopathic ingredient. Strychnine (of Strychnos spp.) is a

			mandatory component of Nux vomica powder. The concentration in the medicine must be no more than 1mg/Kg or 1mg/L or 0.0001%.
3504	NYCTANTHES ARBOR-TRISTIS	A, H	When the plant part is leaf: a) methyl salicylate is a mandatory component of Nyctanthes arbor-tristis; b) not to be included in medicines for use in the eye or on damaged skin; c) when used internally, the concentration of methyl salicylate in the medicine must not be more than 0.001%; d) when the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is other than spray, the medicine requires child resistant packaging; e) when the concentration of methyl salicylate in a liquid preparation is more than 5% and the dosage form is spray, the medicine does not require child resistant packaging if: - the delivery device is engaged into the container in such a way that prevents it from being readily removed; - direct suction through the delivery device results in delivery of no more than one dosage unit; and - actuation of the spray device is ergonomically difficult for young children to accomplish; f) the following warning statement is required on the medicine label: - (METSAL) 'Contains methyl salicylate' (or words to that

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			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 statement is required on the medicine label: - (IRRIT) 'If irritation develops, discontinue use'.
3505	NYLON	E	Only for use in topical medicines for dermal application.
3506	NYLON 6/12	E	Only for use in topical medicines for dermal application.
3507	NYLON-12	E	Only for use in topical medicines for dermal application.
3508	NYMPHAEA ALBA	A, E, H	
3509	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.
3510	NYMPHAEA ODORATA	A, H	
3511	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%.
3512	OAKMOSS ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3513	OAT	E, H	Only for use as an active homoeopathic or excipient ingredient. Gluten is a mandatory component of Oat when the route of administration is other than topical and mucosal.
3514	OAT BRAN	E	Gluten is a mandatory component of Oat bran when the route of administration is other than topical and mucosal.
3515	OATMEAL COLLOIDAL	A, E	Gluten is a mandatory component of Oatmeal colloidal when the route of administration is other

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			than topical and mucosal.
3516	OCIMENE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3517	OCIMENYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3518	OCIMUM BASILICUM	A, E, H	When the plant preparation is oil or distillate, Methyl chavicol, eugenol, methyleugenol and cineole are mandatory components of Ocimum basilicum. The concentration of methyleugenol in the medicine must not exceed 1%. When the concentration of Methyl chavicol in the medicine is more than 5%, the nominal capacity of the container must be no more than 25 millilitres. When the concentration of Methyl chavicol in the medicine is more than 5% and the nominal capacity of the container is 25 millilitres or less, a restricted flow insert must

			be fitted on the container, and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). When the concentration of cineole OR eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of cineole OR eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 millilitres of eugenol and the concentration of eugenol in the product must not be greater than 25%.
3519	OCIMUM KILIMANDSCHARICUM	A, H	Camphor is a mandatory component of Ocimum kilimandscharicum. In solid and semi solid

			preparations, the concentration of camphor must be no more than 12.5%. In liquid preparations, the nominal capacity of the container must be no more than 25 millilitres. In liquid preparations other than essential oils or distillates, the concentration of camphor must be no more than 2.5%. In essential oil or distillate preparations when the concentration of camphor is more than 2.5%, the medicine must have a restricted flow insert fitted on the container and include the following warning statements on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. In essential oil or distillate preparations, if the concentration of camphor is more than 10%, and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must also have a child resistant closure fitted on the container.
3520	OCIMUM MINIMUM	A, H	
3521	OCIMUM TENUIFLORUM	A, H	When the plant part is oil or distillate, eugenol is a mandatory component of Ocimum tenuiflorum. When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label:

			- (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 mL of eugenol and the concentration of eugenol in the product must not be greater than 25%.
3522	OCOTEA ODORIFERA	A, H	Safrole is a mandatory component of Ocotea odorifera. When for internal use then the concentration of safrole in the medicine must be no more than 0.1%. When for topical use then the concentration of safrole in the medicine must be no more than 1%.
3523	OCTACOSANOL	E	
3524	OCTADECANAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total

			flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3525	OCTADECENE/MA COPOLYMER	E	Only for use in topical medicines for dermal application.
3526	OCTAHYDRO-4,7-METHANO-3AH-INDENE-3A-CARBOXYLIC ACID, ETHYL ESTER	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3527	OCTAHYDROCOUMARIN	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3528	OCTAN-1-OL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3529	OCTANAL DIMETHYL ACETAL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a

			medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3530	OCTANOHYDROXAMIC ACID	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 0.5%.
3531	OCTANOIC ACID	A, E	When for topical use, the concentration in the medicine must be no more than 2% (w/w). When for excipient use, permitted for use only in combination with other permitted ingredients as part of a flavour or fragrance proprietary excipient formulation. When used in a flavour, the total flavour proprietary excipient formulation in a medicine must be no more than 5%. When used in a fragrance, the total fragrance proprietary excipient formulation in a medicine must be no more than 1%.
3532	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%.
3533	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.

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			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).
3534	OCTOXINOL 10	E	Only for use in topical medicines for dermal application.
3535	OCTYL ACETATE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3536	OCTYL CROTONATE	E	Octyl crotonate must only be included in medicines when in combination with other permitted ingredients as a fragrance proprietary excipient formulation. The total concentration of the fragrance proprietary excipient formulation containing octyl crotonate must not be more than 1% of the total medicine.
3537	OCTYL HYDROXYSTEARATE	E	Only for use in topical medicines for dermal application.

3538	OCTYL ISOBUTYRATE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3539	OCTYL ISONONANOATE	E	Only for use in topical medicines for dermal application.
3540	OCTYL METHOXYCINNAMATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must 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).
3541	OCTYL PALMITATE	E	Only for use in topical medicines for dermal application.
3542	OCTYL SALICYLATE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 5%. When used in primary sunscreen products, the following warning statements are required on the

			label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).
3543	OCTYL STEARATE	E	Only for use in topical medicines for dermal application.
3544	OCTYLBICYCLOHEPTENEDICARBOXIMIDE	E	Only for use in topical medicines for dermal application. The total concentration of octylbicycloheptenedicarboximide in the medicine must not be more than 10%.
3545	OCTYLDODECANOL	E	Only for use in topical medicines for dermal application.
3546	OCTYLDODECETH-25	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 5%. Residual levels of 1,4-dioxane and ethylene oxide (and related substances) are to be kept below the level of detection.
3547	OCTYLDODECYL CITRATE CROSSPOLYMER	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye or on damaged skin. The concentration in the medicine must be no more than 12%.
3548	OCTYLDODECYL NEOPENTANOATE	E	Only for use in topical medicines for dermal application.

3549	OCTYLDODECYL STEARATE	E	Only for use in topical medicines for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must be no more than 2%.
3550	OCTYLDODECYL XYLOSIDE	E	Only for use in topical medicines for dermal application and not to be included in medicines for use in the eye or on damaged skin. The concentration in the medicine must be no more than 1.5%.
3551	OENANTHATE	E	Permitted for use only in combination with other permitted ingredients as a fragrance. If used in a fragrance the total fragrance concentration in a medicine must be no more than 1%.
3552	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.
3553	OENANTHE CROCATA	A, H	The maximum recommended daily dose must be no more than 1mg of the equivalent dry herbal material.
3554	OENOTHERA BIENNIS	A, E, H	
3555	OENOTHERA STRICTA	A, H	
3556	OKOUBAKA AUBREVILLEI	A, H	
3557	OLDENLANDIA DIFFUSA	A, E, H	
3558	OLEA EUROPAEA	A, E, H	
3559	OLEIC ACID	E	
3560	OLETH-10	E	Only for use in topical medicines

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			for dermal application.
3561	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%.
3562	OLETH-20	E	Only for use in topical medicines for dermal application.
3563	OLETH-3	E	Only for use in topical medicines for dermal application.
3564	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%.
3565	OLETH-5	E	Only for use in topical medicines for dermal application.
3566	OLEYL ALCOHOL	E	Only for use in topical medicines for dermal application.
3567	OLIBANUM OIL	A, E, H	
3568	OLIVE OIL	A, E, H	
3569	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).'
3570	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. The following warning statements are required on the medicine label: - (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).
3571	OMEGA-3-ACID ETHYL ESTERS 90	A	Only for use in oral medicines. The maximum recommended daily dose of the medicine must not provide more than: 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. The following warning statements (or words to the same effect) are required on the medicine label:

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			- (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.'
3572	ONION	E	
3573	ONION OIL	A, H	
3574	ONONIS SPINOSA	A, E, H	
3575	ONOPORDUM ACANTHIUM	A, H	
3576	ONOSMODIUM VIRGINIANUM	A, H	
3577	OPHIOPOGON JAPONICUS	A, H	
3578	OPOPANAX CHIRONIUM	A, E, H	When used as an excipient, permitted for use only in combination with other permitted ingredients as part of a flavour or a fragrance proprietary excipient formulation. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3579	OPOPANAX OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.

3580	OPUNTIA FICUS-INDICA	A, H	
3581	ORANGE	E	
3582	ORANGE FLOWER ABSOLUTE	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3583	ORANGE FLOWER OIL	A, E, H	When used internally, oxedrine is a mandatory component of orange flower oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3584	ORANGE JUICE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3585	ORANGE JUICE OIL	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3586	ORANGE OIL	A, E, H	When used internally, oxedrine is

			a mandatory component of orange oil. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3587	ORANGE OIL BITTER	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavor, the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance, the total fragrance concentration in a medicine must be no more 1%. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' or words to that effect must be include on the medicine label unless the medicine is: a) for internal use; b) in preparations containing 1.4% or less of orange oil bitter; c) for use in soaps or bath or shower gels that are washed off the skin.
3588	ORANGE OIL BITTER COLDPRESSED	A, E, H	When used internally, oxedrine is a mandatory component of orange oil bitter coldpressed. The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams. The warning statement (SENS) 'Application to skin may increase sensitivity to sunlight' (or words to that effect) must be included on the medicine label unless the medicine is:

			a) for internal use; or b) in preparations containing 1.4% or less of orange oil bitter coldpressed; or c) for use in soaps or bath or shower gels that are washed off the skin.
3589	ORANGE OIL COLD PRESSED	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3590	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.
3591	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%.
3592	ORANGE OIL TERPENELESS	A, E, H	When used internally, oxedrine is a mandatory component of orange oil terpeneless.

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			The quantity of oxedrine in the maximum recommended daily dose must be no more than 30 milligrams.
3593	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%.
3594	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.
3595	ORANGE PEEL OIL SWEET TERPENELESS	E	Permitted for use only in combination with other permitted ingredients as a flavour or a fragrance. If used in a flavour the total flavour concentration in a medicine must be no more than 5%. If used in a fragrance the total fragrance concentration in a medicine must be no more 1%.
3596	ORANGE ROUGHY OIL	E	Only for use in topical medicines for dermal application.
3597	ORIGANUM MAJORANA	A, H	Beta-arbutin is a mandatory component of Origanum majorana. When for oral use, the maximum recommended daily dose must not provide more than 500 mg of beta-arbutin.

			When for dermal application exclusively to the face: a) the concentration of beta-arbutin in the medicine must not be more than 7%; b) hydroquinone is a mandatory component; and c) the concentration of hydroquinone must not be more than 10 mg/kg or 10 mg/L or 0.001%. 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%. When the plant preparation is oil or distillate, and the concentration of Origanum majorana oil or distillate within the medicine is more than 50%: a) the nominal capacity of the container must not be more than 50 mL; b) a restricted flow insert must be fitted on the container; and c) the following warning statement is required on the label: - (CHILD) 'Keep out of reach of children' (or words to that effect).
3598	ORIGANUM OIL	E	Permitted for use only in combination with other ingredients as a fragrance. If used as a fragrance the total concentration in the medicine must be no more than 1%.
3599	ORIGANUM OIL SPANISH	A, E, H	
3600	ORIGANUM VULGARE	A, E, H	
3601	ORNITHINE	A, E	
3602	ORNITHINE ASPARTATE	A, E	

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3603	ORNITHINE MONOHYDROCHLORIDE	A, E	
3604	ORNITHOGALUM UMBELLATUM	A, H	
3605	OROSTACHYS FIMBRIATA	A, H	
3606	OROXYLUM INDICUM	A, H	
3607	ORRIS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3608	ORRIS CONCRETE	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3609	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%.
3610	ORRIS ROOT OIL	A, E, H	
3611	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%.
3612	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%.
3613	ORTHOSIPHON ARISTATUS	A, H	
3614	ORYZA SATIVA	A, E, H	
3615	ORYZANOL	E	
3616	OSBECKIA CHINENSIS	A, H	
3617	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%.
3618	OSMANTHUS FRAGRANS	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
3619	OTTELIA ALISMOIDES	A, H	
3620	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%.
3621	OXACYCLOHEXADECAN-2-ONE	E	Only for use in topical medicines for dermal application.
3622	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%.
3623	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%.
3624	OXALIS ACETOSELLA	A, H	
3625	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%.
3626	OXIDISED TAPIOCA STARCH	E	
3627	OXYBENZONE	A	Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect).

3628	OYSTER	E	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.
3629	OYSTER SHELL	A, E, H	The following warning statement is required on the medicine label: - (MOLLUSC) ‘Contains mollusc’ or ’Contains mollusc products’.